

**National
Haemovigilance
Office**

Annual Report 2003



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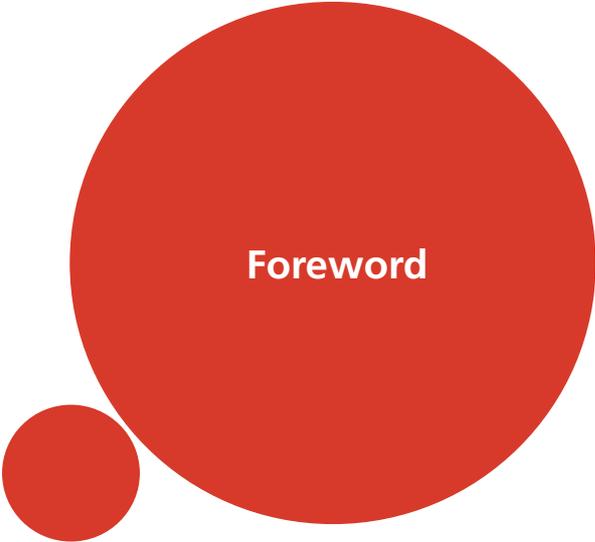
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List of Abbreviations

AA	Severe Acute Anaphylactoid/Anaphylactic Reaction	EPO	Erythropoietin
AAA	Abdominal Aortic Aneurysm	EU	European Union
AABB	American Association of Blood Banks	FBC	Full Blood Count
ACE	Angiotensin-Converting Enzyme	FDA	Food and Drug Administration
A&E	Accident and Emergency	FMH	Feto-Maternal Haemorrhage
AHOSTR	Acute Haemolytic or Other Severe Acute Transfusion Reaction	FFP	Fresh Frozen Plasma
ARDS	Adult Respiratory Distress Syndrome	GI	Gastrointestinal
BCSH	British Committee for Standards in Haematology	GP	General Practitioner
BMT	Bone Marrow Transplant	GTN	Glyceryl Trinitrate
CCU	Coronary Care Unit	Hb	Haemoglobin
CJD	Creutzfeldt Jacob Disease	HBV	Hepatitis B Virus
CMV	Cytomegalovirus	HCV	Hepatitis C Virus
COAD	Chronic Obstructive Airways Disease	HDN	Haemolytic Disease of the Newborn
CVA	Cerebral Vascular Accident	HIV	Human Immunodeficiency Virus
CXR	Chest X-ray	HLA	Human Leucocyte Antigen
CPDA1	Citrate-Phosphate-Dextrose-Adenine	IBCT	Incorrect Blood Component Transfused
DAT	Direct Antiglobulin Test	IBTS	Irish Blood Transfusion Service
DHTR	Delayed Haemolytic Transfusion Reaction	ICU/ITU	Intensive Care Unit/Intensive Therapy Unit
DIC	Disseminated Intravascular Coagulation	ID band	Identity band
DM	Diabetes Mellitus	IgA	Immunoglobulin A
DOB	Date of Birth	IgG	Immunoglobulin G
DoHC	Department of Health and Children	IgM	Immunoglobulin M
DVT	Deep Venous Thrombosis	IM	Intramuscular
ECG	Electrocardiograph	IMB	Irish Medicines Board
		INR	International Normalised Ratio
		ITP	Immune thrombocytopaenic purpura
		IV	Intravenous

JVP	Jugular Venous Pressure	Rh	Rhesus
LDH	Lactate Dehydrogenase	RTA	Road Traffic Accident
LVF	Left Ventricular Failure	SD	Solvent Detergent
MERS-TM	Medical Event Reporting System for Transfusion Medicine.	SHOT	Serious Hazards of Transfusion
MRN	Medical Record Number	SOP	Standard Operating Procedure
MRSA	Methicillin-Resistant Staphylococcus Aureus	Suspected TTI	Suspected Transfusion Transmitted Infection
MSBOS	Maximum Surgical Blood Ordering Schedule	TACO	Transfusion Associated Circulatory Overload
NAT	Nucleic Acid Amplification Testing	TA-GvHD	Transfusion Associated Graft-versus-Host Disease
NCHCD	National Centre for Hereditary Coagulation Disorders	THR	Total Hip Replacement
NEQAS	National External Quality Assurance Scheme	TRALI	Transfusion Related Acute Lung Injury
NHO	National Haemovigilance Office	TSO	Transfusion Surveillance Officer
OPD	Out Patient Department	TTP	Thrombotic Thrombocytopenic Purpura
O ₂	Oxygen	vCJD	variant Creutzfeldt Jacob Disease
PAD	Pre-deposit Autologous Donation	WNV	West Nile Virus
PAS	Patient Administration System		
PBSC	Peripheral Blood Stem Cell		
PCC	Prothrombin Complex Concentrate		
PCR	Polymerase Chain Reaction		
PNH	Paroxysmal Nocturnal Haemoglobinuria		
PO	Per os		
PTP	Post Transfusion Purpura		
QA/QC	Quality Assurance/Quality Control		
RCA	Root Cause Analysis		



Foreword

The publication of the 2003 National Haemovigilance Office (NHO) annual report completes four full years of reporting of serious adverse reactions and events relating to blood transfusion in Ireland and thus is a useful measure of the extent and type of adverse events/reactions associated with transfusion practice in Irish hospitals. As expected, with growing confidence in the scheme, the rate of reporting continues to increase, as does hospital participation, with 100% of hospitals that transfuse blood now taking part.

The vast majority of blood transfusions are given within excellent standards of care, which makes adverse events/reactions rare in proportion to the number of transfusions given in Irish hospitals. When these occur, however, the consequences for patients as well as the distress and concern of the professional caregivers involved can be considerable.

The findings and recommendations of this Report, which are based on detailed analysis of the reports of adverse reactions and events submitted, are summarised at the beginning of this report and expanded upon in the relevant chapters that follow. Of particular concern are the Incorrect Blood Component Transfused and Transfusion Associated Circulatory Overload events as these are preventable. These incidents, combined with events reported to the Near Miss project, highlight errors and high-risk areas in the work process, providing an important

opportunity to effect improvements in practice and the overall quality of care for patients in the context of a no blame culture.

We suggest that multidisciplinary Hospital Transfusion Committees use the findings and recommendations of this report as a benchmarking tool. These committees should be in place in all hospitals that transfuse blood. Such committees provide a no blame environment within which identified errors and their causes can be openly evaluated and also permits the initiation of appropriate actions to improve future performance and ultimately the safety and care of patients.

We are very grateful to the hospital-based Transfusion Surveillance Officers, (TSOs) for their continued work in raising awareness and in developing increased openness and alertness in hospitals to reporting such incidents. The contribution of Transfusion Medical Scientists and Consultant Haematologists is also central to this work.

The continued guidance and advice of the Medical Director and staff of the Irish Medicines Board (IMB) is also acknowledged. Special mention should be made of the staff of the IMB's Pharmacovigilance Department for their expertise and support. The EU Blood Directive 2002/98/EC will come into force in February 2005. This Directive will govern the activities of Blood Transfusion Services and Hospital

Blood Banks and has far reaching consequences for the management and regulation of blood transfusion services in all member states of the EU. (EU Directive 2002)

From a haemovigilance perspective, Article 14 of the Directive contains specific provisions in relation to traceability of blood and blood components as far as the patient. Article 15 requires that all serious adverse reactions attributable to the quality and safety of blood and blood components transfused are captured and reported to the competent authority. These provisions give haemovigilance a firm legislative basis within the EU and remove discretionary elements currently present in relation to reporting of serious adverse reactions.

Central to the concept of haemovigilance is the appropriate use of blood components.

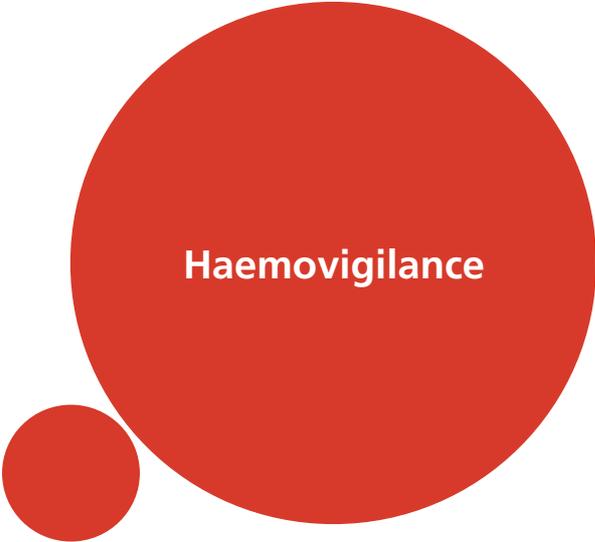
While the risks of transmission of the known viruses HIV, HCV and HBV are now extremely small, the emergence of other infectious diseases such as variant Creutzfeldt-Jakob Disease (vCJD) and West Nile Virus (WNV) as new transfusion risks emphasise the need to use blood appropriately.

During the reporting year 2003, the United Kingdom reported a case of probable transmission of vCJD via blood transfusion and a second possible transmission has been reported while this report was being compiled.

The guidelines published by the National Blood Users Group provide a template for appropriate use. The TSOs, through promotion of guidelines in the appropriate use of blood, have an important role to play in ensuring appropriate blood use, but in the end, appropriate use is the responsibility of each clinical user. A copy of a letter sent in August 2004 by Dr Willy Murphy, National Medical Director of the IBTS, to all registered medical practitioners in the country emphasising this, is included in Appendix 1.

The NHO gratefully acknowledges the continued support of IBTS Chief Executive Mr. Andy Kelly and the staff of the IBTS. Their continued efforts in recruiting voluntary blood donors and in processing and distributing components to the highest safety standards combined with the consistently generous response of voluntary blood donors to support patients in hospitals, are the essential precursors of any haemovigilance scheme. Finally, particular gratitude is extended to all the staff of the NHO for their continued enthusiasm and support in promoting best transfusion practice and in the writing of this report.

Dr. Emer Lawlor
Director
National Haemovigilance Office



Haemovigilance

Haemovigilance has been defined as:

"A set of surveillance procedures, from the collection of blood and its components to the follow-up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence"
(French Law, regulation no.93-5, January 4th, 1993)

The national haemovigilance scheme is a confidential anonymised system similar to that in place for monitoring drug safety, pharmacovigilance. It is dedicated to the achievement of a national standard in practice and quality of care for all patients, before, during and following completion of transfusion. It is the responsibility of all healthcare professionals to support the concept of haemovigilance. From 2005, EU Directive 2002/98 makes reporting of serious reactions observed during or after transfusion which can be attributed to the quality and safety of the blood mandatory.

The remit of the office is to:

- Receive, collate and follow up reports from hospitals and general practitioners of adverse reactions/events connected with transfusion of blood components/products and provide
- feedback information to those making the report as appropriate.
- Advise on the follow-up action necessary particularly with regard to suspected hazards.
- Report adverse reactions to the Irish Medicines Board (IMB) according to an agreed procedure.
- Provide ongoing support to hospital-based TSOs and as appropriate to medical, nursing and technical staff.
- Provide medical, scientific and nursing analysis of reports of adverse reactions.
- Advise on improvements in safe transfusion practice based on the data supplied by hospitals.
- Support development of clinical guidelines for hospitals in relation to the use of blood components/products.
- Support the audit function of hospitals in relation to transfusion practice.
- Promote the development of fully traceable transfusion records at hospital level.

- Report to the National Blood User's Group on a periodic basis with a view to developing national best transfusion practice.

The NHO is located at the National Blood Centre, (NBC) James's St., Dublin 8 and functions under the directorship of a Consultant Haematologist with two and a half fulltime equivalent TSOs, a Programme Administrator and Assistant Administrator. A fulltime TSO has also been appointed to co-ordinate the 'Near Miss Project'.

Hospital Transfusion Committees

The development of an adequately resourced, multi-disciplinary Hospital Transfusion Committee is actively encouraged by the NHO and supported by the Department of Health and Children (DoHC). Smaller centres may share a committee with their supplying hospital. This Hospital Transfusion Committee acts as a forum where local transfusion issues can be openly discussed in a no-blame, non-punitive environment. This multi-disciplinary approach to transfusion supports the development of best practice.

Irish Medicines Board

Staff of the NHO and representatives of the IMB met regularly during this reporting year to review reported incidents. In addition, their Pharmacovigilance Unit provides a valuable resource to the NHO advising in relation to the overall development of the programme.

National Blood Users Group

The Minister for Health and Children established the National Blood Users Group for the purpose of preparing and disseminating guidelines for the use of blood components/products in Ireland.

Membership for this group is drawn from a wide variety of transfusion interested hospital based disciplines, including haematologists, medical laboratory scientists, perfusionists, anaesthetists, surgeons and nurses representing a considerable wealth of knowledge of transfusion practice. The following guidelines have been published:

"A Guideline for Transfusion of Red Blood Cells in Surgical Patients" (2001) "A Guideline for the Use of Blood and Blood Components in the Management of Massive Haemorrhage" (2002) and "Guidelines for the Administration of Blood and Blood Components" (2004) according to the principles of evidence-based medicine. Further guidelines will be published shortly.

Near Miss Research Project

The IBTS has funded a three-year pilot project to capture "near miss" events. Ten hospitals are currently participating, and details of the results are contained in the Near Miss Events chapter of this report.

Education, Promotion and Developments

The NHO encourages and actively supports the development of hospital in-service training programmes by working closely with hospital based TSOs. The office also supports the development of audit functions at hospital level in an effort to promote best transfusion practice. Support is also provided in transfusion education for nursing and laboratory science students.

All newly appointed hospital based TSOs are provided with an information pack and attend an induction programme at the NBC which includes an introduction to Good Manufacturing Practice (GMP) and an overview of the IBTS manufacturing processes at the NBC. As the majority of TSO appointments are confined to the centres with a sizeable blood usage, the NHO has also developed 'in-service' education programmes for smaller centres. Regular correspondence through telephone/e-mail communication and personal visits allows networking among TSOs nationwide.

In October 2003 the NHO hosted an annual conference in Tullamore entitled "Haemovigilance-Learning from Mistakes and the Culture of Errors". Dr. Emer Lawlor, Director of the NHO, presented a summary of the incidents reported to the NHO in 2002. The keynote speaker was Dr. Harold Kaplan, Professor of Clinical Pathology at the College of

Physicians and Surgeons of Columbia University and Director of Transfusion Medicine, New York Presbyterian Hospital, who shared his experiences of analysing medical event reporting. Other presentations included:

- Transfusion Errors in Laboratory by Mr. Gerry Judge, Chief Medical Scientist, Adelaide and Meath Hospital incorporating the National Children's Hospital Dublin.
- Traceability in a European Context by Mr. Paul Ashford, Head of Planning, Facilities and IT, Welsh Blood Service.
- Residual and Emerging Threats to the Irish Blood Supply by Dr. Joan O'Riordan, Consultant Haematologist, IBTS.
- Neonatal Alloimmune Thrombocytopenia NAITP by Dr Joan Fitzgerald Consultant Haematologist IBTS.
- The Near Miss Project: The First 11 Months by Ms. Derval Lundy NHO IBTS.
- Education in Haematology – Does it Influence Nursing Practice? by Ms. Catherine Roche TSO.

The NHO also hosted a poster competition during this conference, which was kindly judged by Dr. Harold Kaplan. The winning poster displayed details of a retrospective transfusion request form audit and was compiled by the members of the North Dublin Haemovigilance Working Group.

The **NHO News**, a newsletter circulated to all TSOs, provides an informal forum for the reporting of work carried out by TSOs, including results of audits, local education and training initiatives and social events which are of interest to other TSOs. Details of events of national interest are also reported.

Information on haemovigilance can be directly accessed on the IBTS website @ www.ibts.org.

Definition of Terms used in Haemovigilance

Adverse *Event*:

Definition: An undesirable experience occurring following administration of a blood component/product.

Serious Adverse *Event*:

Definition: Any untoward occurrence associated with the collecting, testing, processing, storage and distribution of blood and blood components that might lead to

- Death
- Life-threatening
- Disabling or incapacitating conditions for patients which results in, or prolongs, hospitalisation or morbidity

Adverse *Reaction*:

Definition: A reaction which is harmful and unintended and which occurs following transfusion of therapeutic volume of a blood component.

Serious Adverse *Reaction*:

Definition: An unintended response in the patient associated with the collection or transfusion of blood and blood component that is

- Fatal
- Life-threatening
- Disabling
- Incapacitating which results in, or prolongs hospitalisation or morbidity

'Did Not Progress'

A total of 191 transfusion reactions/events were reported. Of these, 11 did not fulfil the criteria for a haemovigilance event, as further investigation revealed either that the symptom was attributable to the patient's underlying condition or that a serious reaction had not occurred.

'Nil to Report'

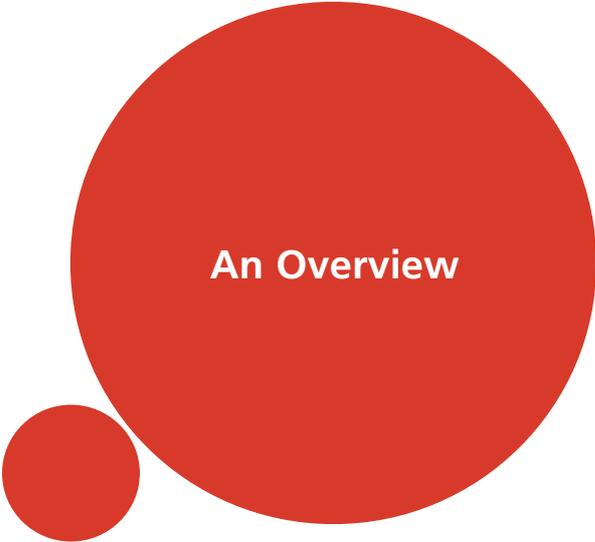
100% (81) of hospitals participated in the scheme by returning a 'Nil to Report Form' in 2003. Forty seven of those hospitals (58%) reported a transfusion reaction or event compared to 41 hospitals (49%) in 2002. This shows an increase in hospital reporting of 9%.

NHO Reports by Category

Table 1 NHO-Confirmed Reports by Category

Total Incidents	IBCT	A/A	TACO	DHTR	AHOSTR	PAD	TTI	TRALI
180	115	23	14	9	8	6	4	1
100%	64%	13%	8%	5%	4%	3%	2%	1%

<i>IBCT</i>	Incorrect Blood Component/Product Transfused.
<i>A/A</i>	Severe Acute Anaphylactoid or Anaphylactic Transfusion Reaction.
<i>TACO</i>	Transfusion Associated Circulatory Overload
<i>AHOSTR</i>	Acute Haemolytic or Other Severe Transfusion Reaction.
<i>TRALI</i>	Transfusion Related Acute Lung Injury
<i>TTI</i>	Suspected Transfusion Transmitted Infection.
<i>DHTR</i>	Delayed Haemolytic Transfusion Reaction
<i>PAD</i>	Pre-deposit: Autologous Donor incident



An Overview

THE FIRST FOUR YEARS OF THE NATIONAL HAEMOVIGILANCE SCHEME

Findings: 2000-2003

The NHO scheme has been fully operational since January 2000, and has published annual reports for 2000, 2001 and 2002. This year represents the fourth year of reporting and presents an opportunity to review the findings for the previous four years.

Approximately 693,818 blood components were issued during the four-year period 2000–2003 and a total of 564 adverse transfusion reactions/events were reported to the NHO. During 2000, the first full year of reporting, there were 85 incidents which fulfilled the criteria for a reportable event (NHO Annual Report, 2000). By 2003, the number of events has doubled with 180 incidents fulfilling the criteria for a haemovigilance event.

Incorrect Blood Component Transfused (IBCT)

This category captured 302 of the 564 incidents and in keeping with other haemovigilance schemes that collect similar data, it is the largest category reported. It also includes errors and omissions relating to blood products such as anti-D and factor concentrates as these also allow evaluation of the quality of systems in place for transfusion practice.

However suspected adverse drug reactions associated with use of these licensed medicinal products continue to be reported to the Irish Medicines Board (IMB) as the competent authority for licensing of medicinal products.

In 2001, in response to feedback, the IBCT incidents were divided into levels of severity (NHO Annual Report, 2001).

- Level 1 incidents are defined as those with the potential for permanent injury or are life threatening, and include wrong blood for wrong patient and the transfusion of blood components/products, which were not required. Level 1 incidents include all blood and blood components intended for another patient, even if ABO and Rhesus (Rh) D compatible, inappropriate transfusions, Rh D positive components administered to a Rh D negative patient in error and anti-D immunoglobulin or factor concentrates administered or omitted in error. During the three-year period 2001-2003, 140 (52%) of all IBCT incidents reported were stratified as level 1 incidents.
- Level 2 incidents were classified as unlikely to cause permanent harm. Between 2001- 2003, 86 (31%) of all IBCT were captured in this group.

- Level 3 incidents pose no risk to patients but indicate defects in the quality of service delivered. Between 2001-2003, 45 incidents (17%) were reported.

patients who received an ABO incompatible red cell transfusion had symptoms of an acute transfusion reaction. However, all recovered and no fatalities were reported from the reaction.

Wrong ABO Transfusion

During the four-year period 2000- 2003, 18 reports were received of incorrect ABO group red cells transfused. In 12 of these cases, the red cells were ABO incompatible. The total number of red cells and whole blood issued for this period was 502,968. Therefore, the risk of receiving a wrong ABO red cell transfusion is about 1:27,942 units issued and of receiving an ABO incompatible red cell transfusion is of the order of 1:41,914 units issued. Six of the 12

Table 2 Breakdown of NHO incidents (2000-2003) (n=564)

YEAR	IBCT	A/A	TACO	DHTR	TTI	TRALI	PAD	Unusual	AHOSTR	TOTAL
2000	31	22	8	2	7	-	-	1	14	85
2001	69	35	16	1	2	3	3	3	12	144
2002	87	31	10	9	3	2	5	-	8	156
2003	115	23	14	9	4	1	6	-	8	180
TOTAL	302	111	48	21	16	6	14	4	42	564
	54%	20%	8%	4%	3%	1%	2%	1%	7%	100%

Figure 1 Breakdown of NHO incidents (2000-2003) (n=564)

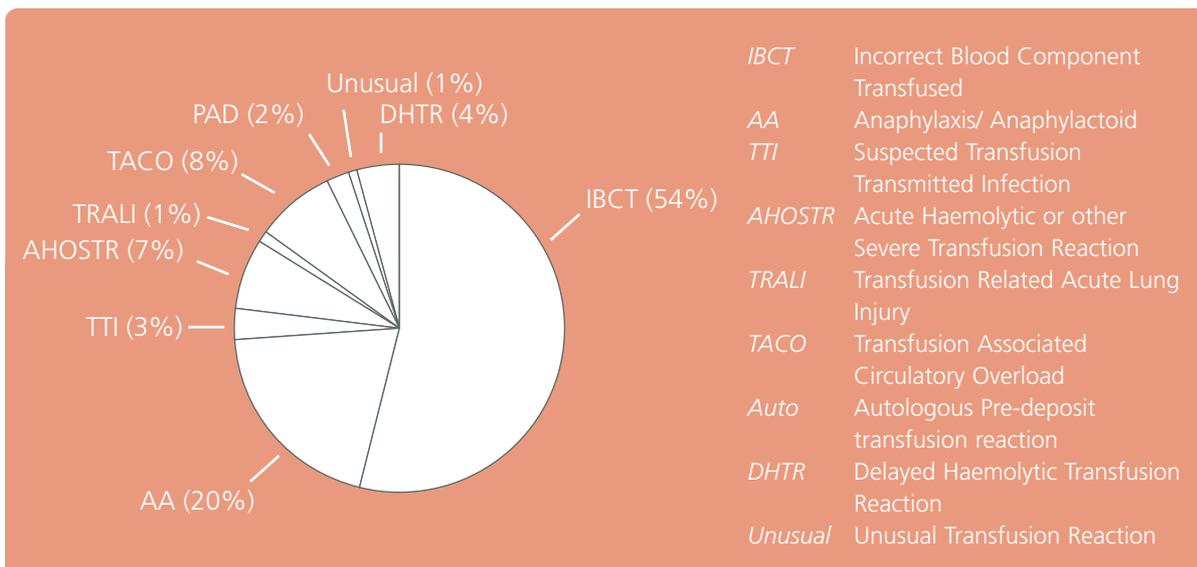
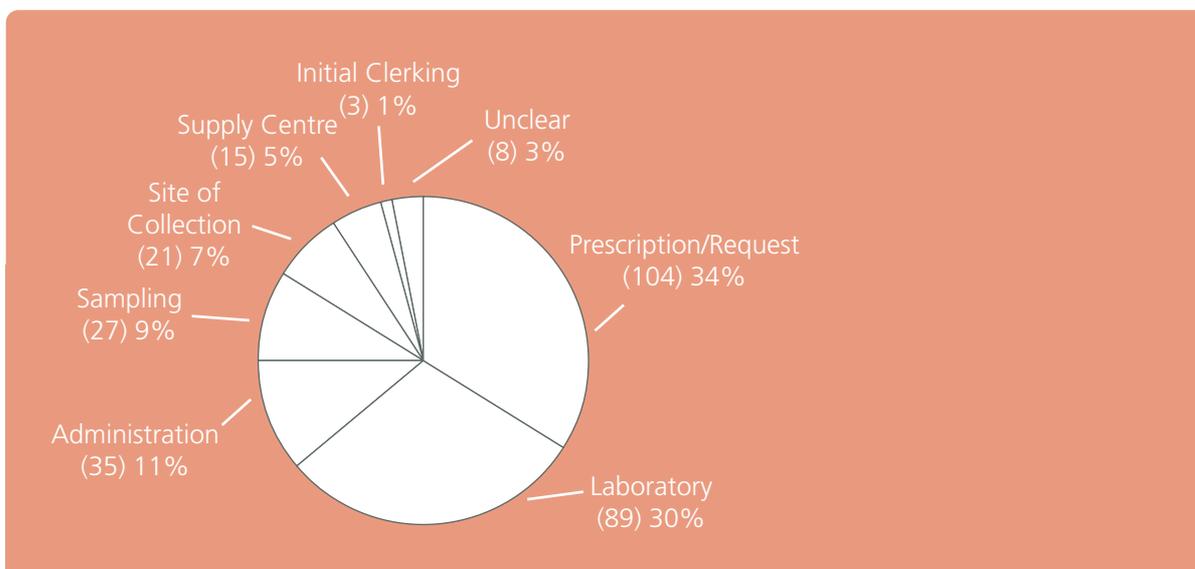


Table 3 Wrong ABO red cell transfusions 2000-2003

Year	Total IBCT	Total IBCT involving incorrect ABO group red cells administered	IBCT involving ABO incompatible red cells administered	Units of red cells & whole blood issued
2000	31	3	2	124,797
2001	69	6	4	120,482
2002	87	4	1	127,601
2003	115	5	5	130,088
Total	302	18	12	502,968
Number per units transfused		1:27,942	1:41,914	

Figure 2 Site of first error 2000-2003 (n=302)



Site of First Error

Prescription and Request

In 104 cases (34%) the error was the first stage of the transfusion process i.e. at prescription and request indicating the importance of continuing education for medical and nursing staff involved in prescribing and ordering blood components.

Pre transfusion sampling

Pre transfusion sampling has been identified as the

site of first error in 27 (9%) cases. Five of these events were associated with the transfusion of ABO incompatible red cells. This highlights the importance of secure procedures for positive patient identification and emphasises the necessity for each patient to wear a secure ID band at the time of sampling. The introduction of automated solutions i.e. sample bar-coding (Turner *et al*, 2003), extended/24 hours phlebotomy services, as well as the provision of an ongoing transfusion education programme are key recommendations.

Laboratory Procedures

In 89 cases (30%), the first error occurred in the laboratory. In many cases, the error occurred on call and often involved staff from other laboratory disciplines covering the transfusion laboratories indicating the importance of regular training of on call staff. The use of automated grouping and automated transmission of results would help reduce human error through transcription and reading errors.

Site of Collection

In 21 cases (7%), the first error was at the site of collection. These resulted from absence or inadequacy of checking procedures at the time of collecting the component. Adequate checking systems must be in place at the site of collection of blood components/products from either the hospital transfusion laboratory or the satellite fridge.

Bedside administration

In 35 cases (11%), the site of first error involved the final bedside checking procedure with a failure to accurately identify the patient or the component/product pre transfusion. This resulted in an incorrect component/product being administered. The reasons for such errors are varied but as the final bedside check provides the opportunity to detect and prevent earlier errors its importance is highlighted. The patient must be positively identified and an identity (ID) band must be worn at the time of the pre-transfusion sampling and must be in place at the time of transfusion.

The site of first error in the remaining IBCT cases involved incidents occurring at the initial clerking stage or at the supply centre or were unclear.

Wrong haematology values resulting in unnecessary transfusions

In 24 cases (8%), transfusion was based on inaccurate or absent haematology results or inadequacy of the checking procedure. In 17 of these cases, transfusion of red cells was involved. Errors in communication can be minimised by using

automated transfer of laboratory information to hospital patient identification systems. All clinical areas should have easy access to these systems and staff should be trained in their use so that transfusion decisions are based on the most up-to-date and correct results.

Inappropriate transfusion

Inappropriate transfusions were reported in 33 (10%) cases. Eleven (4%) of these cases resulted in an unnecessary transfusion of either SD plasma or FFP. In addition, nine reactions captured within the A/A category were as a result of the inappropriate use of plasma. Adherence to national guidelines is important to avoid inappropriate use of blood components and unnecessary donor exposure.

Blood product administration

Forty-four of these IBCT reports related to errors in the administration of blood products, 34 (77%) of which involved the administration of anti-D. Each hospital should have clear policies and procedures for the prescription and administration of anti-D and the management of Rh D negative women during pregnancy.

Reactions

Severe Acute Anaphylactoid or Anaphylactic Transfusion Reactions (A/A)

Severe acute anaphylactoid or anaphylactic transfusion reactions were the largest category of serious adverse reactions with 111 incidents (20%) reported. Of these 60 (55%), were associated with platelets, the vast majority, 46 of 60 (77%), associated with the transfusion of pooled platelet concentrates. Twenty-two cases involved the use of fresh frozen plasma (FFP), six of which were for warfarin reversal as a result of over anticoagulation not in compliance with current guidelines (Appendix 2). The number of reactions associated with plasma has fallen consistently since the first year of reporting. In 2003, there was only one anaphylactoid / anaphylactic transfusion reaction associated with the use of SD plasma. In all cases

the patients recovered from the reactions without complications. Some of these transfusions were however considered to be inappropriate.

Acute Haemolytic or Other Severe Acute Transfusion Reaction (AHOSTR)

There were 42 incidents (7%) reported in this category. Red cells transfusion was involved in 37 (88%). None showed evidence of haemolysis due to red cell incompatibility or evidence of bacterial contamination. However, six of the 12 incidents involving ABO incompatible red cell transfusions, reported in the IBCT category were accompanied by symptoms of an acute transfusion reaction. In total, therefore, of 48 red cell transfusion reactions reported to the NHO during this period, 6 (12.5%) were due to ABO incompatibility. This confirms the need to fully investigate all reactions associated with the transfusion of red cells.

Thirty-four (71%) TACO incidents related to the transfusion of red cells. Thirty cases (63%) involved patients aged 70 years or over. There is an increased risk of volume overload in the elderly, with or without underlying cardiac, respiratory or renal disease, highlighting the importance of careful attention while transfusing this group of patients. Monitoring the patient's fluid balance, transfusing as slowly as possible and observing closely for signs and symptoms of volume overload during and soon after transfusion is recommended to minimise the risk. The use of prophylactic diuretics is also recommended.

Transfusion Associated Circulatory Overload (TACO)

Table 4 Numbers of reports of TACO by component and reporting year

Component transfused	2000	2001	2002	2003	Total
Red cells	3	9	10	12	34
Pooled Platelets	1	-	-	-	1
FFP or SD Plasma	3	6	-	1	10
Multi components	1	1		1	3
Total	8	16	10	14	48

Transfusion associated circulatory overload (TACO) was reported in 48 (8%) transfusions, of which 10 (21%) were associated with the use of plasma. In at least six of these 10 (60%), the transfusion was considered inappropriate and in two cases may have contributed to mortality. In light of these findings, the NHO issued an information leaflet on the use of FFP. This leaflet outlined the firm indications for the transfusion of FFP and highlighted the risks associated with its use. This has since been updated to reflect changes following the introduction of solvent detergent (SD) treated pooled plasma in March 2002 (Appendix 2).

Suspected Transfusion Transmitted Infection (TTI)

There were 16 cases (3%) of suspected transfusion transmitted infection (TTI) reported. Investigation of these reports confirmed one case of bacterial contamination, which involved a pooled unit of platelets from which coagulase negative staphylococcus was cultured from both the patient and the unit. The patient recovered without complications.

Thirteen cases of possible viral transmission were investigated: five Hepatitis C virus (HCV), six Hepatitis B virus (HBV), two Human immunodeficiency virus (HIV) and one case of co-

infection with both HBV and HCV. Transfusion has been excluded as the source of infection in 14 of the 16 cases by re-testing of donors or the archived samples from the time of donation. In one case, one donor could not be traced and so HBV could not be excluded, although the patient had other risk factors. In the outstanding case of suspected HBV, investigations are ongoing but the patient has other risk factors. This low incidence of confirmed TTI is in keeping with the estimated risk of transfusion transmitted viral infection which has been estimated at 1 in 3.3 million units transfused for HIV, 1 in 500,000 units transfused for HCV and 1 in 100,000 units transfused for HBV (O’Riordan, 1999). These residual risk estimates are based on serological testing between 1993-1996, prior to the introduction by IBTS of nucleic acid amplification testing (NAT) for HCV in November 1999, HIV in September 2001 and Hepatitis B core antibody testing in January 2002. The current risk is therefore estimated to be considerably lower.

Delayed Haemolytic Transfusion Reaction (DHTR)

There were 21 (4%) reports received which were categorised as DHTRs during 2000-2003. There were no fatalities. These reactions, which are largely unavoidable, are likely to increase as our patient population, particularly the elderly, receive more transfusions. In 12 (57%) of the 21 cases, the patients were aged over 70 years.

Transfusion Related Acute Lung Injury (TRALI)

Six cases (1%) suggestive of Transfusion Related Acute Lung Injury (TRALI) were reported. Three cases involved red cells, one was associated with pooled platelets, one with fresh frozen plasma and one case involved multiple blood products. TRALI was confirmed in one case and considered highly probable in three cases, one of which was associated with fatality. It was considered possible in one case and unlikely in a final case.

Post-Transfusion Purpura (PTP) and Transfusion-Associated Graft-versus-Host Disease (TA-GvHD)

There were no incidents reported in these categories during the first four years.

Pre-deposit Autologous Donor Incident (PAD)

In 2001 the NHO began to collect reports relating to pre-deposit autologous donor incidents. Fourteen (2%) incidents were reported. None of the adverse events involved hospitalisation of the patient or rescheduling of surgery. However, in a number of cases, the donated blood was not required suggesting the importance of careful donor selection for PAD.

Current Participation

The number of incidents submitted to the NHO has continued to rise. Because of the anonymity of the scheme, it is difficult to determine if the increase is as a result of an improved detection rate in hospitals that have always participated and/or a general increase in participation as further hospitals report to the programme. The success of the scheme to date can be directly attributed to the work and enthusiasm of the hospital based TSO’s, and the support they receive from transfusion medical scientists and consultant haematologists. However, in order to encourage reporting and ensure the recommendations from the reports are adopted further work is required.

Table 5 Hospital Participation (2000–2003)

Year	2000	2001	2002	2003
Submitted incident	37%	50%	49%	58%
Nil to Report	31%	27%	44%	42%
Participation	68%	77%	93%	100%

A number of strategies are currently being examined to improve the reporting rates, which include:

- A change to the "Nil to Report" form, which will allow anonymised feedback to hospitals of their reporting rates in comparison to hospitals with similar transfusion requirements.

- Two audits to evaluate the effectiveness of the NHO scheme have been carried out in 2004. The first audit measures the level of satisfaction amongst hospital based TSOs with the support offered by the NHO. The second aims to obtain a clear picture of requirements for effective hospital-based haemovigilance. This will enable the development of comprehensive guidelines for standard delivery of haemovigilance.
- *NHO Steering Group*
As highlighted in the first SHOT report in 1996, transfusion is a complicated process involving a multidisciplinary team. While acknowledging the considerable help provided by the National Blood Users Group, a formal Haemovigilance Steering Group composed of the major stakeholders involved in transfusion is now needed. This strategic group could greatly assist in reviewing incident trends, promoting reporting and ensuring support at hospital level for practice improvement.



Key Recommendations

This section consolidates the key recommendations from this year's report. The full recommendations can be found in the relevant chapter.

Incorrect Blood Component Transfused

Clinical areas

- Best transfusion practice should be an integral part of induction training and education programmes for all staff involved in prescribing, ordering and administering transfusions. New staff or those returning to work following a career break or a long period of absence have particular training needs.
- Hospitals must have secure documented procedures in place and provide formal training for staff involved in blood sampling and transfusion.
- Electronic forms of patient and blood component/product identification are now available and are recommended as they provide the highest degree of security. Where these systems are not in place, manual bedside identification procedures at sampling and administration must be strictly adhered to (NBUG, 2004).
- Positive patient identification at sampling is essential. The patient must have a secure ID band in place at the time of pre-transfusion sampling and administration. This ID band must contain three identifiers, i.e. full name, date of birth and a unique identification number.
- In order to help reduce sampling errors extended or 24 hour phlebotomy services are recommended.
- In the absence of electronic forms of patient and blood component/product identification systems, two people must verify the ABO and Rh D group identity of the patient and unit at the bedside. Where possible, the patient must be involved.
- It is desirable where possible to transfuse only when adequate staff are on duty and to avoid routine transfusions at night wherever possible.
- Ongoing education is required to ensure correct administration of blood components, and should include training on the use of medical devices such as infusion pumps.
- Hospitals need to have protocols to cover massive transfusions (NBUG, 2002). These should include timeframes for the provision of crossmatched,

group specific and un-crossmatched blood taking into account the specific physical location of the laboratory/blood fridges and clinical areas.

- There should be a designated person to check and record units during transfusion for massive haemorrhage to ensure traceability of all blood components and products.
- Alert stickers placed on the front of the medical record to alert clinical staff of special requirements is recommended. This is particularly important when patients are being transfused in clinical areas not normally transfusing haematology/oncology patients.

Laboratory Operations

- Hospital laboratories should have a standard operational procedure or policy for acceptance and or rejection of incorrectly labelled samples. This policy should cover amendments which are acceptable and those which require a further sample to be taken.
- Formal written policies should be easily accessible for reference and all staff should be familiar with these.
- Transfusion cover on call has been identified in this report as presenting a particular problem. The five ABO incompatible red cell transfusions reported this year occurred on call.
- Adequate numbers of properly trained laboratory staff are needed to ensure the safety of transfusion.
- Medical scientists providing cross call cover from other disciplines should have the opportunity for rotation through the transfusion laboratory. Regular training and updating should be provided in order to become familiar with current practice and provide knowledge of appropriate products available for issue. This is particularly important in the neonatal setting.
- Difficulties may also arise from having only one person covering call for all laboratory areas. During emergencies a system should be in place to contact additional staff members to assist.
- It is recommended that only emergency blood samples should be processed on-call
- Previous transfusion records should be available at all times and checked. The transfusion records of patients who may have been transfused in another hospital should be confirmed with the original hospital, wherever possible.
- It is of vital importance that an uninterrupted working environment is maintained during crossmatch and issue of units to avoid distraction and or transposition.
- There should be a dedicated area in the laboratory for labelling products. At the time a unit is issued, there shall be a final check of transfusion service records and each unit of blood or component (AABB, 2003). Only units for one patient should be labelled up at any one time. Automated systems for labelling and checking would enhance the security of the process.
- Computer systems should be designed with audible alarms/alerts to minimise opportunities to override screen warnings. Preferably any such overrides should require a reason or explanation as this should lead to questioning the need to override. An audit trail of any overrides should also be kept.
- Once a clinically significant red cell antibody has been detected in the past, the patient should always receive antigen negative blood, even though the antibody is no longer detectable, except in an emergency situation where antigen negative blood is not available.
- Consideration should be given to issuing antibody cards to all patients with clinically significant

antibodies (NBUG 2002). The possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated.

- Systems are required to ensure that where care is shared between centres patients receive the appropriate blood components.

Improperly Stored or Handled Components

- Under no circumstances should any blood product or component that has been pierced or 'spiked' with an administration set or other device be stored with the intention to re-transfuse. The importance of this cannot be over emphasised, as there is a serious risk of bacterial contamination.
- It is important to ensure that the patient has a patent IV cannula and that all documentation is correct prior to collection of the unit.
- Documentation containing three minimum patient identifiers must be brought to the fridge when collecting a unit of blood in order to verify unit and patient details.
- Should an unforeseen delay in the commencement of the transfusion occur, it is necessary to return the unit to controlled storage within thirty minutes and inform the laboratory to ensure the unit is being returned to the appropriate fridge.
- It is important that hospitals which accept blood units accompanying patients have policies in place to determine the circumstances in which they can be used for the patient rather than discarded.
- Systems are required which incorporate all satellite fridges within the monitoring procedures of the hospital blood bank. The transfusion laboratory should collect crossmatched red cell units from satellite fridges if they have not been used within 24-48 hours of the time they were originally requested (McClelland, 1999).

- There should be specifically designated areas within laboratories for blood components/products assigned for discard, to ensure such units are not accessible for transfusion.

Inappropriate/Unnecessary Transfusions

- All clinical staff involved in transfusion must be familiar with guidelines for administration of components. Adherence to these guidelines particularly for plasma will help avoid unnecessary transfusions.
- SD plasma or FFP is only required for the reversal of over anticoagulation in the presence of major bleeding or emergency surgery (Appendix 2).
- Patients with iron deficiency respond quickly to specific therapy and rarely need transfusion.

Transfusions Based on Inaccurate/Absent Haematology Results

- Care is needed in laboratory identification procedures for haematology samples.
- The most recent Hb result must be checked prior to prescribing and administering a red cell transfusion. When transfusing more than one unit, regular monitoring of post transfusion Hb levels is strongly recommended, ideally on a unit-by-unit basis.
- Where anomalous Hb results are found, a repeat Hb sample should be obtained before a decision to transfuse is made.

Improving Communication

- Ideally all requests for components should be made in writing. Hospitals need to develop protocols for exceptions such as emergencies or remote geographical locations of laboratories. Such protocols could include a verbal request followed by a confirmatory written request.
- An electronic ordering system for blood components would overcome this and should be developed similar to systems already available for blood test ordering.
- It is important to provide clinical details on the transfusion request form which would alert laboratory personnel to any special requirements which may be necessary, or to previous transfusion history.
- Systems and procedures need to be put in place to ensure that patients with special transfusion requirements e.g. CMV negative and/or irradiated cellular components, receive the required components. This is particularly the case where care is shared between two centers.
- Errors in communication can be minimised by using automated transfer of laboratory information to allow access to current records. All clinical areas should have easy access to these systems and staff should be trained in their use so that transfusion decisions are based on the most up-to-date and correct results.
- If results are taken over the phone, the details should be clearly entered on the patient's chart and should include details of date, time and name of the person giving the result and signed by the person taking the result.

Hospital Records

- Three of the incidents in 2003 involved errors as a direct result from the initial registration of the

patient at the hospital which emphasise the need for accuracy during this procedure.

- Patients admitted must have a unique hospital number assigned. Although full medical records may not be available, it is necessary to have access to the previous medical record number (MRN) and also have the facility to generate a new MRN on a 24-hour basis.
- The initial recording of the patients primary identifiers is of vital importance, as this information allows access to all pertinent information should this patient have had a previous admission.
- Staff admitting patients should take care to obtain details of previous admissions to ensure that their previous MRN number and records are retrieved.
- If the patient is admitted via the A&E Department and given an emergency number, it must be possible to merge this number at a later stage with the actual unique hospital number in the computer system.
- All healthcare professionals must be aware of the importance of correct patient identification and ensure that details accompanying patients requiring transfer to another facility for further treatment are correct.

Anti-D immunoglobulin Incidents

- There is a need to develop a co-ordinated system to ensure that decisions to issue and administer Anti-D are not made on assumptions but on the documented Rh group of the mother, her antibody status and the Rh group on the cord blood. The findings in this report illustrate the difficulties in ensuring this happens.
- While many hospitals issue Anti-D through the laboratory as they have access to both the mother

and/or baby's group and antibody records and can issue the Anti-D labelled for the patient, the findings suggest a co-ordinated approach to review of all laboratory results is necessary to ensure correct issue of product.

- Whether hospital blood banks or clinical obstetric areas take responsibility for prophylactic Anti-D administration, there is a need for ongoing education of all staff involved in prescription/administration of Anti-D prophylaxis.
- Hospitals should have a system in place to check the Rh D status of all deliveries in the previous 24 hours to ensure that cord bloods are taken from Rh D negative mothers at the time of delivery. If an omission does occur, a sample can be then be taken from the baby for assessment.
- When a mother is found to be Rh D negative, an alert to this fact should be placed on the medical record/hospital computer to alert all staff to the necessity of checking the Rh D group of the infant.
- As it is important to avoid errors due to transcription of results, a laboratory computer generated alert is the safest option where the information system in the laboratory and hospital are linked.
- Laboratory errors can occur during the night when laboratory scientists, not normally working in transfusion and often working alone, are providing cross call cover. It may be prudent to process samples which lead to the issue of anti-D the following morning. However, this needs to be balanced against the fact that patients are now being discharged earlier following delivery so it is important that systems are in place to ensure that these patients are not missed (case 17).
- Systems are required to ensure easy access to current laboratory results, either in written or electronic format. Both the prescriber and the person administering anti-D should always check

the most recent report of the patient's Rh D and antibody screen and the Rh D status of the cord blood to assess the need for the product prior to administration. Transcribed Rh D results must not be accepted; the original reports must always be consulted.

- Where mothers or babies are being nursed outside the normal clinical areas it should be the responsibility of the referring unit to follow up these patients and ensure that clinical staff are aware of specific requirements.
- Medical and Nursing staff working in all clinical areas where Rh D negative women are being treated should be familiar with Anti-D guidelines in order to avoid omission or delay in the administration of Anti-D.
- Where Anti-D has not been administered within the 72 hour period every effort should still be made to administer the anti-D within 9-10 days of the sensitising event as this may afford some protection (BCSH, 1999).

Transfusion Reactions

Serious Adverse Reactions including Severe Acute Anaphylactoid or Anaphylactic and Acute Haemolytic and Other Severe Acute Transfusion Reactions

- Protocols and training for the management of severe reactions should be in place in each hospital and all staff involved in transfusion should be familiar with their use.
- The importance of only prescribing transfusions that are necessary cannot be over emphasised. Inappropriate transfusions increase donor exposure unnecessarily and can put the patient at risk of a transfusion reaction.
- Where patients are transfused in day care settings, it is important that written post-

transfusion information is given to the patient prior to discharge explaining whom to contact and symptoms to look for, in case of a reaction following discharge.

- Where patients are receiving shared care, systems must be in place so that all relevant details relating to transfusion such as history of reaction/allergy and/or premedication requirements can be communicated between centres effectively.
- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly, and the patient observed closely, for the first 15 minutes / 50mls as severe reactions are most likely to occur within this time.
- Classical allergic or anaphylactoid reactions do not routinely require culture of the unit or pack or serological investigations. However, where atypical symptoms such as fever are present in a suspected A/A reaction or where skin manifestations are absent, it is important to culture the implicated unit/s and the patient to rule out underlying sepsis and/or bacterial infection in the unit and in the case of red cells exclude red cell incompatibility.

Transfusion Associated Circulatory Overload

- All patients receiving blood components should be assessed carefully but particular attention should be paid to at risk patients and to the identification of such patients. At risk patients include low weight patients, the elderly, infants and children, medically compromised patients especially with a history of cardiac, respiratory and renal insufficiency or chronic anaemia.
- In susceptible patients, transfusions should be administered slowly (1ml/kg of body weight/hour) (Popovosky, 2001).

- An accurate intake and output record should be maintained.
- The risk of overloading the circulation can be minimised by administering a prophylactic diuretic in addition to maintenance diuretic therapy.
- Transfusion should be on a unit-by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component.
- It may be prudent to transfuse only one unit in a 24-hour period in high-risk patients. Some subjects take as long as 24 hours to readjust blood volume and the effects of the transfusion of large amounts of blood must always be carefully monitored, particularly in those patients whose venous pressure is already raised before transfusion had begun (Mollison *et al* 1998).

Delayed Haemolytic Transfusion Reaction

- These reactions, which are largely unavoidable, are likely to increase as our patient population, particularly the elderly, receive more transfusions. A DHTR should be suspected when there is a falling Hb or jaundice some days post transfusion.
- Careful history taking in relation to transfusion and pregnancies by the requesting physician is important. However, up to 12% of patients do not realise that they have had a transfusion. Therefore, access to and checking of previous transfusion records are essential.
- Use of three cell screening panels, sensitive antibody screening techniques and satisfactory participation in external quality assurance schemes such as NEQAS, should minimise failures to detect weak antibodies.
- As antibodies can develop rapidly, patients requiring repeated transfusion, depending on the interval between transfusions should have a fresh

sample submitted within 24-72 hours of a transfusion.

- When investigating a DHTR, a serum sample should be used for antibody detection as some antibodies, particularly weakly complement binding antibodies not detectable in plasma specimens may be detected in serum samples.
- Where there are multiple antibodies, it may not always be possible to find fully compatible blood and it may be necessary to issue least incompatible blood. In these cases, specialist advice should be sought as inordinate delays in transfusion may be detrimental to the patient and outweigh the risks of transfusion.
- Particular attention at pre-donation assessment should be paid to first time donors, as these are more likely to have reactions. Popovsky *et al* (1995) also identified an increased risk of adverse reaction in female donors of lower weight. Attention should also be paid to psychological factors such as fear of needles, which may predispose the donor to an adverse reaction.
- It is essential that up to date criteria be used for identifying procedures where blood is likely to be needed. Donors should not be exposed to the risks of donation if the blood is unlikely to be required.

Transfusion Related Acute Lung Injury

- It is important that hospital staff be made more aware of this complication of transfusion which occurs within six hours of transfusion to recognise it and treat it appropriately. This would also facilitate prompt investigation and case review.
- The IBTS has put in place measures to minimise the risk from TRALI namely avoiding the use of plasma from female donors both for suspension of pooled platelets and as FFP. From early 2004 new and lapsed female apheresis donors with a history of pregnancy have been deferred from donating.
- SD Plasma which is the standard plasma product, has not to date, been convincingly implicated in TRALI.

Pre Autologous Donation

- Pre-deposit Autologous Donation clinics must have procedures to deal with donor reactions. All serious reactions should be documented and reported to the NHO.

Incorrect Blood Component Transfused

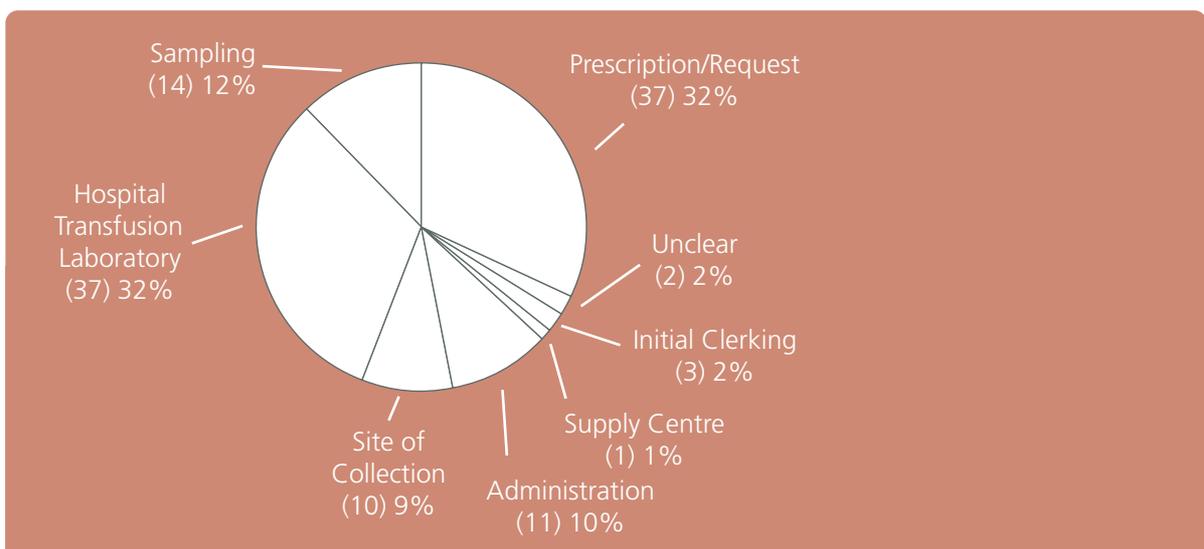
Definition: Incorrect blood component transfused (IBCT) is the transfusion of a blood component/ product which did not meet appropriate requirements and/or was intended for another patient (SHOT 1999).

This category accounted for 64% of incidents reported (115 of 180).

Site of First Error

Figure 3 indicates the stage in the transfusion chain process where the IBCT first occurred.

Figure 3 Site of first error - IBCT Cases (n=115)



Introduction

In 2001 the NHO introduced stratification of incidents by level of severity in the IBCT category. The following classification system is used:

- **Level 1**

Events with the real potential for permanent injury or to be life threatening.

- **Level 2**

Events that are very unlikely to cause permanent harm or have the potential for minimal or transient harm.

- **Level 3**

Events with no realistic potential for harm.

See pages 10 and 11 for details of classifications.

In 2003, there were 62 cases (54%) which were classified as Level 1 incidents, 32 (28%) as Level 2 and 21 (18%) as Level 3.

Summary of IBCT Findings and Recommendations

Tables of cases, detailed case histories and the detailed findings and recommendations are included in the relevant subsections. For the purpose of this report Anti D IBCT incidents are presented in a separate section at the end of this chapter.

Blood components of the wrong ABO or Rh group, or wrong component given

Findings:

- There were 13 level one incidents where the patient received blood of the wrong ABO group or components not intended for that patient.
- Eleven of the incidents originated in the laboratory and two occurred during administration when the units were remotely checked from the patient.

- All recovered from the implicated transfusions and had no long term complications, but in one case, the patient subsequently died from his underlying condition, two weeks later.
- Detailed findings are listed below by implicated component.

ABO incompatible red cells

- Five of these involved the transfusion of ABO incompatible red cells (Cases 28, 63, 70, 88 and 118) all of which occurred in the laboratory on-call. Four of these (Cases 28, 63, 70 and 118) occurred when a medical scientist not normally working in blood transfusion provided cross call cover.
- Symptoms ranged from mild fever <1.5°C, tachycardia, hypotension with temporary increase in bilirubin. In one patient (Case 88) who was ill, septic and hypotensive as a result of his underlying condition, the contribution of the incompatible transfusion was impossible to determine.
- All five patients recovered from the transfusion but in Case 88 the patient subsequently died two weeks later of his underlying condition unrelated to the transfusion.
- One case (Case 90) involved both red cells and platelets transfused in an emergency to a post BMT transplant patient where the required groups for platelets and red cells were reversed in error.

ABO incompatible plasma

- Three incidents involved transfusion of ABO incompatible SD plasma. (Cases 39, 79 and 97)

Wrong blood component given to a patient

- In one case (Case 23), a compatibility label was put on an uncrossmatched, but fortunately compatible, red cell unit.
- Three incidents (Cases 15, 49 and 101) involved platelet transfusions which were assigned for a certain patient being transfused to a different patient, two of which originated in the laboratory on call. One occurred at administration when the units were remotely checked from the patient.

Recommendations:

- An adequate number of appropriately trained laboratory staff are needed to ensure the safety of transfusion.
- Transfusion cover on-call has been identified in this report as presenting a particular problem. The five ABO incompatible red cell transfusions occurred during the on-call period.
- The issue of cross call cover where medical scientists from another discipline cover call in transfusion presents difficulties. These scientists should have the opportunity for rotation through the transfusion laboratory and regular updating to ensure familiarity with current practice to maintain the requisite level of expertise.
- Difficulties may also arise from having only one person covering call for all laboratory areas. During emergencies a system should be in place to contact additional staff members to assist.

- Formal written policies should be easily accessible for reference and all staff should be familiar with these.

- An uninterrupted working environment must be maintained during crossmatch and issue of units, to avoid distraction and/or transposition.

- Wherever possible only the units from one crossmatch should be issued at any given time to avoid errors.

- The importance of the bedside checking procedure is again highlighted.

Failure to give antigen negative blood (n=8)

- There were 8 cases where patients had a previous history of antibodies or exposure to products giving rise to a risk of a delayed haemolytic transfusion reaction.

Recommendations

- The correct recording of the patient's primary identifiers at admission is of vital importance. This information allows access to all previous records should this patient have had a previous admission.
- The importance of filling in the patient's clinical and past transfusion history on the request form is highlighted as it enables the medical scientist to check previous transfusions which may have occurred and ensure that the correct product is being issued.
- Historical transfusion records, manual and computer, should be checked for all patients requiring transfusion.

- Antibody investigations for patients who may require blood in an emergency should be completed as soon as possible after receipt. Where this is not possible, the computer or manual records should clearly document this. In cases of clinical emergency, it may be necessary to issue blood to these patients before investigations are completed but computer alerts to incomplete antibody investigations should be difficult to override inadvertently.
- Hospital transfusion laboratories need to be informed when patients are transferred between hospitals. This will enable them to contact the referring hospital and confirm transfusion history. This information should also be included in the written communication accompanying the patient from the clinical team where possible.
- Consideration should be given to issuing antibody cards to all patients with clinically significant antibodies (NBUG 2002).
- The possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated.

Errors surrounding collection, storage or improper handling of products. (n=10)

Findings

- Three incidents concerned units of red cells left out of the fridge in excess of the recommended time, then returned to the fridge and later transfused.
- Two cases demonstrate the dangerous practice of re-transfusing already pierced or 'spiked' units. The risk of bacterial contamination of these units cannot be over-emphasised.
- One case (Case 53) involved a unit that had been discontinued because of a suspected transfusion reaction, stored in the wrong fridge while

awaiting investigation, collected and re-transfused to the same patient, 24 hours later.

- The second (Case 32), where the pierced unit was stored for 15 hours before transfusion, highlights the importance of ensuring that the patient has patent venous access and that all documentation is correct prior to collection of the unit.
- A third (Case 73), highlights the importance of ensuring that all staff handling blood are aware of storage requirements.
- Two of the incidents were discovered during investigation of febrile transfusion reactions.
- None of the patients suffered any adverse effects.

Recommendations

- Under no circumstances should any blood product or component that has been pierced or 'spiked' with an administration set or other device be stored with the intention to re-transfuse. The importance of this cannot be over emphasised as there is a serious risk of bacterial contamination.
- Should an unforeseen delay in starting the transfusion occur, the unit must be returned to controlled storage within thirty minutes and the laboratory informed to ensure the unit is returned to the appropriate fridge.
- Documentation of patient details containing three unique identifiers must be brought to the fridge when collecting blood or blood components.
- Inspection of the unit and documentation at the time of collection may identify abnormalities in either the unit or labelling.
- Systems are required which incorporate all satellite fridges within the monitoring procedures of the hospital blood bank. The transfusion laboratory should collect crossmatched red cell

units from satellite fridges if they have not been used within 24 to 48 hours of the time they were originally requested (Mc Clelland, 2001).

- Computerised systems of blood storage monitoring which prevent errors of collection are recommended.
- It is important that hospitals that accept blood units accompanying patients have policies in place to determine the circumstances in which they can be used for the patient rather than discarded.

Transfusions based on incorrect or absent haematology results (n=7)

There were seven reported cases, six involving red cells and one involving plasma, where the transfusion was based on inaccurate or old haematology results.

Findings:

- In three cases transfusions were prescribed or continued based on old Hb results, although current Hb results were available but not checked.
- Three cases involved incorrect Hb results. In one case the sample was transposed in the haematology laboratory. In a second case, a normal result was misread and in the final case, it has not been possible to determine the reason.
- One of these cases resulted in the patient, an elderly female, receiving four units of blood, when the Hb level was actually 13g/dl.
- One case involved apparently abnormal coagulation results. The sample was taken from an arterial line and the abnormal result was shown subsequently to be due to heparin in the sample. This led to unnecessary plasma transfusions.

Recommendations:

- A current Hb result should be checked prior to prescribing and administering a transfusion.
- When Hb samples are taken between units as recommended, it is important to check the result prior to further transfusion.
- Medical and nursing staff must be educated in correct blood sampling techniques.
- Care is needed in laboratory identification procedures for haematology samples.
- Where anomalous Hb results are found, a repeat Hb sample should be obtained before a decision to transfuse is made.

Failure to supply special requirements in CMV negative and/or irradiated components (n=12)

Findings

There were 12 cases reported in this category.

- Eight cases occurred due to prescription and/or request errors where special requirements were not stated or the clinical history, which would have raised the laboratory's awareness to the requirement, was omitted.
- None of the cases resulted in complications for the patient.

Recommendations

- The number of cases reported in this category emphasises the need for ongoing education and training of staff involved in prescribing, ordering and administering transfusions. The significance and importance of the bedside checking procedure cannot be over-emphasised.
- As eight of the twelve incidents are associated with failure to prescribe the correct products, systems need to be put in place within hospitals to ensure that the requirements of such patients are highlighted which include:
- Education of prescribing doctors to highlight the importance of accurate completion of prescription and clinical details on request forms.
- Alert stickers placed on the front of the medical record to alert clinical staff of the special requirements. This is particularly important when patients are being transfused outside clinical areas normally transfusing haematology/oncology patients.
- Systems need to be put in place to ensure that where care is shared between centres, patients receive the correct products.
- On going education should be provided for medical scientists who are involved in cross call cover and do not normally work in transfusion to highlight special requirements for certain patients.
- Once again a failure to heed computer warnings (Case 3) has highlighted the fact that as recommended in the NHO Annual Reports 2001 and 2002, computer systems should be designed with audible alarms/alerts to minimise opportunities to override screen warnings. Preferably any such overrides should require a reason or explanation, as this should question the need to override. An audit trail of any overrides should also be kept.

- In high risk areas such as busy haematology units, a blanket policy of the use of irradiated product for all patients with suspected malignant haematological disorders may be advisable.

IBCT transfused not using a filter or infusion device (n=5)

Findings

- Two incidents involved the administration of red cells and one case involved the administration of SD plasma. All were transfused without using a blood administration set with an integral 160-220 micron filter.
- In addition, one of the cases highlighted the need to ensure accurate recording of unit numbers transfused in emergency situations.
- Two cases involved the use of an electronic infusion device.

Recommendations

- Ongoing education is required to ensure correct administration of blood components.
- This should include training on the use of medical devices such as infusion pumps.
- There should be a dedicated person to check and record transfusions during massive haemorrhage to ensure traceability of all blood components and products.

Incorrect details recorded during initial admission (n=5)

Findings

- Of the five cases reported in this section, two resulted from a failure to check whether the patient had been previously admitted to the hospital and a new MRN was assigned. Previous transfusion records were then unavailable.

- One case involved a patient with two MRNs as this hospital allows allocation of more than one MRN per patient when the admission occurs out of hours. These numbers are never merged within the system.
- One case illustrates how poor and unclear communication resulted in a patient being hospitalised and treated using a different patient's record.
- None of the incidents were associated with complications.
- In order to reduce sampling errors extended or 24 hours phlebotomy services are recommended.
- It is important that existing policies are fully understood and regularly updated. On-going education must highlight to all medical, nursing and laboratory staff, especially those not regularly working in transfusion, the importance of strict compliance.
- In an emergency where there is insufficient time to obtain results from a fresh sample, the policy should include the use of emergency O negative blood until the patient has been regrouped.

Recommendations

- Patients admitted must have a unique hospital number assigned, either their previous MRN number or a new number, if the patient has no history at this hospital.
- Staff admitting patients should take care to obtain details of previous admissions to ensure that their previous MRN number and records are retrieved.
- If the patient is admitted via the A&E Department and given an emergency number, it must be possible to merge this number at a later stage with the actual unique hospital number in the computer system.
- All healthcare professionals must be aware of the importance of correct patient identification and ensure that details accompanying patients requiring transfer to another facility for further treatment are correct.
- Automated barcode systems which print transfusion labels at bedside from the patient's wristband, are available and would prevent the errors described.
- The linkage of the laboratory computer system and the hospital PAS system would also help detect these errors.

Incorrect/missing details on ID wristband (N=7)

- The importance of positive patient Identification using an accurate ID wristband has been highlighted over several years through both the NHO and SHOT Reports (NHO & SHOT).
- A secure patient identification procedure should be in place in all hospitals. The ID wristband should be worn at the time of taking of the crossmatch sample and should be in place before transfusion. This ID wristband should contain three unique identifiers, which include the patient's full name, date of birth and unique identification number (NBUG 2004).
- The importance of asking the patient to identify themselves prior to sampling and administration in order to identify any discrepancies is again highlighted.
- Hospital laboratories should have SOPs or Policies for the acceptance or rejection criteria for incorrectly labelled samples. Such policies should cover amendments, which are acceptable, and those which are unacceptable and require a fresh sample to be taken.

- Electronic forms of patient and blood component/product identification are now available and are recommended as they provide the highest degree of security. Where these systems are not in place, manual bedside identification procedures at sampling and administration remain the gold standard and must be strictly adhered to (BCSH 1999).

Unit labelling errors (n=9)

- Nine cases reported involved errors in labelling units in the laboratory for transfusions.
- Electronic systems in the laboratory and at the bedside that reduce errors are recommended.
- As nurses are the last line of defence in providing safe effective care for their patient, the final bedside check provides an opportunity to detect and prevent preceding errors.

TABLE 6 WRONG UNITS TRANSFUSED (N=14)

Level	Case Number	ABO and Rh D Group of Patient	ABO and Rh D Group of IBCT	Volume of Incorrect Blood Component	Symptoms/Signs	Outcome	Cause of Error
1	IBCT Case 28 *	Group O Rh D positive	Group A Rh D positive	Two units of red cells	Mild fever, tachycardia mild hypotension.	Required further transfusion but recovered with no complications.	Two samples were processed simultaneously leading to a transposition error and this ABO incompatible transfusion.
1	IBCT Case 63 *	Group O Rh D Positive	Group A Rh D Positive	Six units of red cells	Temporary increase in the serum bilirubin.	Recovered with no complications.	Labelling error of the patient sample in the laboratory resulted in the patient being transfused with six units of ABO incompatible red cells.
1	IBCT Case 70 *	Group O Rh D positive	Group B Rh D positive	Two units of red cells	No symptoms of acute haemolysis. A raised serum bilirubin was noted three days post transfusion associated with a falling Hb on day five.	Required further transfusion but recovered with no complications.	A lapse of concentration during the grouping procedure led to the recording of this patient as AB Rh D positive instead of group O Rh D positive.
1	IBCT Case 88 *	Group B Rh D positive	Group A Rh D positive	200mls of red cells	Patient had been admitted with septic shock, electrolyte imbalance and coagulopathy.	No evidence of haemolysis post transfusion. Died two weeks later as a result of the underlying septicemia following two further surgical interventions.	Failure to identify correct patient sample for testing resulted in an ABO incompatible transfusion.
1	IBCT Case 118 *	Group A Rh D positive	Group AB Rh D positive	Two units of red cells	None	Post transfusion DAT positive but the patient had no complications as a result of this transfusion.	Incorrect group result interpretation complicated by the absence in reverse group of anti B isoagglutinin due to patient's underlying condition.
1	IBCT Case 90 *	Group A Rh D positive	Group A Rh D positive and Group O Rh D positive	Eight units of A positive red cells and two units O positive platelets	None	No complications as a result of this transfusion.	The patient was post BMT; the donor group was O Rh D positive. Hospital policy stated the patient required transfusion with group O Rh D positive red cells and group A Rh D positive platelets. During an emergency transfusion the policy was misinterpreted.

* Included as full case history

TABLE 6 (CONTINUED) WRONG UNITS TRANSFUSED (N=14)

Level	Case Number	ABO and Rh D Group of Patient	ABO and Rh D Group of IBCT	Volume of Incorrect Blood Component	Symptoms/Signs	Outcome	Cause of Error
1	IBCT Case 39 *	Group A Rh D negative	Group O SD Plasma	Four units of SD plasma	None	No complications as a result of this transfusion.	Incorrect blood group result obtained. Testing not performed in accordance with laboratory policy.
1	IBCT Case 79 *	Group B Rh D positive	Group A SD Plasma	One and a half units of SD plasma.	None	No complications as a result of this transfusion.	Two incorrect SD plasma units thawed and assigned to patient of a different blood group in laboratory.
1	IBCT Case 97 *	Group O Rh D positive	Group B SD Plasma	One unit of SD plasma	None	No complications as a result of this transfusion.	One unit of SD plasma was checked at the nurse's station and hung for the wrong patient who was sharing the same room as the intended patient.
1	IBCT Case 49 *	Group A Rh D positive	Group A Rh D positive	< 50mls pooled platelet concentrate	None	No complications as a result of this transfusion.	Very busy workload, two patients receiving platelet transfusions at the same time. Units transposed in ward.
1	IBCT Case 101 *	Group O Rh D positive	Group O Rh D positive	One unit of apheresis platelets	None	No complications as a result of this transfusion.	Two patients with the same name in the ward. Platelets ordered by phone from the ward, no MRN requested or given. Platelets were issued for the wrong patient. The patient had no wristband due to a faulty printer. Two qualified staff carried out the bedside check remote from the patient.
1	IBCT Case 15 *	Group O Rh D positive	Group O Rh D positive	Two units of pooled platelet concentrate	None	No complications as a result of this transfusion.	One of the units of platelets transfused was actually for a different patient and incorrectly labelled in the laboratory.

* Included as full case history

TABLE 6 (CONTINUED) WRONG UNITS TRANSFUSED (N=14)

Level	Case Number	ABO and Rh D Group of Patient	ABO and Rh D Group of IBCT	Volume of Incorrect Blood Component	Symptoms/Signs	Outcome	Cause of Error
1	IBCT Case 23 *	Group O Rh D positive	Group O Rh D positive	One unit of red cells	None	No complications as a result of this transfusion.	Label for crossmatched unit attached in error to an uncrossmatched, but group compatible unit. Unit then issued and transfused uneventfully.
2	IBCT Case 18 *	Group O Rh D negative post BMT	Group O Rh D positive	Two units red cells and pooled platelets	None	No complications as a result of this transfusion.	Failure to record history of BMT on the transfusion request form led to the transfusion laboratory issuing Rh D positive red cells to a Rh D negative male patient.

* Included as full case history

Blood components of the wrong ABO or Rh group or wrong component given. (n=14)

We describe all the cases in detail.

ABO incompatible red cells

Level 1 IBCT Case 28

This 50-year-old female with symptomatic postoperative anaemia Hb 5.9g/dl required an emergency transfusion of two units of red cells. The patient had been grouped before. A medical scientist not normally working in the transfusion laboratory processed the sample on call. Two pre-transfusion samples from different patients were processed simultaneously. The scientist failed to carry out the necessary checking procedures which led to a transposition of the two samples. The patient was grouped as A Rh D positive. The historical grouping record was not checked against the current result. The patient's correct group, group O RhD positive, was documented on the transfusion request form but was also missed. Two units of group A Rh D positive red cells were crossmatched, issued and transfused to this patient. The second patient's sample was for type and screen and no blood was actually crossmatched. During transfusion, symptoms of tachycardia and mild hypotension were recorded, but attributed to the underlying condition. There was also a low-grade fever. The error was discovered the next working day by laboratory staff when routinely rechecking all on-call work. Retrospective testing of the pre-transfusion sample and historical records confirmed the patient was in fact group O Rh D positive. The patient recovered from this incident but required two further units of red cells Hb 7.3g/dl. This second transfusion episode was uneventful.

Level 1 IBCT Case 63

This patient presented with a symptomatic anaemia Hb 5g/dl following several episodes of melaena and required a transfusion of six units of red cells. The patient had no previous transfusion records. A basic grade medical scientist, not normally working in transfusion, was doing the crossmatch on-call.

Simultaneously two other urgent specimens were also being processed. When the scientist placed the sample test tube with a unique numbered sticker in the centrifuge he was unaware that another specimen had been left there from a previous crossmatch. During the crossmatch procedure, repeated calls were received from the A&E department for an urgent crossmatch for a different patient. When the scientist returned to the centrifuge to remove the specimen tube, the incorrect one was inadvertently removed and labelled with this patient's details. Following further interruptions, the scientist, realising the initial error, began the process with a fresh specimen but as the other specimen was still in the centrifuge the mistake was repeated and the incorrect specimen tube was again labelled with details from this patient. The patient's blood group was recorded as group A Rh D positive. The patient subsequently received the six units of group A Rh D positive blood within a 72-hour period. While he experienced a slight rise in temperature during the first and second unit, it never rose above 1.5°C and was ascribed to an underlying chest infection and not the transfusion. The error was discovered five days later when the patient was regrouped as O Rh D positive. The patient suffered no adverse effects as a result of this transfusion apart from a temporary increase in bilirubin.

Level 1 IBCT Case 70

This elderly female patient required transfusion of two units of red cells for a symptomatic anaemia of chronic disease Hb 8.5g/dl. The pre-transfusion sample was processed over the weekend when only a limited service is provided. The medical scientist who did not normally work in transfusion was distracted by problems in another laboratory. The blood group result was recorded incorrectly as group AB Rh D positive as the grouping card in reverse in error. The actual result was group O Rh D positive. The patient had been grouped at this hospital previously but as the laboratory had only recently been computerised, the historical grouping record was available on a manual system only and the current group was not checked against the manual

historical records. The crossmatch, performed according to laboratory policy, was incompatible. However the medical scientist was simultaneously working on another sample and failed to read this crossmatch result. Three units of group B Rh D positive red cells were labelled and issued (B Rh D positive red cells would have been appropriate for a group AB patient). Two of the three units were transfused over the weekend uneventfully. Laboratory staff discovered the error during routine checking of all on-call work on the next working day. There were no symptoms of acute intravascular haemolysis but a transient rise in the serum bilirubin was noted three days post transfusion. This was associated with a falling haemoglobin five days following transfusion and further transfusion was required which was uneventful.

Level 1 IBCT Case 88

This patient required an emergency transfusion of two units of red cells following major abdominal surgery. The patient was extremely ill and septic on admission. A medical scientist regularly working in blood transfusion did the crossmatch on-call. The patient grouped as A Rh D positive. Two units of group specific crossmatched red cells were issued to the ICU. Because of the patient's deteriorating condition, a decision was made to transfuse both units simultaneously. In the laboratory, the medical scientist on-call was double-checking the results from call when the error was discovered. Following shift changeover, the on-call medical scientist had thought that there was only one specimen and one request form for processing. However, the previous medical laboratory scientist had left another non-urgent specimen from a different patient on the bench, without a crossmatch form. This incorrect specimen with the request form for the correct patient was used in the crossmatch for this patient. Ward staff were immediately alerted and the transfusion was discontinued. The patient regrouped as group B RhD positive. At this stage a combined 200mls approximately of both units had been transfused. Pre-transfusion the patient had an electrolyte imbalance, coagulopathy and required

inotropic support for hypotension. Laboratory investigations did not show evidence of haemolysis. The patient required two further surgical procedures as a result of his underlying condition and subsequently died two weeks later following a stormy post-operative period.

Level 1 IBCT Case 118

This patient with anaemia Hb 7.4g/dl and associated immunodeficiency required a transfusion of two units of red cells. This was a non-emergency transfusion, administered over a weekend period and a medical scientist on-call, not normally working in transfusion did the cross match. The patient's blood grouped as AB RhD positive and two units of group AB crossmatched blood were issued and transfused to the patient without complications. Repeat testing of the pre-transfusion sample using column technology during routine check of on call work showed the patient's blood group was in fact A RhD positive, but the patient sample lacked the anti B isoagglutinin. Post transfusion the antibody screen was negative and the DAT was positive in IgG but the eluate was non reactive. The patient suffered no complications. As a result of this incident, column technology, which is felt to be less prone to reading errors, will be introduced for all grouping done on-call out of hours.

Level 1 IBCT Case 90

This patient with a malignant haematological disorder post Bone Marrow Transplant (BMT) required an emergency transfusion of eight units of CMV negative and irradiated red cells and two units of CMV negative and irradiated platelets for bleeding. The BMT donor was O Rh D positive and the patient was A Rh D positive. A specific policy outlining requirements was entered on the laboratory computer which advised that the patient should receive group O Rh D positive red cells and group A Rh D positive platelets in the event of transfusion. During this emergency transfusion, the policy was misinterpreted and eight units of group A Rh D positive red cells and two units of group O Rh D positive platelets were inadvertently issued. These

units were then transfused to the patient. There were no complications as the patient had not developed anti A isoagglutinins. As a result of this incident all laboratory staff have been reminded of the importance of ensuring special requirements are correctly interpreted.

Cases involving the transfusion of plasma

Level 1 IBCT Case 39

This 55- year old male with a history of hepatomegaly, hepatic congestion, underlying metastatic deposits and cardiomegaly suffered an epistaxis with bleeding uncontrolled by Vitamin K. The pre-transfusion INR was >10 and four units of SD plasma were prescribed. A permanent member of transfusion laboratory staff performed grouping on call. The medical scientist read the group correctly as group A Rh D negative, but the result was recorded incorrectly as group O Rh D negative. Four units of group O SD plasma were issued and transfused. During routine checking of on-call work the following day, the error was discovered and the specimen was grouped as A Rh D negative. The patient did not suffer any complications.

Level 1 IBCT Case 79

This elderly patient required an emergency transfusion for a massive haematemesis. There was no previous transfusion history. The patient's group was recorded as B Rh D positive and the patient was issued with group B red cells. In addition two units of SD plasma were prescribed. A tray containing group A SD plasma was removed from the freezer and a laboratory medical scientist on-call who did not regularly work in blood transfusion, thawed two group A units in error. The laboratory computer does not have the facility to print the patient's group onto the plasma issue labels or issue vouchers but the patient's blood group was documented on the laboratory reference section of the transfusion request form. The error was not identified at the time of administration as the group was not printed on the issue voucher and there was no previous transfusion history in the medical record. The patient

had received one and a half units of incorrectly grouped SD plasma when the laboratory staff realised the mistake and communicated this to the ward. The transfusion was discontinued. The patient experienced no complications related to this transfusion. As a result of this incident, proposed changes to the laboratory computer system are in place to print the patient's group onto the issue labels and issue vouchers of plasma.

Level 1 IBCT Case 97

This group O Rh D positive male patient, with an underlying malignancy received a transfusion of one unit of group B SD plasma, which was intended for another patient. Four units of SD plasma had been ordered as an emergency transfusion for the intended patient. The ward was extremely busy that night and the transfusion took place at 02.00am. The first unit was checked by two nurses at the nurse's station and taken to the room shared by two patients. The unit was administered by a nurse covering a different section of the ward and did not include positive patient identification at the bedside. The error was noticed during the checking procedure for the second unit which was carried out at the bedside and included the patient in the process as per hospital policy. The patient was reviewed immediately and required no treatment. The patient for whom the plasma was intended was then transfused with the remaining three units from this issue.

Incidents involving the transfusion of platelets

Level 1 IBCT Case 15

This O Rh D negative patient required a transfusion of one unit of platelets for postoperative bleeding for drug induced platelet dysfunction. Another patient, group O Rh D positive, also required a pre operative transfusion of platelets. The two units of platelets were issued from the supply centre to the hospital laboratory. It was not noted on the delivery docket that the units were for two different patients. Both units were labelled and issued during normal working hours by a transfusion medical scientist for the one patient. The first unit of

platelets was transfused intra-operatively in theatre uneventfully. The nurses taking care of the patient were assured by a nurse in theatre that the platelets had been prescribed and all checking procedures had been carried out and were correct and the second unit was commenced. The laboratory noted the discrepancy during a review of routine work and contacted ICU where transfusion of the second unit was underway. The surgical team, when contacted, advised continuing the transfusion as the patient was bleeding post operatively. The patient suffered no complications as a result of this transfusion. There was delay supplying a further unit of platelets for the patient for whom they had been intended.

Level 1 IBCT Case 49

This young male patient (patient X) required transfusion for thrombocytopenia secondary to a malignant haematological disorder. A second patient on the same ward, patient Y, required a platelet transfusion and both units were delivered to the clinical area in the early evening. Two nurses took both units on two different trays with accompanying documentation and checked the unit for patient X outside his room on the corridor. During the checking procedure, they were interrupted and the staff nurse, who was to commence the transfusion, was called away. On her return, she picked up the tray with platelets labelled in patient Y on it and went alone to the bedside of patient X and commenced the transfusion without any formal identification of the patient. She then proceeded to check the second unit for transfusion to patient Y with a second nurse. During this procedure the error was identified and the transfusion was discontinued. Less than 50mls of incorrect platelets had been transfused. There were no complications to this transfusion as the incorrect platelets were ABO and Rh D compatible and both units of platelets were also CMV negative and irradiated. This staff nurse was the only nurse on her team that day certified competent to administer drugs, fluids or blood via a Hickman line. However, three nurses competent to access a Hickman line were on another team in the same ward but were not asked for assistance.

Level 1 IBCT Case 101

This young man with a malignant haematological disorder required a non-emergency transfusion of CMV negative and irradiated platelets. The request was telephoned to the laboratory. The MRN was not checked at the time of the request. There were two patients with the same name in the ward both of the same blood group and same special requirements and a unit for the wrong patient was issued. The pre-transfusion check took place remote from the patient. The date of birth and the MRN did not match but the error was not detected. The patient was not wearing a wristband, as the wristband printer was out of order but the patient should have been given a handwritten wristband. The patient suffered no complications as a result of this transfusion. The laboratory staff realised the error on the next issue of platelets for this patient.

Uncrossmatched Unit Red Cell Issued

Level 1 IBCT Case 23

This baby required a non-emergency transfusion of one unit of red cells for symptomatic anaemia secondary to sepsis Hb 6.2 g/dl. A laboratory scientist not normally working in transfusion processed the sample during on-call hours. One unit of group compatible red cells was issued. However the issue label was inadvertently attached to an uncrossmatched group compatible unit, which was then placed in the issue fridge for transfusion. The discrepancy between the issue label and the donation information on the front of the pack was not identified at time of collection, nor during the pre-transfusion checking procedure and the transfusion proceeded uneventfully. Laboratory staff discovered the error when checking stocks the following day. Retrospective cross-matching of the pre-transfusion sample and transfused unit was performed and the unit was confirmed to be compatible. There were no complications to this incorrect transfusion.

Rhesus incompatible units transfused

Level 2 IBCT Case 18

This male patient received one unit of pooled CMV negative irradiated platelet concentrate for thrombocytopenia associated with a malignant haematological disorder. The patient details on the transfusion request form did not include the fact that the patient had had a BMT two months previously at another centre. The patient had been transfused one year earlier at this hospital and had grouped as group O Rh D positive on that occasion. On this occasion, he again grouped as O Rh D positive. One unit of group O Rh D positive platelets were issued and transfused uneventfully. Twelve days later there was a request for two units of red cells for anaemia –Hb 8.1 g/dl. Again there was no reference to the BMT on the transfusion request form. He grouped as O Rh D positive and two units of crossmatch compatible red cells were issued and transfused uneventfully. Three weeks later a sample sent to the laboratory showed a "mixed field reaction" on Rh grouping. It was then discovered that this patient had received a BMT two months previously and the donor had been group O Rh D negative. The BMT recipient should be transfused with the bone marrow donor's Rh group post transplant. The patient did not suffer any complications.

Failure to give antigen negative red cells (n=8)

Seven cases were reported where antigen negative blood should have been provided as the patient had current or previously detected antibodies. An additional case involved the continued use of Rh positive blood in a Rh negative patient after the initial exposure due to a communication failure.

In four cases the antibodies were anti-E (one of which only reacted in enzyme and therefore was of doubtful clinical significance only). In the remaining four cases, the antibodies were an anti Jk^a, an anti Fy^a, an anti-E and anti-Jk^b and an anti-C, -D, -E.

Failure to provide antigen negative blood leads to the risk of a delayed haemolytic transfusion reaction but in these eight cases there were no reported complications.

Findings

- In three cases (Cases 21, 60 and 24), the patient's historical records were not accessed either through failure of initial patient identification at admission (Case 21), or failure to check manual records (Case 60) or retrieval of the wrong records (Case 24). In one further case (Case 59), the medical record was accessed but the information in the medical record was ignored.
- Three cases (Cases 24, 50 and 62) involved failure in laboratory workup procedures.
- In one case (Case 24), where the incorrect historical records were retrieved, the current antibody screen was negative and antigen negative blood was not selected.
- In a second case (Case 50), an antibody investigation was not completed at the end of the working day and when blood was urgently required, the incomplete antibody investigation went unnoticed and antigen negative blood was not selected.
- In the final case (Case 62), the sample used for crossmatch was seven days old and a fresh sample was not requested although the patient had a subsequent transfusion. In this case, the patient had developed antibodies since the previous transfusion.
- Four of these cases (Cases 24, 59, 60 and 62) also involved on-call cover, which in three cases was being provided by a medical scientist not normally working in the transfusion laboratory.

- Two cases (Cases 56 and 68) highlighted the lack of communication between hospitals and the failure of medical staff to realise the importance of this clinical information. Case 56 involved a patient previously transfused in another hospital where he had had a transfusion reaction. However, the clinical details were not recorded on the request form in the second hospital and as the antibody screen was currently negative, antigen negative blood was not issued.
- Case 68 involved a massive transfusion of Rh D positive red cells to a male Rh D negative patient in line with guidelines. When the patient was transferred to another hospital, this information was not passed on. The patient, who grouped as Rh D positive, went on to receive further transfusions of Rh D positive blood. While it was appropriate to continue to transfuse Rh D positive blood until the acute bleeding episode was resolved, transfusion of Rh D positive blood after that ran the risk of a delayed haemolytic reaction. A post transfusion antibody screen some months later was positive for anti-C, -D, -E.
- Antibody investigations for patients who may require blood in an emergency should be completed as soon as possible after receipt. Where this is not possible, the computer or manual records should clearly document this. In cases of clinical emergency, it may be necessary to issue blood to these patients before investigations are completed but computer alerts to incomplete antibody investigations should be difficult to override inadvertently.
- Hospital transfusion laboratories need to be informed when patients are transferred between hospitals. This will enable them to contact the referring hospital and confirm transfusion history. This information should also be included in the written communication accompanying the patient from the clinical team where possible.
- Consideration should be given to issuing antibody cards to all patients with clinically significant antibodies (NBUG, 2002).
- The possibility of a national antibody register for patient with red cell antibodies should also be evaluated.

Recommendations

- The patient's primary identifiers at admission must be recorded correctly. This information allows access to all previous records should this patient have had a previous admission.
- The importance of filling in the patient's clinical and past transfusion history on the request form is highlighted as it enables the medical scientist to check previous transfusions which may have been administered and ensure that the correct product is issued.
- Historical transfusion records, manual and computer, should be checked for all patients requiring transfusion.

TABLE 7 FAILURE TO GIVE ANTIGEN NEGATIVE RED CELLS (N=8)

Level	Case Number	Antibody Specificity	Volume of red cells transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 21 *	Anti-Jk ^a	Three units	No complications as a result of this transfusion.	Incorrect DOB and address given on admission creating a new patient ID. Patient had been an in-patient previously. When original MRN and records were retrieved the patient had a documented anti-Jk ^a antibody.
1	IBCT Case 24 *	Anti-E	Two units	No complications as a result of this transfusion.	Failure to check historical records. Compatible antigen negative red cells not selected.
1	IBCT Case 50 *	Anti-E	< 50mls	No complications as a result of this transfusion.	Product issued from the laboratory prior to completion of alloantibody identification.
1	IBCT Case 56 *	Anti-Fy ^a	Two units	No complications as a result of this transfusion.	Failure to check historical records.
1	IBCT Case 59 *	Anti-E	Two units	No complications as a result of this transfusion.	Antigen negative blood not selected by on-call laboratory scientist as antibody screen negative. Previous antibodies on historical record not noticed.
1	IBCT Case 60	Anti-E	Two units	No complications as a result of this transfusion.	Patient had a previously documented anti-E in enzyme only. Antibody screen negative. Previous records not checked and antigen negative red cells not selected.

* Included as full case history

TABLE 7 (CONTINUED) FAILURE TO GIVE ANTIGEN NEGATIVE RED CELLS (N=8)

Level	Case Number	Antibody Specificity	Volume of red cells transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 62 *	Anti-E Anti-Jk ^b	Four units	DAT positive post transfusion. No complications as a result of this transfusion.	The crossmatch was done on a seven-day-old sample instead of a new sample. The patient had developed antibodies since the previous transfusion.
2	IBCT Case 68 *	Anti-C, -D, -E	Five units and two units of pooled platelet concentrate	No complications as a result of this transfusion.	Massively haemorrhaging Rh D negative male patient transfused with eight units of Rh D positive red cells in line with policy. On transfer to a tertiary care centre staff were unaware of the original Rh group and the patient grouped as Rh positive. A further five units of RhD positive red cells and two units of RhD positive platelets were transfused.

* Included as full case history

Failure to give antigen negative red cells (n=8)

We describe seven cases in detail

Level 1 IBCT Case 21

This male patient was admitted via the A&E Department. He had a historical record but on this occasion was given a new MRN because the ambulance crew gave the location where the patient was collected which was not his home address and an incorrect date of birth was found on a letter from a GP in the patient's pocket. When this data was entered onto the hospital computer patient system, the patient was not recognised. A new patient identity was generated and a new MRN issued. The patient was not well enough to confirm these details. The pre-transfusion sample sent to the

laboratory grouped as O Rh D positive, antibody screen negative and three units of red cells were crossmatched and issued for transfusion. The first two units were transfused while the patient was still unwell and unable to confirm his details. By the pre-transfusion checking of the third unit, his condition had improved. When asked to state his full name and date of birth it became evident that the wrong date of birth had been used and the clinical staff contacted the laboratory to inform them of the error. It was decided that this was a clerical error but that it was safe to proceed with the transfusion. All three units were transfused uneventfully. The following day it was discovered the patient had in fact a historical record and the original medical record number was retrieved. Using this information the transfusion laboratory staff found this patient

had an anti-Jk^a previously. The units he received during this transfusion episode were crossmatch compatible but had not been antigen screened because the patient history was not elicited. The second and third units transfused were checked for antigen compatibility and found to be compatible but the first unit transfused had been discarded in the A&E Department. Retrospective testing of the pre-transfusion sample confirmed that the patient was currently antibody negative. Post transfusion testing showed the same results.

Level 1 IBCT Case 24

This postoperative patient with pneumonia required transfusion of two units of red cells for a anaemia Hb 9.8g/dl. The crossmatch sample was drawn outside normal working hours and details of previous transfusion including the group and the fact that the patient had antibodies was recorded on the request form in the laboratory. The historical group was checked using manual records, but the unique hospital identification number or date of birth were not checked and the name only was used to confirm sample identification. As a result, an incorrect patient of the same name and blood group was chosen. The pre-transfusion sample was antibody screen negative. Crossmatch compatible cells were issued but antigen negative red cells were not selected. The error was identified the following day during review of all on-call work. A fresh sample identified the antibody specificity as anti-E. Subsequent investigation revealed that the two units were in fact E antigen negative.

Level 1 IBCT Case 50

This patient with a history of malignancy required one unit of red cells for anaemia Hb 7.1g/dl. An antibody was detected but the investigations were not completed by the end of routine working hours. The following day, an alert warning of the incomplete antibody investigation went unnoticed and a crossmatched unit of red cells was issued for transfusion from the laboratory prior to completion of alloantibody investigations. When two further units of red cells were required that day the laboratory

scientist noticed the computer warning. The ward was contacted and advised to stop the transfusion. The alloantibody was identified as being an Anti-E. The remains of the component was sent to the laboratory for retrospective genotyping. This testing found the component was E antigen negative.

Level 1 IBCT Case 56

This middle-aged male patient with an underlying malignancy required a transfusion of two units of red cells pre operatively for anaemia due to active bleeding Hb 7 g/dl. The patient had been transfused in the past in a different hospital and had had a previous transfusion reaction but this information was not recorded on the transfusion request form. Pre-transfusion the antibody screen was negative. Two units of red cells were transfused uneventfully. The patient became very unwell as a result of his underlying illness and surgery was cancelled due to progression of an underlying sepsis. Three weeks later, a pre operative transfusion sample showed a positive antibody screen with anti Fy^a specificity. The medical scientist processing this sample checked the historical records from the previous hospital and found the patient previously had antibodies and should have received antigen negative red cells but this information had not been relayed to the transfusion laboratory.

Level 1 IBCT Case 59

This female patient with a symptomatic anaemia Hb 7.6 g/dl, required a transfusion of two units of red cells. The sample was sent to the laboratory on call. The patient had a history of a previous anti-E on laboratory computer. On this occasion the patient's antibody screen was negative. The on-call medical scientist, who does not normally work in the transfusion laboratory, consulted the historical record but did not notice the antibody results and did not select antigen negative red cells for crossmatch and issue. The error was discovered by laboratory staff the following morning when checking on-call work. A repeat antibody screen post transfusion was also negative.

Level 1 IBCT Case 62

This elderly male patient required a transfusion of red cells for a symptomatic anaemia, following a gastrointestinal bleed, Hb 6.4g/dl. A telephone request was made to the laboratory to crossmatch four units on call. The medical scientist processing the request did not regularly work in the blood transfusion laboratory. The patient had been transfused seven days earlier but a new specimen was not requested and the four units were crossmatched using the original specimen which had been stored. The crossmatch was negative and the patient was transfused uneventfully with one of these units. The following morning during a check of on-call work, the laboratory staff noted the error and a new sample from the patient was requested. The antibody screen was now positive with anti E and Jk^b antibodies. The DAT was positive for IgG and C₃d. Antigen negative blood was selected for the remaining three units, which were transfused uneventfully. The patient remained symptom free and made a good recovery from his underlying illness. Five days later a fresh sample was requested from the laboratory and the antibody specificity was confirmed as anti-E plus Jk^b.

Level 2 IBCT Case 68

This young male patient was admitted to a regional hospital following an RTA with a massive haemorrhage as a result of multiple injuries. The patient grouped as O Rh D negative. During the resuscitation period 14 units of red cells, four units of SD Plasma and four units of platelets were transfused. However in accordance with the massive transfusion policy to conserve stocks of Rh D negative blood, eight of the 14 units of red cells transfused during this episode were group O Rh D positive. When the patient had stabilised he was transferred to a tertiary care centre for further management. The nursing and medical transfer letters outlined the blood components and products transfused during the resuscitation period but failed to state that it had been necessary to change to group O Rh D positive red cells. A pre-transfusion sample was taken on arrival. The group was recorded

as O Rh D positive, antibody screen negative. Two units of group O Rh D positive pooled platelet concentrates and five units of group O Rh D positive red cells were transfused uneventfully over the following 72 hours. A sample was processed three days later and again the group was O Rh D positive. At this point the patient was transferred to another tertiary care centre for specialist management and grouped as O Rh D positive, although he did not require further transfusion.

Eleven weeks later he was re-admitted to the tertiary hospital for evaluation. The pre-transfusion sample at this point confirmed that he was in fact group O Rh D negative. At this time because of his previous exposure to Rh D positive blood he now had anti-C,-D,-E antibodies and a positive DAT. The communication error was discovered when historical records were checked and a full investigation was carried out by the TSO.

Transfusion based on incorrect result (n=7)

There were seven reported cases, six involving red cells and one involving plasma, where the transfusion was based on inaccurate or old haematology results.

Findings:

- In three cases (Cases 11, 102 and 109), transfusions were prescribed and administered based on old Hb results, although current Hb results were available but not checked.
- Three cases involved incorrect Hb results. In one case (Case 54), the sample was transposed in the haematology laboratory. In a second case, a normal result was misread (Case 99) and in the final case (Case 91), it has not been possible to determine the reason.
- One of these cases (case 54) resulted in an elderly female patient receiving four units of blood, when the pre transfusion Hb level was actually 13g/dl.

- One case (Case 9) involved apparently abnormal coagulation results. The sample was taken from an arterial line and the abnormal result was shown subsequently to be due to heparin in the sample. This led to unnecessary plasma transfusions.

Recommendations:

- A current Hb result should be checked prior to prescribing and administering a transfusion.
- When Hb samples are taken between units as recommended, it is important to check the result prior to further transfusion.

- Medical and nursing staff must be educated in correct blood sampling techniques.
- Care is needed in laboratory identification procedures for haematology samples.
- Where anomalous Hb results are found a repeat Hb sample should be obtained before a decision to transfuse is made.

TABLE 8 TRANSFUSION BASED ON INCORRECT RESULT (N=7)

Level	Case Number	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 11 *	Two units of red cells	No complications as a result of this transfusion.	Hb 5.9g/dl. Transfused with two units of red cells. Hb post transfusion 10.2g/dl. Report not noted by clinical staff and a further two units administered. After this second transfusion Hb 12.9g/dl.
1	IBCT Case 54 *	Four units of red cells	No complications as a result of this transfusion.	Incorrect Hb result due to transposition of FBC sample. This elderly female patient had a post transfusion Hb 16.9g/dl.
1	IBCT Case 91 *	One unit of red cells	No complications as a result of this transfusion.	Hb result of 7g/dl reported actual result 10.3g/dl.
1	IBCT Case 99	One unit of red cells	No complications as a result of this transfusion.	Near patient testing Hb level 8.5 g/dl misread. Repeat Hb 12.2g/dl.

* Included as full case history

TABLE 8 (CONTINUED) TRANSFUSION BASED ON INCORRECT RESULT (N=7)

Level	Case Number	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 102 *	One unit of red cells	No complications as a result of this transfusion.	Prescribed and administered without checking the most recent Hb. Actual Hb pre-transfusion was 12.7g/dl.
1	IBCT Case 109 *	Two units of red cells	No complications as a result of this transfusion.	Prescription based on an old Hb result in the patient's chart.
1	IBCT Case 9 *	Three units of SD plasma	No complications as a result of this transfusion.	The initial PT and APTT had been taken from the arterial line and three units of plasma were prescribed on the result. A second specimen post transfusion identified heparin in the first sample as the cause.

* Included as full case history

Transfusion based on incorrect results (n=7)

We describe six cases in detail. None of the cases suffered complications but all were exposed to unnecessary transfusion(s).

Red Cells

Level 1 IBCT Case 11

This elderly female patient required a transfusion of two units of red cells for anaemia Hb 5.9g/dl due to post-operative oozing. The transfusion was uneventful and the post transfusion Hb was 10.2g/dl. However, medical staff did not see this report and went on to prescribe a further two units of red cells. Post transfusion of these two units. The Hb was 12.9g/dl. The TSO discovered this error during a routine review.

Level 1 IBCT Case 54

This elderly female patient required an emergency

transfusion of four units of red cells for an apparent anaemia associated with haemoptysis Hb 7.3g/dl. A transposition error occurred in the laboratory when entering data from two different patients FBC sample tubes onto the laboratory computer on call. As a consequence the results were transposed and incorrect haemoglobin results were assigned to each patient. The patient's actual Hb was 13.1g/dl. On the basis of this inaccurate result and clinical symptoms the patient was transfused with four units of red cells without checking the Hb between units. The patient was over transfused with a post transfusion Hb of 16.9g/dl but did not suffer any adverse symptoms or complications.

Level 1 IBCT Case 91

This male patient presented with haematemesis and a transfusion of three units of red cells was prescribed for anaemia Hb 7.1g/dl. Following transfusion of the first unit of red cells the nurse looking after the patient repeated the FBC and the

actual Hb was found to be 10.3g/dl. The initial sample, which was still in the laboratory, was rechecked and the Hb result was 7.1g/dl. Either a specimen mix up or insufficient blood in the sample tube to perform accurate testing was suspected but neither possibility could be confirmed.

Level 1 IBCT Case 102

This elderly patient with an underlying history of carcinoma, hypertension and anaemia required transfusion over a seven-day period with seven units of red cells. Hb on admission was -6.4g/dl and the transfusions were administered uneventfully. Prior to the administration of the seventh unit, a Hb result of 12.7g/dl was available on the ward but was not checked prior to prescription or administration.

Level 1 IBCT Case 109

This postoperative patient was prescribed a transfusion of two units of red cells overnight for a blood loss of 1420 ml which was not symptomatic. The prescription was based on a pre operative haemoglobin result of 12g/dl. This was in fact an old report dated from the previous year and the pre operative Hb had in fact been 15g/dl. As it was night-time, the clinical staff were reluctant to contact the prescribing physician. Both units were transfused and the postoperative Hb three days later was 13g/dl.

Plasma

Level 1 IBCT Case 9

An elderly patient was prescribed an emergency transfusion of three units of SD plasma for an elevated PT 47.6 and APTT>120 attributed to disseminated intravascular coagulation (DIC). The original coagulation studies had been carried out using the arterial line. The transfusion was uneventful, but repeat coagulation studies post transfusion showed no improvement (PT 20.3, APTT 180). Following consultation with the haematologist who suspected heparin contamination of the sample, a peripheral line sample was tested and the repeat results were normal with no evidence of DIC.

Laboratory investigation confirmed that the results were due to heparin. Following discussion with hospital staff, there was no evidence that the arterial line had been flushed with heparin. Investigation of the possibility that the line was manufactured with a heparin coating also proved negative. One possibility is that a blood gas sample, which had been taken before the coagulation sample, left a heparin residue in the arterial line. The patient subsequently died as a result of his underlying condition unrelated to transfusion.

Unnecessary components transfused (n=11)

We received 11 reports of unnecessary transfusions.

Findings

Five of these cases (Cases 64, 87, 93, 98 and 105) involved the use of **plasma**.

- All of these incidents involved an inappropriate prescription of plasma where national guidelines were not followed.

Four cases involved the use of **red cells** (Cases 51, 112, 115 and 119).

- Three cases (Cases 112, 115 and 119) involved inappropriate prescription, two of which (Cases 115 and 119) were for treatment of iron deficiency in young women. The third was in a postnatal patient.
- In one case, (Case 51) a further prescription was written without cancelling the previous one.

Two cases involved the transfusion of **platelets** (Cases 72 and 110).

- In one case (Case 72), the initial platelet count was incorrect but the prescription for platelets was not cancelled.
- The other case (Case 110) involved an extra unit of platelets transfused based on prescription by volume in a paediatric patient and is described in the Paediatric chapter.

Recommendations

- Adherence to guidelines for the appropriate use of components, in particular the use of plasma, will avoid unnecessary transfusions. SD plasma should not be used for the reversal of over anticoagulation with warfarin where there is no evidence of severe bleeding or for reversal of over anticoagulation with warfarin prior to surgery except in emergency situations. Reversal can be achieved by stopping warfarin and/or use of low dose vitamin K (NHO leaflet, 2003, Appendix 2)
- Patients with iron deficiency anaemia respond quickly to specific iron therapy and rarely need transfusion.
- Unused and discontinued versions of documents should be removed from circulation when a new version is issued.

TABLE 9 UNNECESSARY COMPONENT TRANSFUSED

Level	Case Number	Volume of IBCT transfused	Symptoms & Outcome	Cause of Error
Cases involving SD plasma				
1	IBCT Case 64 *	Two units	No complications as a result of this transfusion.	Guidelines for the use of SD plasma not followed.
1	IBCT Case 87	Four units	No complications as a result of this transfusion.	Guidelines for the use of SD plasma not followed.
1	IBCT Case 93	Three units	No complications as a result of this transfusion.	Guidelines for the use of SD plasma not followed.
1	IBCT Case 98 *	Two units	No complications as a result of this transfusion.	Guidelines for the use of SD plasma not followed.
1	IBCT Case 105 *	Five units	No complications as a result of this transfusion.	Guidelines for the use of SD plasma not followed.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 9 (CONTINUED) UNNECESSARY COMPONENT TRANSFUSED

Level	Case Number	Volume of IBCT transfused	Symptoms & Outcome	Cause of Error
Cases involving red cells				
1	IBCT Case 112 *	Two units	No complications as a result of this transfusion.	Inappropriate prescription of red cells. Discontinued on consultant's advice.
1	IBCT Case 115	Three units	No complications as a result of this transfusion.	Inappropriate prescription of red cells. Discontinued on consultant advice.
1	IBCT Case 119 *	One unit	No complications as a result of this transfusion.	Postnatal patient required transfusion for symptomatic anaemia –Hb 6.7g/dl- Following two units red cells, symptoms resolved, Hb 8.5g/dl. One further unit given inappropriately based on prescription.
1	IBCT Case 51 *	One unit of red cells	No complications as a result of this transfusion.	The first prescription stated six units of red cells, three of which were transfused. The patient was reviewed and two of the remaining three units were prescribed, but the old prescription was not cancelled. The patient received all three units before the mistake was discovered.
Cases involving platelets				
1	IBCT Case 72 *	One unit of apheresis platelets	No complications as a result of this transfusion.	Discrepant platelet result. Prescription for platelets not cancelled in writing.
2	IBCT Case 110 *p	Two units of CMV negative and irradiated apheresis platelets	No complications as a result of this transfusion.	300mls of platelets were prescribed pre-operatively platelet count 19×10^9 One unit contained 200mls. The platelet count post transfusion of this unit was $118 \times 10^9/L$. The patient was transfused with a further unit of platelets. Post transfusion platelet count $155 \times 10^9/L$.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Unnecessary component transfused

Plasma

We describe three cases in detail involving the transfusion of Plasma.

Level 1 IBCT Case 64

This patient with newly diagnosed atrial fibrillation was admitted with nocturnal dyspnoea, excessive sweating and a possible chest infection. The initial management involved the use of antibiotics and warfarin. Following warfarin treatment for three days, the INR was 3. However the following day, the INR was 9.9 with no evidence of bleeding. The patient was transfused with two units of SD plasma. This was discovered during a routine audit by the TSO. The prescribing doctor was not aware of current National Guidelines (Appendix 2). This incident has highlighted the importance of education in the hospital.

Level 1 IBCT Case 98

This elderly patient with a history of ischaemic heart disease, TIAs and a deep vein thrombosis, was referred to hospital by his local GP for management of an INR > 10, as a result of over anticoagulation. The patient had no signs or symptoms of bleeding or bruising at the time of admission. Two units of SD plasma and 10mg of intravenous Vitamin K were prescribed and administered uneventfully. This incident was discovered during a routine audit of transfusion by the TSO.

Level 1 IBCT Case 105

This postoperative patient on warfarin therapy which had not been discontinued pre-operatively, had a raised INR 3.8 and was prescribed a non-emergency transfusion of five units of SD plasma. The approved protocol in this hospital for reversal of over anticoagulation is Vitamin K orally. The nurse on the ward was aware of this protocol and informed the prescribing doctor but it was decided to go ahead with the transfusion, as there were reservations expressed as to the efficiency of Vitamin K and how easily control of anticoagulant therapy could be restored.

Red Cells

We describe in detail three of the four cases involving red cells.

Level 1 IBCT Case 112

This young patient with an underlying congenital coagulation disorder required investigation of severe iron deficiency anaemia Hb. 6.9 g/dl associated with weakness and menorrhagia. The presenting symptoms in the A&E Department included dyspnoea and syncopal episodes. However, the patient's vital signs were stable and the patient was taking oral iron and tranexamic acid. Three units of red cells were prescribed on-call. Two units of red cells were transfused. During review the following morning by the Consultant Haematologist it was decided that it was an inappropriate transfusion and no further transfusions were administered.

Level 1 IBCT Case 119

This young female postnatal patient required a transfusion of red cells for a symptomatic anaemia Hb 6.7g/dl. There was no history of post partum haemorrhage. The patient was reluctant to agree to a blood transfusion but following detailed discussion consented and two units of red cells were prescribed and transfused. The patient's symptoms resolved. A third unit of red cells was transfused as the prescription stated that if the haemoglobin was less than 10g/dl one further unit of red cells was to be transfused. The Consultant Haematologist subsequently reviewed the case and highlighted current guidelines for red cell transfusion.

Level 1 IBCT Case 51

This elderly male patient with underlying cardiac disease and a stable abdominal aortic aneurysm presented with anaemia Hb 4.9 g/dl, and required transfusion with six units of red cells with diuretic cover. Following transfusion of the first three units, the patient asked for a rest from transfusion as he was having difficulty getting any sleep. During medical rounds the next morning, two units of red cells were prescribed to replace the previous prescription which was not cancelled. Later that day, a third unit of red cells was requested from the

laboratory on the basis of the old prescription. The error was discovered while writing the nursing report at the end of shift by which time the third unit was in progress.

Platelets

We describe one case in detail involving platelets. Case 110 is detailed in the Paediatric chapter.

Level 1 IBCT Case 72

This elderly female patient with sepsis required a transfusion of platelets for a platelet count recorded as $20 \times 10^9/L$. A second sample requested by the laboratory taken that day showed the patient's actual platelet count was $115 \times 10^9/L$ but the doctor had written the prescription before the repeat result was available to save time. The doctor felt that she had subsequently cancelled the order for platelets with the transfusion laboratory. However there was no record of this in the laboratory and the prescription was not cancelled on the prescription form. The unit was issued by the laboratory, checked against the prescription and transfused uneventfully. On investigation of this incident, the ward had two different prescription forms in circulation; the outdated one contained the original platelet prescription which had not been cancelled. A new updated prescription form was also used to prescribe a unit of red cells for this patient. As the platelet prescription was not on this form, the doctor would not have been prompted to cancel the previous platelet prescription.

Wrong Components Issued or Administered (n=4)

Findings

There were three incidents reported in this section where cross call cover was being provided out of hours in the laboratory and a lack of knowledge of the appropriate product currently in use allowed issue of a wrong component. One case involved an adult and the other two were paediatric cases. The final case (Case 42) involved the inappropriate use of Rh D negative emergency stock by medical staff.

- Cases 13, 27 and 45 involved a lack of knowledge of the appropriate product for issue from the laboratory and of those, two were issued by medical scientists not regularly working in blood transfusion but providing cross call cover.
- In two of the cases (Cases 13 and 27) involving neonatal patients, the product of choice would have been group specific SD plasma but Uniplas was selected and issued. These two cases are described in detail in the Paediatric chapter.

Recommendations

- Continuing education is necessary for staff providing cross call cover who may not be familiar with current guidelines.
- Medical staff need to be aware of the appropriate use of Rh D negative emergency stock.

Wrong Components Issued or Administered (n=4)

We describe one case in detail, Cases 13 and 27 are discussed in the Paediatric chapter.

Level 2 IBCT Case 42

This elderly female patient was admitted for investigations of a gastrointestinal bleed Hb 6g/dl. A sample was taken for crossmatch and was being processed in the laboratory. At the same time, a decision was made by the doctor on-call to transfuse the patient with two units of the designated emergency O Rh D negative blood stock. However, each unit of blood was to be administered over a three-hour period. Clinical staff questioned the appropriateness of the units for transfusion during the final bedside administration check, as there was no crossmatch report form available, but as they were junior staff, they were encouraged to continue with the transfusion. There were no complications as a result of this transfusion. The TSO discovered the incident during a routine audit of emergency O Rh D negative stock.

TABLE 10 WRONG COMPONENTS ISSUED OR ADMINISTERED (N=4)

Level	Case Number	ABO and Rh D Group of Patient	ABO and Rh D Group of IBCT	Volume of IBCT Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 13 *p	Group A Rh D positive	Uniplas	18mls of Uniplas given	No complications as a result of this transfusion.	Transfusion scientist on call thought Uniplas was the product of choice for neonates.
1	IBCT Case 27 *p	Group A Rh D Positive	Uniplas	Less than 50mls of Uniplas	No complications as a result of this transfusion.	Transfusion scientist thought Uniplas was the product of choice for neonates.
2	IBCT Case 45	Group AB Rh D positive	Group A SD plasma	12 units of A SD plasma	No complications as a result of this transfusion.	Incorrect units issued on-call by person not normally working in transfusion laboratory. Product of choice Uniplas.
2	IBCT Case 42 *	N/A	N/A	Two units of emergency O Rh D negative blood	No complications as a result of this transfusion.	Failure to prescribe correct component.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Errors surrounding collection, storage or improper handling of components n=10

Findings

- Three incidents (Cases 73, 82 and 89) concerned units of red cells left out of the fridge in excess of the recommended time, then returned to the fridge and later transfused.
- Two cases (Cases 32 and 53) demonstrate the dangerous practice of re-transfusing already pierced or 'spiked' units. The risk of bacterial contamination

of these units cannot be over-emphasised. In case 32, the pierced unit was stored for 15 hours before transfusion, which highlights the importance of ensuring that the patient has patent venous access and that all documentation is correct prior to collection of the unit.

- Case 53 involved a unit that had been discontinued because of a suspected transfusion reaction, stored in the wrong fridge while awaiting investigation, collected and re-transfused to the same patient, 24 hours later.

- Case 73 highlights the importance of ensuring that all staff handling blood are aware of storage requirements.
- Two of the incidents (Cases 6 and 82) were discovered during investigation of febrile transfusion reactions.
- None of the patients suffered any adverse effects.

Recommendations

- Under no circumstances should any blood product or component that has been pierced or 'spiked' with an administration set or other device be stored with the intent of re-use. The importance of this cannot be over emphasised as there is a serious risk of bacterial contamination.
- Should an unforeseen delay in starting the transfusion occur, it is necessary to return the unit to controlled storage within thirty minutes and inform the laboratory to ensure the unit is being returned to the appropriate fridge.

- Documentation containing details of three minimum patient identifiers must be brought to the fridge when collecting a unit of blood in order to verify unit and details.
- Inspection of the unit and documentation at the time of collection may identify abnormalities in either the unit or labelling.
- Systems are required which incorporate all satellite fridges within the monitoring procedures of the hospital blood bank. The transfusion laboratory should collect crossmatched red cell units from satellite fridges if they have not been used within 24 to 48 hours of the time they were originally requested (Mc Clelland, 2001).
- Computerised systems of blood storage monitoring which prevent errors of collection are recommended.
- It is important that hospitals that accept blood units accompanying patients transferred from other hospitals have policies in place to determine the circumstances in which they can be used for the patient rather than discarded.

TABLE 11 ERRORS SURROUNDING COLLECTION, STORAGE OR IMPROPER HANDLING OF PRODUCTS N=10

Level	Case Number	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 32 *	Less than 50mls of red cells.	No complications as a result of this transfusion.	Transfusion set up prior to checking patency of access. Transfusion not commenced until the following morning. Pierced unit stored for 15 hours in the satellite fridge before transfusion.
1	IBCT Case 53 *	Less than one unit of red cells.	No complications as a result of this transfusion.	Fever after first 50mls of cells. Transfusion discontinued. Placed in satellite fridge in error instead of being returned to laboratory. Unit collected 24 hours later for subsequent transfusion. Cord clamp used to seal the unit was not noticed during pre-transfusion check.

* Included as full case history

TABLE 11 (CONTINUED) ERRORS SURROUNDING COLLECTION, STORAGE OR IMPROPER HANDLING OF PRODUCTS N=10

Level	Case Number	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 37 *p	32mls of red cells	No complications as a result of this transfusion.	Emergency un-crossmatched group O Rh D negative red cells for adult use collected from a satellite fridge instead of emergency group O Rh D negative paedipack for emergency neonatal use.
2	IBCT Case 4 *	Two units of red cells.	No complications as a result of this transfusion.	Two units of un-crossmatched O red cells removed from stock shelf of fridge for unexpected blood loss. Two units of designated emergency group O Rh D negative red cells were available.
2	IBCT Case 89 *p	One unit of red cells	No complications as a result of this transfusion.	Unit out of fridge for one hour then returned to fridge for twenty minutes then removed and transfused.
2	IBCT Case 73 *	One unit of red cells	No complication as a result of this transfusion.	Blood out of fridge for 2 hrs 25 mins then returned to the fridge by untrained attendant and subsequently removed six hours later and transfused.
3	IBCT Case 6	Four units of red cells.	Fever >1.5°C No complications as a result of this transfusion. ABO incompatibility outruled.	Incident discovered during febrile transfusion reaction investigation. The units should have been withdrawn 48 hrs after crossmatch in compliance with hospital policy.
3	IBCT Case 61 *	Two units of red cells	No complications as a result of this transfusion.	Two units accompanied the patient on transfer from a different hospital and were transfused as no crossmatched blood was available.

* Included as full case history

TABLE 11 (CONTINUED) ERRORS SURROUNDING COLLECTION, STORAGE OR IMPROPER HANDLING OF PRODUCTS N=10

Level	Case Number	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
3	IBCT Case 82	One unit of red cells	Fever > 1.5°C No complications as a result of this transfusion. Cultures from patient & unit negative ABO incompatibility outruled.	Incident discovered during febrile transfusion reaction investigation. Unit removed from controlled storage for over 45 minutes and returned to the fridge. Subsequently removed and transfused to the patient over 90 minutes later.
3	IBCT Case 116	One unit of red cells	No complications as a result of this transfusion.	The transfused unit had been stored in the satellite fridge and had expired the previous day.

* Included as full case history

Errors surrounding collection, storage or improper handling of products. (n=10)

We describe five cases in detail. Cases 37 and 89 are detailed in the Paediatric chapter.

Level 1 IBCT Case 32

This patient required transfusion of two units of red cells for anaemia of malignancy Hb 8.6 g/dl. The first unit was collected from the satellite refrigerator and signed out of the laboratory register. However, the patient's venous access was not checked prior to delivering the unit to the clinical area. Two staff nurses checked and set up the transfusion at the bedside performing the pre-transfusion checking procedure as per policy. The component was attached to the administration set for transfusion via a central line. Immediately prior to commencing the transfusion there was no blood return from the central line and the transfusion could not be

commenced. It was then decided that the unit, intact with the administration set, would be returned to the satellite refrigerator overnight and further attempts to transfuse would begin in the morning. The central line was accessed successfully the following morning and the same unit which had been pierced more than 15 hours previously was recommenced. The error was identified when laboratory staff contacted the TSO and advised that a pierced unit had been stored in the satellite refrigerator overnight. On investigation the transfusion had just begun and was discontinued when less than 50mls had transfused.

Level 1 IBCT Case 53

This patient required an emergency transfusion of four units of red cells for anaemia secondary to a post-partum haemorrhage Hb 6.4 g/dl. When approximately 50mls of the first unit had been transfused, the patient developed a fever and the

unit was discontinued. The unit was disconnected from the administration set and sealed with a cord clamp. The incompletely transfused unit was placed in error in the satellite fridge with the remaining three units from the same crossmatch, all of which should have been returned to the laboratory for investigation. Twenty-four hours later the patient was transferred to another ward and transfusion was again attempted. The incompletely transfused unit, with the cord clamp in place, was collected in error from the satellite fridge. The presence of the cord clamp went unnoticed during the pre-transfusion checking procedure. The transfusion was commenced spiking the pack via the other port with a new blood administration set. Some time later the error was discovered as the use of the cord clamp on the unit was questioned. This unit was then discontinued and the error was reported to the TSO. The unit was returned to the laboratory for investigations. However, the remaining units from this crossmatch were not recalled as per the hospital reaction investigation protocol and the patient was transfused later with the two units of blood which remained in the satellite fridge.

Level 2 IBCT Case 4

This elderly Rh positive female patient required an emergency transfusion of two units of red cells for an unexpected blood loss via a surgical drain post operatively. Pre-operatively a group and screen only had been requested. As there were no red cells crossmatched for this patient, two units of un-crossmatched O red cells were collected from the blood bank. However they were not the group confirmed O negative units designated for emergency stock. In this hospital, stock blood and blood for issue are stored in the same fridge. However the shelf for group O Rh D negative red cells for emergency use is clearly marked and is separated from the stock units. The two units were checked at the bedside and transfused uneventfully. The error was discovered the following morning by laboratory staff when checking stock levels.

Level 2 IBCT Case 73

This patient with a malignant haematological disorder required a non-emergency transfusion of one unit of red cells for anaemia Hb 8.1g/dl. The unit was collected from the laboratory but at that time the patient was unavailable for transfusion and it was decided the unit should be returned to the satellite fridge. The unit was not returned for 2 hours and 25 minutes. Staff were unaware of the time lag and the attendant who returned the blood to the fridge was not aware of the 30 minute return guideline. Six hours later the same unit was collected and transfused uneventfully. All times of removal and return were recorded accurately in the laboratory register and subsequently the laboratory discovered the error during a review of the records.

Level 3 IBCT Case 61

This young male patient required surgery following an RTA. He had initially been evaluated and resuscitated at the nearest hospital and then transferred from this hospital for further management. He had been crossmatched for four units of blood and these units along with a crossmatch form accompanied the patient on transfer. In the second hospital, the patient was stable and not considered an emergency. The blood, which should have been returned to the primary hospital, was put into the bottom shelf of the fridge for discard at a later date. No specimen was taken for crossmatch at the second hospital. The crossmatch report from the original hospital was filed in the patient's chart. Later that evening a decision was made to operate and the patient entered the theatre suite still wearing the ID wristband from the original hospital that contained name, date of birth and unique hospital number. Once the surgery had commenced the patient bled heavily and two of the units on the crossmatch form were requested. As there were no crossmatched units available, a clinical decision was taken to use the units in the fridge, which had been set aside for discard while a fresh specimen was being crossmatched. These two units were checked in theatre using the original hospital ID wristband, the

original hospital crossmatch report form and labels, which had been attached by the original hospital.

Failure to supply special requirements in CMV negative and/or irradiated components (n=12)

Findings

There were 12 cases reported in this category, 11 which are classified as level 2 incidents. The remaining incident was classified as level 3 as the unit was actually CMV negative and irradiated, but this information was incorrectly entered on the laboratory computer.

- Eight cases occurred due to prescription and/or request errors where special requirements were not stated or the clinical history, which would have raised the laboratory's awareness to the requirement, was omitted (Cases 1, 8, 40, 58, 66, 78, 100 and 34).
- None of the cases resulted in complications for the patient.
- In three cases (Cases 3, 43 and 44), errors in the hospital transfusion laboratory led to the issue of units that did not meet the special requirements.
- In one of these cases (Case 3), a visual computer warning which prompted that CMV antibody negative and irradiated components had been issued for this patient in the past, was displayed on screen but overridden because the laboratory staff were very busy.
- In one case (Case 41), CMV negative and irradiated platelets were requested from the IBTS. However, due to stock shortage, CMV safe leucodepleted platelets were issued but the irradiation request was overlooked. This error went undetected when the unit was received and processed through the hospital laboratory out of hours.

- In six cases (Cases 1, 3, 8, 41, 43 and 100), the final bedside checking procedure should have alerted clinical staff to the lack of provision of special requirements and prevented the transfusion of these components.

Recommendations

- The number of cases reported in this category emphasises the need for ongoing education and training of staff involved in prescribing, ordering and administering transfusions. The significance and importance of the bedside checking procedure cannot be over-emphasised.
- As eight of the twelve incidents are associated with failure to prescribe the correct products, systems need to be put in place within hospitals to ensure that the requirements of such patients are highlighted, which include:
 - Education of prescribing doctors to highlight the importance of accurate completion of prescription and clinical details on request forms.
 - Alert stickers placed on the front of the medical record to alert clinical staff of the special requirements. This is particularly important when patients are being transfused outside clinical areas not normally transfusing haematology/oncology patients.
 - Systems need to be put in place to ensure that where care is shared between centres, patients receive the correct products.
- On going education should be provided for medical scientists who are involved in cross call cover and do not normally work in transfusion to highlight special requirements for certain patients.
- Once again a failure to heed computer warnings (Case 3) has highlighted the fact that as recommended in the NHO Annual Reports 2001 and 2002, computer systems should be designed with audible alarms/alerts to minimise

opportunities to override screen warnings. Preferably any such overrides should require a reason or explanation, as this should question the need to override. An audit trail of any overrides should also be kept.

- In high risk areas such as busy haematology units, a blanket policy of the use of irradiated product for all patients with suspected malignant haematological disorders may be advisable.

TABLE 12 ERROR IN CMV NEGATIVE AND IRRADIATED COMPONENT ADMINISTRATION (N=12)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms and Outcome	Cause of Error
2	IBCT Case 1 p*	Three units of SAG-M red cells. Seven aliquots of paedipack red cells	No complications as a result of this transfusion.	Failure to prescribe/request special component needs.
2	IBCT Case 3 *	Three units of red cells	No complications as a result of this transfusion.	Requirement for CMV negative irradiated components not noticed in laboratory.
2	IBCT Case 8 p*	Three units of SAG-M red cells, two units of apheresis platelets. Five aliquots of one paedipack.	No complications as a result of this transfusion.	Failure to prescribe/request irradiated cellular components.
2	IBCT Case 34	One unit of pooled platelet concentrate	No complications as a result of this transfusion.	Failure to prescribe CMV negative irradiated platelets.
2	IBCT Case 40 *	One unit of red cells	No complications as a result of this transfusion.	Irradiated red cells not prescribed for patient awaiting transplant. Noted by anaesthetist prior to transfusion but unit required urgently for intra-operative bleed.
2	IBCT Case 41 *	One unit of apheresis platelets.	No complications as a result of this transfusion.	CMV negative platelets not available from IBTS. CMV safe platelets issued instead on advice from Consultant Haematologist but request for irradiated platelets not fulfilled. Non irradiated platelets issued from IBTS, processed through hospital laboratory and transfused without noticing error.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 12 (CONTINUED) ERROR IN CMV NEGATIVE AND IRRADIATED COMPONENT ADMINISTRATION (N=12)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms and Outcome	Cause of Error
2	IBCT Case 44 *p	45mls red cells	No complications as a result of this transfusion.	CMV negative red cells not selected although available in laboratory.
2	IBCT Case 58	Two units of red cells	No complications as a result of this transfusion.	Failure to prescribe CMV negative irradiated components.
2	IBCT Case 66 *	Two units of red cells	No complications as a result of this transfusion.	Failure to prescribe CMV negative irradiated components.
2	IBCT Case 78	Four units of red cells	No complications as a result of this transfusion.	Failure to request/prescribe CMV negative irradiated red cells for a patient with a suspected malignant haematological disorder.
2	IBCT Case100	Two units of red cells and one unit of pooled platelets	No complications as a result of this transfusion.	CMV negative irradiated products not prescribed for patient awaiting transplant. Peri-operatively three units red cells and one unit of platelets were transfused.
3	IBCT Case 43	One unit of apheresis platelets, CMV negative and irradiated	No complications as a result of this transfusion.	CMV negative irradiated blood issued by IBTS but special requirements not entered onto the laboratory computer system or not documented on the compatibility label or crossmatch report form.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Error in the administration of CMV negative or irradiated products (n=12)

We describe four cases in detail. Cases 1, 8 and 44 are covered in Paediatric chapter

Level 2 IBCT Case 3

Three units of irradiated CMV negative red cells were prescribed and requested for this patient with a haematological malignancy. The computer alerted (visually, not an audible alarm) the medical scientist to the CMV and irradiated requirement in the past. This went unnoticed and three units were issued which were not CMV negative or irradiated. The issue was within normal working hours but the laboratory workload was extremely heavy. The error was not noted during the pre-transfusion check at the bedside although the prescription form stated the requirements. When the workload had eased, the error was recognised by the medical scientist.

Level 2 IBCT Case 40

This patient with cardiac and underlying renal disease awaiting transplant required a transfusion of one unit of CMV negative and irradiated red cells for an emergency intraoperative bleed, Hb 7.6g/dl. The correct component was not prescribed or requested preoperatively. Standard red cells were cross-matched and issued for surgery. This was the patient's first transfusion in this hospital. When surgery had commenced, the anaesthetist noted that special requirements had been omitted and contacted the laboratory to order the correct product. However, the patient began to bleed and as the correct blood was not immediately available, a decision was made to use one unit of the non-irradiated CMV untested blood as an emergency.

Level 2 IBCT Case 41

This patient, with a malignant haematological disorder, required transfusion with one unit of CMV negative and irradiated platelets for aspirin induced platelet dysfunction. The hospital transfusion laboratory made the request to the IBTS, but CMV negative platelets were not available. Following a discussion with the Consultant Haematologist at the IBTS it was decided to issue CMV leucodepleted 'safe' platelets for this

patient. However, in error, the request for irradiated components was not filled and one unit of CMV 'safe', non-irradiated platelets were issued from the IBTS. The hospital transfusion laboratory received this unit on call and issued it to the clinical area where they were transfused without noticing the error. A senior medical scientist identified the error when reviewing all on-call work the following day.

Level: 2 IBCT Case 66

This patient, with a relapsing malignant haematological disorder post BMT required a transfusion of two units of CMV negative and irradiated red cells. The patient was being transfused in the day ward setting. Neither the prescription nor request form stated that special requirements would be needed. The patient had never been transfused previously in this facility and the laboratory had no previous record so two units of standard red cells were issued. As the prescription did not state the requirements, the error was not identified during the bedside administration. The TSO identified the error during a routine hospital audit of transfused units.

IBCT transfused not using a filter or infusion device (n=5)

Findings

- Two incidents involved the administration of red cells (Cases 33 and 35) and one case (Case 7) involved the administration of SD plasma. All were transfused without using a blood administration set with an integral 160-220 micron filter.
- In addition, one case (Case 35) highlighted the need to ensure accurate recording of unit numbers transfused in emergency situations
- Two cases involved the use of an electronic infusion device (Cases 65 and 76).
 - Case 65 involved the transfusion of platelets using a device unsuitable for this purpose.
 - Case 76 involved an incorrect timeframe entered on the infusion pump, which delivered a unit of red cells more quickly than prescribed.

TABLE 13 IBCT TRANSFUSED NOT USING A FILTER OR THROUGH INCORRECT INFUSION DEVICE (N=5)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
2	IBCT Case 7	Two units of SD Plasma	No complications as a result of this transfusion.	Two units of SD plasma administered unfiltered through a fluid administration set.
2	IBCT Case 33	Between 50-100mls of red cells	An urticarial rash developed during transfusion, patient recovered with no ill effects without medication.	Transfusion given via a standard fluid administration set without an appropriate filter in place.
2	IBCT Case 35 *	11mls of red cells	No complications as a result of this transfusion.	Transfusion to neonate via a syringe without an integral filter in place. Unsure which unit of red cells was used.
2	IBCT Case 65 *p	One unit of platelets for neonatal use	No incremental rise following transfusion. The infant required a further transfusion to increase the platelet count to acceptable levels.	This platelet transfusion was given via an electronic infusion device unsuitable for infusing platelets.
2	IBCT Case 76	One unit of red cells	No complications as a result of this transfusion.	Unit transfused through infusion pump, which had been inadvertently set to run over 1.5 hours instead of four hours as prescribed.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Recommendations

- Ongoing education is required to ensure correct administration of blood components
- This should include training on use of medical devices such as infusion pumps.
- There should be a dedicated person to check and record transfusions during massive haemorrhage to ensure traceability of all blood components and blood products.

IBCT transfused not using a filter or through incorrect infusion device

We describe one of these cases in this section because, although it is a neonatal case, the problem occurred in an adult centre. The incident also highlights the importance of accurate recording of units transfused even during emergency situations. Details of Case 65 are included in the Paediatric chapter

Level 2 IBCT Case 35

This infant required a transfusion of red cells as a life saving measure post delivery in a tertiary adult care centre. The blood was taken from a uncrossmatched unit of O Rh D negative designated emergency stock. This incident took place in a busy A&E department where two resuscitation rooms were in use simultaneously. Six units of emergency uncrossmatched O Rh D negative blood were brought to the A&E resuscitation rooms. 11mls of red cells were removed from an un-crossmatched unit and the transfusion was administered via a syringe through the umbilical vein without using a blood administration set. The unit from which this blood was transfused could not be subsequently identified.

Incorrect details recorded during initial admission (n=5)

Findings

- Of the five cases reported in this section, two (Cases 10 and 26) resulted from a failure to check

whether the patient had been previously admitted to the hospital and assigning a new MRN. Previous transfusion records were then unavailable.

- The third case (Case 19) involved a patient with two MRNs as this hospital allows allocation of more than one MRN per patient when the admission occurs out of hours. These numbers are never merged within the system.
- The fourth case (Case 48) illustrates how poor and unclear communication resulted in a patient being hospitalised and treated using a different patient's record.
- The final case (Case 85) relates to old case notes being used on this admission, which contained an incorrect DOB for the patient and despite the current notes being available during transfusion, this error went unidentified.
- None of the incidents were associated with complications.

Recommendations

- Patients admitted must have a unique hospital number assigned, either their previous MRN number or a new number, if the patient has no history at this hospital.
- Staff admitting patients should take care to obtain details of previous admissions to ensure that their previous MRN number and records are retrieved.
- If the patient is admitted via the A&E Department and given an emergency number, it must be possible to merge this number in the computer system at a later stage with the actual unique hospital number.
- All healthcare professionals must be aware of the importance of correct patient identification and ensure that details accompanying patients requiring transfer to another facility for further treatment are correct.

TABLE 14 INCORRECT DETAILS RECORDED DURING INITIAL ADMISSION (N=5)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms and Outcome	Cause of Error
1	IBCT Case 48 *	Two units of red cells.	No complications as a result of this transfusion.	Patient transferred from a residential centre using a different date of birth and first name, which referred to another patient. This other patient's chart was then used throughout this patient's hospital stay.
3	IBCT Case 10 *	One unit of red cells	No complications as a result of this transfusion.	Pre-transfusion sample labelled correctly, no ID wristband. During clerical admission, incorrect DOB entered and new unique identification number created. Remote checking of the unit failed to note these discrepancies.
3	IBCT Case 19 *	Three units of red cells	No complications as a result of this transfusion.	Patient's first name and unique hospital number incorrect on the pre-transfusion sample. This error carried on throughout the transfusion.
3	IBCT Case 26	Two units of Red Cells	No complications as a result of this transfusion.	Admissions staff issued this patient with a second MRN without searching computerised records for an original identification number.
3	IBCT Case 85	One unit of red cells	No complications as a result of this transfusion.	Addressograph labels from old case notes were used for this admission. They contained the wrong DOB. This was used on the sample tube, request form, issue label, compatibility form and the patient's ID wristband.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Incorrect details recorded during initial admission (n=5)

Of the five cases received, we describe three cases that illustrate the problems that arise.

Level 1 IBCT Case 48

This patient (Patient X) was admitted via the admissions unit having been referred from a residential centre by a general practitioner (GP).

The details on the referral letter stated the patient's preferred name, which was not her birth-registered name and an incorrect date of birth (that of another resident who had the same surname). The correct surname and address were used. At this hospital, the medical records tracking system relies primarily on the correct date of birth to identify patients on the hospital computer system during the admission procedure. On this occasion, the hospital records of a different patient, patient Y, were identified with this date of birth, address, surname, and first name. As the patient was unable to confirm her own details, patient Y's chart was used throughout her ten-day admission, during which time she received two units of red cells. The error was identified when the discharge letter was received at the residential centre at which both patients lived. Both patients had a history at this hospital but only one, patient X, had a transfusion history. As a result of this incident this patient's historical transfusion record was not retrieved. All patient X's records have been amended accordingly.

Level 3 IBCT Case 19

This elderly female required a transfusion for a significant bleed associated with underlying malignancy Hb 5g/dl. The ID wristband contained an incorrect first name. A failure to verbally identify the patient led to this information being recorded onto the sample. There was also a discrepant MRN as this hospital allows allocation of more than one hospital number per patient if the admission occurs out of hours. A previous MRN was recorded on the outside cover of the patient's chart with a different one on the inside. These numbers are never merged within the system. There is no link between the laboratory

and admissions computer systems and the laboratory staff are totally dependent on a correctly labelled sample and request form as they have no other means of checking details. During bedside administration, verbal patient identification was not carried out and the ID wristband, compatibility form and the unit all contained this incorrect information. The patient's medical record, however, contained the correct patient name. Three units were transfused without incident. During bedside checking of the fourth unit, the difference in the MRN was noted and when questioned, the patient stated her correct name. The laboratory was contacted and a repeat crossmatch specimen was taken.

Level 3 IBCT Case 10

This patient with severe symptomatic iron deficiency anaemia, a history of CCF and a right pleural effusion required an emergency transfusion of two units of red cells Hb 8.2g/dl. The patient had a history of underlying severe CCF. The pre-transfusion sample was taken in the A&E and correctly labelled with a unique transfusion label, as no MRN was available. The patient had no ID wristband as no clerical cover is provided outside normal working hours. During clerical admission the following day, an incorrect DOB was recorded and entered into the hospital identification system. No matching details were found and a new patient record was created with a new MRN and the wrong date of birth. Two units of red cells were issued with the correct patient details and unique transfusion sticker number, which had been taken from the sample. Remote checking of the unit pre-transfusion failed to identify that the ID wristband contained a different date of birth and MRN number to the label on the unit and the crossmatch form. The error was only discovered during the pre-transfusion bedside checking of the second unit. The patient suffered no complications as a result of this transfusion.

Incorrect details on ID wristband/Missing ID wristband (n=7)

Findings

- Three reports involved problems with special transfusion stickers used for patient identification at transfusion sampling and administration.
- A further three involved incorrect DOB details on the ID wristband.
- In the final case, there was no ID wristband on the patient.

Recommendations:

- The importance of positive patient identification using an accurate ID wristband has been highlighted over several years through both the NHO and SHOT reports. (NHO 2002, SHOT 2003)

- A secure patient identification procedure should be in place in all hospitals and the ID wristband should be worn at the time of taking of the crossmatch sample and should be in place before transfusion. This ID wristband should contain three unique identifiers which include the patient's full name, date of birth and unique identification number. (NBUG, 2004).
- The importance of asking the patient to identify themselves prior to sampling and administration in order to identify any discrepancies is again highlighted.
- Electronic forms of patient and blood component/product identification are now available and are recommended as they provide the highest degree of security. Where these systems are not in place, manual bedside identification procedures at sampling and administration must be strictly adhered to (BCSH, 1999).

TABLE 15 INCORRECT DETAILS OR MISSING IDENTITY BAND (N=7)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
2	IBCT Case 95 *	One unit of red cells	No complications as a result of this transfusion.	The patient's ID wristband was removed prior to transfusion and the patient was not positively identified at the bedside.
3	IBCT Case 74	Three units of red cells	No complications as a result of this transfusion.	Incorrect DOB on wristband. Transfused with unique blood transfusion number, correct hospital number and patient name.
3	IBCT Case 92	Three units of red cells	No complications as a result of this transfusion.	Pre-transfusion sample had new Typenex number. Patient not wearing corresponding ID wristband.
3	IBCT Case 94	Two units of red cells	No complications as a result of this transfusion.	ID wristband contained incorrect DOB. Completed report not received before going to press.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 15 INCORRECT DETAILS OR MISSING IDENTITY BAND (N=7)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
3	IBCT Case 103	One unit of red cells	No complications as a result of this transfusion.	Unit of blood commenced using only two identifiers. No chart number on ID wristband and the unique transfusion sticker had fallen off.
3	IBCT Case 113	Three units of red cells	No complications as a result of this transfusion.	Incorrect DOB on wristband not verified during sampling or at the final bedside check. Unique transfusion sticker also missing from ID wristband.
3	IBCT Case 117	Four units of red cells	No complications as a result of this transfusion.	Incorrect DOB on wristband, issue voucher and unit. Not verbally checked with the patient who was conscious and coherent.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Incorrect details or missing identity band (n=7)

We describe one case to emphasise that the bedside check is still not being performed correctly in all instances.

Level 2 IBCT Case 95

This elderly patient with an underlying malignancy required a transfusion of three units of red cells for a postoperative anaemia Hb 7.5/dl. The patient's ID wristband was removed prior to the transfusion. The nurse intended to replace the ID wristband but forgot and the final bedside check did not include confirmation of the patient's identity at the bedside by two people. One unit of red cells was administered uneventfully and the error was identified on the ward prior to administration of subsequent units. When asked about the omission of bedside check, the nurse felt that she knew the patient really well and therefore did not check her identity.

Incorrect details on sample (n=7)

Findings

Seven incidents related to pre-transfusion sample errors resulting in errors in the unit issue labels. The mistakes were not identified prior to administration

but all errors were subsequently identified by clinical ward staff and reported to the TSO.

- In four cases, an incorrect date of birth was recorded on the sample and in one case the sample contained an incorrect name.
- Four cases involved samples labelled with an incorrect MRN and of these two had an additional incorrect date of birth and one an incorrect first name.
- In one case (Case 12), the wrong date of birth on the sample led to failure to access previous records.
- In three cases (Case 12, 46 and 104), the error was discovered pre-transfusion but despite hospital policy, the decision was made to transfuse the units.
- This can, as in Case 46, cause considerable distress for the clinical staff involved as the advice given was in direct contradiction to the hospital policy.
- In three cases, the errors were discovered following transfusion of subsequent units from the crossmatch.

- In Case 84, the wrong MRN used would have been detected if the laboratory computer and the hospital computer systems were interfaced.

Recommendations

- Hospital laboratories should have SOP or Policies for the acceptance or rejection criteria for incorrectly labelled samples. Such policies should cover amendments, which are acceptable, and those which are unacceptable and require a fresh sample to be taken.
- In order to reduce sampling errors extended or 24 hours phlebotomy services are recommended.
- It is important that existing policies are fully understood and regularly updated. It is critical to ensure that on going education highlights to all medical, nursing and laboratory staff, especially those not regularly working in transfusion, the importance of strict compliance.
- In an emergency, where there is insufficient time to obtain results from a fresh sample, the policy should include the use of emergency O negative blood until the patient has been regrouped.
- Automated barcode systems which print transfusion labels at bedside from the patient's wristband are available and would prevent the errors described.
- The linkage of the laboratory computer system and the hospital PAS system would also help detect these errors.

TABLE 16 INCORRECT DETAILS ON SAMPLE (N=7)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
2	IBCT Case 12 *	Two units of red cells	No complications as a result of this transfusion.	Wrong DOB used on pre-transfusion sample and no unique hospital number used.
2	IBCT Case 46 *	One unit of red cells	No complications as a result of this transfusion.	Incorrect first name and no MRN on sample and request form. Patient unable to self identify. MRN added after nurse brought omission to the notice of laboratory personnel and unit transfused against hospital policy.
2	IBCT Case 104	Two units of red cells	No complications as a result of this transfusion.	Incorrect DOB on sample tube, wristband, request and crossmatch form. Units transfused despite patient giving correct DOB during final checking procedure.
3	IBCT Case 5	Four units of red cells	No complications as a result of this transfusion	Incorrect DOB and MRN transcribed onto sample tube.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 16 (CONTINUED) INCORRECT DETAILS ON SAMPLE (N=7)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
3	IBCT Case 29	Three units of red cells	No complications as a result of this transfusion.	Patient's surname mis-spelt on initial sample. Further transcription error in laboratory giving totally new name. Three units administered before the error was noticed.
3	IBCT Case 80	One unit of red cells	No complications as a result of this transfusion.	One digit of DOB transcribed incorrectly on crossmatch form and sample tube. One unit of red cells was transfused before error detected.
3	IBCT Case 84	Two units of red cells	No complications as a result of this transfusion.	Incorrect MRN on sample tube and request form. Incorrect MRN transcribed onto the blood pack and compatibility form. No MRN on wristband.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Incorrect details on sample (n=7)

We report two cases in detail as they illustrate the problems that are caused when patient details are not filled in correctly on pre-transfusion samples.

Level 2 IBCT Case 12

This female patient who had previously been an in-patient in this hospital was admitted via the A&E Department with a suspected ectopic pregnancy that required immediate surgery. A pre-transfusion group and crossmatch was taken. The patient was not wearing an ID wristband and did not have an MRN at the time of sampling as the A&E Department cannot assign a new MRN out-of-hours. A wrong date of birth was recorded on the sample. Hospital policy states that incorrectly or incompletely labelled pre-transfusion samples should be rejected and a repeat sample requested. In this instance, policy was not adhered to as it was felt that the cross matching should proceed due to the nature of the emergency. However there were four units of

designated emergency group O Rh D negative red cells available. Three units of red cells were crossmatched and issued on-call without an MRN and with a wrong date of birth by a medical scientist who does not regularly work in transfusion. The transfusion took place in theatre and the error was not identified during the checking procedures at the time of collection or during the pre-transfusion checking procedure. During the bedside checking procedure of the third unit, the error was discovered and the unit was returned to the laboratory for re-labelling. There were no complications to this transfusion. Re-education regarding pre-transfusion checking procedures has been undertaken.

Level 2 IBCT Case 46

This elderly patient with symptomatic anaemia Hb 3.9g/dl was prescribed five units of red cells. The sample and the request form contained an incorrect first name and no MRN. The patient had not previously been transfused in this hospital. The on-call medical scientist who did not normally work in

the transfusion laboratory processed the sample without the MRN and crossmatched the units. The first unit was collected from the laboratory and during the final bedside administration check, clinical staff noticed the first name was incorrect and there was no MRN on the crossmatch form. When the medical scientist was contacted about this, the MRN was added to the unit and clinical staff were advised to transfuse the unit. Although contrary to hospital policy, the doctor on-call advised that the transfusion could proceed and the first unit of red cells was transfused. The TSO was informed the next morning and a repeat specimen was taken from the patient. Four further units were issued and transfused. The patient suffered no complications as a result of this incident. However, it caused delay in transfusion for the patient and considerable distress for staff as the hospital policy was not adhered to.

Unit labelling errors (n=9)

Findings

Nine cases reported involved errors in the laboratory in labelling units for transfusion. These incidents highlight the importance of accurate patient identification and checking documentation during bedside administration. In all cases, these errors went unnoticed during the final bedside check. None caused complications for the patients.

- Two cases (Case 38 and 86) involved the transfusion of pooled platelets and SD plasma without unit labels.

- In two cases (Cases 71 and 81), the labels on units which were crossmatched for the intended patient were inadvertently transposed.
- In one case (Case 108), the crossmatch report forms issued with two units were mixed up during an emergency massive haemorrhage.
- The final four cases (Cases 2, 57, 75 and 114) contained discrepancies in MRN numbers, date of birth or laboratory unit number.

Recommendations

- An uninterrupted working environment is recommended at all stages during the transfusion process.
- As nurses are the last line of defence in providing safe effective care for their patient, the final bedside check provides an opportunity to detect and prevent preceding errors.
- There should be a designated person to check and record units during transfusion for massive haemorrhage to ensure traceability of all blood components and products.
- Electronic systems in the laboratory and at the bedside that reduce errors are recommended.

TABLE 17 UNIT LABELLING ERRORS (N=9)

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
2	IBCT Case 38	One unit of pooled platelet concentrate	No complications as a result of this transfusion.	One unit of unlabelled pooled platelet concentrate delivered directly to ward. Advice from laboratory was to administer the unit and return the bag for labelling in the morning. Platelets were administered with no issue form or label to cross check against.
2	IBCT Case 71	One unit of red cells	No complications as a result of this transfusion.	Two compatible units where issue labels were transposed were not discovered until checking the second unit.
2	IBCT Case 81	Two units of red cells as a result of this transfusion	No complications as a result of this transfusion.	During the labelling procedure a transposition of labels occurred on two compatible units designated for this patient. Error not detected prior to transfusion.
2	IBCT Case 86	Six units of SD plasma	No complications as a result of this transfusion.	Six units of SD plasma were issued and transfused with no patient issue label attached to the bag.
2	IBCT Case 108	Two units of red cells	No complications as a result of this transfusion.	Massive transfusion occurred on-call and the compatibility issue reports were mixed up for two of the units involved. Both units were for the same patient.
3	IBCT Case 2	Three units of red cells.	No complications as a result of this transfusion.	Error in patient's DOB by one digit on the request form which was amended but incorrect on unit issue label and compatibility report.
3	IBCT Case 57	One unit of red cells	No complications as a result of this transfusion.	Erroneous entry of MRN into laboratory computer resulting in wrong MRN on computer generated issue label.
3	IBCT Case 75	One unit of red cells	No complications as a result of this transfusion.	Number on the unit label did not correspond with the number on the crossmatch form. At collection and administration only one side of the unit was checked with the compatibility report form.
3	IBCT Case 114	One unit of red cells	No complications as a result of this transfusion.	IT failure led to handwritten issue label which was incorrectly transcribed from the sample tube.

TABLE 18 MISCELLANEOUS INCIDENTS (N=5)

Due to the relatively minor nature of these incidents (apart from case 52) they are included in Table form only

Level	Case Number	Volume of Incorrect Blood Component	Symptoms & Outcome	Cause of Error
IBCT involving Factor Concentrate (n=1)				
1	IBCT Case 52 *p	8000 iu of Refacto	No complications as a result of this transfusion.	Refacto was prescribed instead of Recombinate for a patient with high responding inhibitors. It was highlighted on the computer system that this patient normally receives Recombinate or Novoseven. Laboratory staff questioned request but were asked to issue the product.
Prescription (n=2)				
2	IBCT Case 20	One unit of apheresis platelets	No complications as a result of this transfusion	Verbal order for platelets, written prescription for FFP. Platelets issued and transfused, error in written prescription not noted.
2	IBCT Case 77	One unit of red cells	No complications as a result of this transfusion.	Daily red cell requirement for four days documented in patients medical record. The Hb was being checked daily following each unit. The last unit was not prescribed until after unit had commenced.
Expired sample (n=1)				
2	IBCT Case 96	One unit of red cells	No complications as a result of this transfusion.	Crossmatch sample should have been repeated as more than 72 hours had elapsed since the original crossmatch had been taken. The patient had been transfused within that time.
Crossmatch Form (n=1)				
3	IBCT Case 83	Two units of red cells	No complications as a result of this transfusion.	Incorrect DOB recorded on past admission. Historical record used to print crossmatch form.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Incorrect Blood Component Transfused: Incidents involving Anti-D Immunoglobulin

Incidents involving errors or omissions relating to Anti-D or factor concentrates are collected by the NHO as they also relate to transfusion practice. Any adverse reactions to the administration of Anti-D or factor concentrates are reportable directly to the IMB under the Pharmacovigilance Scheme. If received by the NHO, these reports are forwarded to the IMB and are not covered in this report.

Findings:

- There were eleven incidents involving the administration of Anti-D. Ten were classified as serious or level 1. Six incidents involved errors in administration of Anti-D, four involved a delay in administration and there was one incident where Anti-D was omitted.
- Four of these occurred due to errors in the clinical area, four in the laboratory and two involved communications between the laboratory and clinical area.

Anti-D given in error (n=6)

- In one of the six cases involving errors in administration of Anti-D, the patient was Rh positive (Case 30).
- In three cases (Cases 30, 36, and 107), instead of checking the records, assumptions were made on the basis of cord blood or Kleihauer requests/results that the mother required Anti-D. In case 30, the mother was in fact Rh positive, in case 36, the mother was already alloimmunised and in case 107, the baby was Rh negative and Anti-D was not required.
- One case involved an error in cord blood grouping by on-call medical scientist not normally working in blood transfusion (Case 16).
- One case involved a prescription written up for the wrong patient and administered without checking the baby's group which would have detected the error (Case 47).

- In the final case (Case 106), the vial of anti D had a label which contained incorrect patient details.
- None of the patients suffered complications as a result of these incidents but in five of the cases were exposed unnecessarily to a blood product.

Omission/delay (n=5)

In four of the five cases, Anti-D was given five to nine days after delivery and in the final case, Anti-D was never given.

- Two errors arose in the clinical area (Case 31 and 22), two involved the clinical/laboratory interface (Case 17 and 69) and one occurred in the laboratory (Case 25).
- In the one incident where Anti-D was never given (Case 17), a number of factors were responsible. The patient's chart was not stamped as Rh negative, as was hospital policy, the patient wished to leave hospital very soon after delivery before antenatal arrangements were made and the maternal Rh and cord blood results were not yet available. When available, they seem to have been filed in the chart without review.
- One incident (Case 25) was a transcription error of a cord blood result which was recorded correctly in the laboratory record book and computer but incorrectly on the manually generated report form which was sent to the clinical area.
- One incident (Case 69) involved a telephoned result from the laboratory to the ward but the ward had no recollection or record of the call.
- In one incident (Case 31), cord bloods were not taken following an elective Caesarean section.
- The final incident (Case 22) involved a patient in a general hospital nursed in a general surgical ward where the omission was only detected on transfer to the gynaecology ward.

All of the patients are being followed up to exclude sensitisation but the period of follow up to date is too short to completely exclude sensitisation.

Recommendations

- There is a need to develop a co-ordinated system to ensure that decisions to issue and administer Anti-D are not made on assumptions but on the documented Rh group of the mother, her antibody status and the Rh group on the cord blood. The findings in this report illustrate the difficulties in ensuring this happens.
- While many hospitals issue Anti-D through the laboratory as they have access to both the mother and/or baby's group and antibody records and can issue the Anti-D labelled for the patient, the findings suggest a co-ordinated approach to review all laboratory results is necessary to ensure correct issue of product.
- Whether the hospital blood banks or clinical areas take responsibility for prophylactic Anti-D administration, there is clearly a need for education of all staff involved in prescription/administration of Anti-D prophylaxis. Assumptions are made when the knowledge/understanding is lacking.
- Hospitals should have a system in place to check the Rh D status of all deliveries in the previous 24 hours to ensure that cord bloods are taken from Rh D negative mothers at the time of delivery. If an omission does occur a sample can then be taken from the baby for assessment.
- When a mother is found to be Rh D negative, an alert to this fact should be placed on the medical record/hospital computer to alert all staff to the necessity of checking the Rh D group of the infant.
- As it is important to avoid errors due to transcription of results, a laboratory computer generated alert is the safest option where the

information system in the laboratory and hospital are linked.

- The importance of access via computer to the current results or to a written or computer generated report on mother and baby and not a verbal report is emphasised. Wherever possible, these written results rather than telephone results should be used to prescribe and administer Anti-D.
- If results are taken over the phone. details should be clearly entered on the patient's chart and should include date, time and name of the person giving the result and signed by the person taking the result.
- Where possible, cord blood specimens taken and sent to the laboratory at the time of delivery out of hours should be tested the following morning. This will avoid testing by scientists not normally working in transfusion, Anti-D can then be issued and administered during day-time working hours.
- However this needs to be balanced against the fact that patients are now being discharged earlier following delivery so it is important that systems are in place to ensure that these patients are not missed. (Case 17)
- Where mothers or babies are being nursed outside the normal clinical areas, it should be the responsibility of the referring unit to follow up these patients and ensure that clinical staff are aware of specific requirements.
- Medical and Nursing staff working in all clinical areas where Rh D negative women are being treated should be familiar with Anti-D guidelines in order to avoid omission or delay in the administration of Anti-D.
- Where Anti-D has not been administered within the 72 hour period every effort should still be made to administer the anti-D within 9-10 days of the sensitising event as this may afford some protection (BCSH, 1999).

Incorrect administration or omission of Anti-D (n=6)

Cord blood sent to laboratory and the assumption made that the mother must be Rh D negative

Level 1 IBCT Anti-D Case 30

This baby delivered by caesarean section to a Rh D positive mother during normal working hours had a cord blood sample taken for antibody screen only as Anti-M antibodies had been identified in the mother's sample during the antenatal period. Clinical details were not documented on the request form, although there was a record of unidentified antibodies on the laboratory computer system. Inadvertently, a group was also performed and the baby was correctly found to be Group O Rh D positive. The medical scientist processing the request normally works in the transfusion laboratory and assumed that if a baby's cord blood sample was received, then the mother must be Rh D negative. Without checking the mother's historical grouping records, anti-D was labelled and issued for the mother. The product compatibility report form generated stated the ABO and Rh D status of both the mother and the baby, but this information was overlooked. Clinical staff were informed that the anti-D was available for collection for this patient. Subsequently Anti-D was prescribed, collected and administered without reference to the Rh D status of the mother. A senior transfusion scientist discovered the error during routine checking of all work at the end of the working day. By this time, the Anti-D had been administered. The laboratory computer system has been reviewed and an alert has been put in place to warn the user not to issue Anti-D to Rh D positive mothers.

TABLE 19 ADMINISTRATION OF ANTI-D IN ERROR (N=6)

Level	Case Number	ABO and Rh D Group of Patient	ABO and Rh D Group of IBCT	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Anti-D Case 16*	Group AB Rh D negative	Cord Blood: Group AB Rh D negative	1250iu Anti-D	No complications.	Cord blood grouped as Rh D positive in error and Anti-D given accordingly.
1	IBCT Anti-D Case 30*	Group O Rh D positive	Baby: Group O Rh D positive	1250iu Anti-D	No complications.	Cord blood sent for antibody screen only but group done as routine on this sample. Baby Rh D positive. Need for Anti-D was assumed without checking the mothers Rh D status.
1	IBCT Anti-D Case 36*	Group B Rh D negative	Baby: Group B Rh D positive	1250iu Anti-D	No complications.	Unnecessary Kleihauer requested. Prophylactic Anti-D issued and administered in error to already sensitised patient.
1	IBCT Anti-D Case 47*	Group O Rh D negative	Baby: Group A Rh D negative	1250iu Anti-D	No complications.	Prescription written in wrong patient's drug record. Anti-D issue report form and baby's group not included in the checking procedure.
3	IBCT Anti-D Case 106	Group A Rh D negative	Baby: Group A Rh D negative	1250iu vial Anti-D	No complications.	Issue label and issue voucher contained incorrect surname of patient. Noted at the time of collection but administration continued on the advice of the laboratory scientist.
1	IBCT Anti-D Case 107*	Group O Rh D negative	Baby: Group O Rh D negative	1250iu Anti-D	No complications.	Positive Kleihauer result following large FMH. Baby's group assumed Rh positive and not checked. Anti-D administered.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 20 OMISSION/DELAY IN ADMINISTRATION OF ANTI-D (N=5)

Level	Case Number	ABO and Rh D Group of Patient	ABO and Rh D Group	Delay/omission in administration of Anti-D	Symptoms & Outcome	Cause of Error
1	IBCT Anti-D Case 17*	Group O Rh D negative	Cord Blood: Group O Rh D positive	Anti-D omitted	Negative antibody screen two months later.	Cord blood grouped as Rh D positive. Patient discharged prior to report being available. Report filed in chart unseen
1	IBCT Anti-D Case 22*	Group O Rh D negative	Cord Blood: N/A	Five day delay	No complications. Antibody screen negative three weeks later.	Patient was on a general surgical ward, omission not noted until the patient was transferred to gynaecological ward
1	IBCT Anti-D Case 25*	Group O Rh D negative	Cord Blood: Group O Rh D positive recorded in error	Ten day delay	No complications	Discrepancy in labelling of sample and request form led to sample not being processed in sequence and incorrectly transcribed as Rh D negative. Discrepancy not discovered during final cross check as number out of sequence
1	IBCT Anti-D Case 31*	Group O Rh D negative	Baby: Group B Rh D positive	Five day delay	No complications. For antibody screen six months post incident.	Cord blood not taken at delivery. Error noted prior to discharge when baby's group checked and found to be Rh D positive.
1	IBCT Anti-D Case 69*	Group O Rh D negative	Cord blood: Group O Rh positive	Five day delay	No complication. For antibody check six months post incident.	Phoned report that cord blood was Rh D positive not acted on.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Assumption that anti-D needed because unnecessary Kleihauer sent as mother already sensitised

Level 1 IBCT Anti-D Case 36

This Rh D negative mother who had documented Anti-D antibodies during pregnancy had a blood sample taken for grouping, antibody screening and estimation of fetomaternal haemorrhage (FMH) following the delivery of a healthy Rh D positive baby. The grouping sample was processed outside normal working hours and again anti-D was detected. The following morning, a locum basic grade transfusion scientist processed the FMH estimation request unnecessarily and issued anti-D to this already sensitised patient. The Anti-D was subsequently delivered to the clinical area, prescribed and administered unnecessarily. Laboratory staff detected the error later that day when retrospectively checking all work, by which time the anti-D had been administered.

Assumption based on results of Kleihauer test that the baby was Rh D positive

Level 1 IBCT Anti-D Case 107

Post emergency caesarian section, this Rh D negative mother had a Kleihauer test in order to quantify the extent of a large foetal maternal haemorrhage. The result of the Kleihauer, 24mls was sent to the post natal ward. The baby was being nursed at this time in the special care baby unit. The baby's blood group was not done but presumed by the staff caring for the mother to be Rh D positive due to the Kleihauer result. Because of the extent of the fetomaternal haemorrhage, intravenous Anti-D was administered. Subsequently blood for flow cytometry was sent to another laboratory to determine if an adequate amount of Anti-D had been given. Testing showed the baby to be Rh D negative. This administration was contrary to local guidelines, which require an official report to be viewed prior to the prescription and administration of Anti-D.

Prescription written in the incorrect drug record and Anti-D administered in error to the wrong patient

Level 1 IBCT Anti D Case 47

A Rh D negative mother delivered an Rh D positive baby and Anti-D was labelled and issued from the laboratory to the clinical area for her accompanied by the issue report form containing her details. Although hospital policy states that the record of the Rh D status of both the mother and the baby must be seen before prescribing and administering Anti-D, the prescribing doctor wrote the prescription on the wrong patient's drug record, the Rh D status of the wrong patient's baby who was Rh D negative was not checked nor were the details on the Anti-D issue report form. The error was discovered by the staff who administered the anti-D when filing the issue report form. The Rh negative patient for whom the Anti-D was intended received Anti-D within 72hrs of delivery as recommended. The patient who had received the Anti-D in error was informed of the event.

Error in cord blood testing

Level 1 IBCT Anti-D Case 16

This Rh D negative mother delivered her baby during the weekend. A medical scientist not normally working in transfusion processed the cord blood on call. The cord blood was grouped in error as Rh D positive and Anti-D was issued and administered accordingly. During a routine check of all on-call work on the next working day, the error was identified and the clinical staff were alerted to the error. At this time the anti-D had already been given and the patient exposed to an unnecessary blood product. The cord blood had been grouped by column technology and it is unclear how the error occurred.

Omission/ Delay in the Administration of Anti-D (n=5)

Failure to check Rh group prior to early discharge and failure to follow up cord blood results

Level 1 IBCT Anti-D Case 17

This young Rh D negative mother had a cord blood sample taken following delivery. The mother was extremely anxious for discharge and following review by the obstetric team was discharged quickly before arrangements had been completed for postnatal care. In this hospital, all of the group and antibody screen reports are filed in the patient's notes on a mount sheet. The midwives and doctors refer to these reports prior to Anti-D administration. However the blood group and antibody screen results are transcribed with a 'Rh Negative' stamp on the front of the patient's notes. This serves to highlight women who are Rh D negative. On this occasion, the patient's blood group was not transcribed on the front of the medical record and the staff were not alerted to the Rh D negative status of the mother. Prior to discharge the patient's Rh D negative status went unnoticed and the cord blood, which was Rh D positive, was unavailable. It is unknown how the cord result ended eventually in medical records for filing. The omission was discovered six weeks later by the TSO during a routine audit of Anti-D usage. The patient returned to the clinic two months post delivery and was informed of the omission. An antibody screen taken at this time was negative.

Transcription error in cord blood group

Level 1 IBCT Case 25

A cord blood from a Rh D negative mother was sent to the laboratory for ABO and Rh D grouping. Due to a recent change in the allocation of hospital numbers (all newborns now have their own unique hospital number), a discrepancy occurred in the initial labelling of the cord blood and request form. The person taking the specimen was contacted and during

correction of the discrepancy, the sequencing of laboratory numbers was interrupted. The result of the screening obtained was manually recorded correctly in the group and antibody book as O Rh D positive but incorrectly recorded manually on the report form as O Rh D negative. This manual report was sent to the ward. The final cross-reference check of the group between the antibody record book, the information recorded on the laboratory computer system and the generated report failed due to discrepant sequencing of numbers. This hospital always manually records the RhD status of the mothers on the original request form, which comes from the ward and a copy of this is retained in the lab. This is because the form is a different colour and alerts ward and laboratory staff to the Rh D status of their patients. During a routine check by the TSO of the antibody record book, the omission of Anti-D immunoglobulin was noted. The patient was contacted and received anti-D within 10 days post delivery.

Failure to take cord samples

Level 1 IBCT Anti-D Case 31

This Rh D negative mother delivered a healthy infant by elective caesarean section during normal working hours. Cord bloods to confirm the Rh D group of the baby were not taken at the time of delivery according to hospital policy. The error was discovered five days later, prior to discharge, and a sample taken then found the baby was Rh D positive. The antibody screen taken from the mother at this time was negative. Anti-D was given five days post delivery. As a result of this incident, the transfusion laboratory will in future check the Rh D status of all women who have delivered in the previous 24 hours to ensure that cord bloods have been taken.

Problem with telephone results

Level 1 IBCT Anti-D Case 69

This Rh D negative mother delivered a Rh D positive baby which was confirmed on the cord blood sample. The ABO and Rh D group results of mother and infant were telephoned from the laboratory to the ward. The staff on the ward did not recall this telephoned information and there was no documented note of it. However, the mother's Rh D negative status was already clearly documented in her medical record. Five days later, it was noticed that the patient had not received Anti-D. The patient was contacted and Anti-D was then administered five days post delivery. As a result of this incident, the hospital have issued additional local policy recommendations regarding the administration of Anti-D.

Lack of awareness in general hospital of Anti-D requirements

Level 1 IBCT Anti-D Case 22

This Rh D negative female patient underwent emergency surgery for an ectopic pregnancy. For the first four days post operatively the patient was nursed on a general surgical ward. On day five the patient was transferred to a gynaecological ward within the hospital and it was discovered that administration of Anti-D had been omitted. Five days post-operatively, the patient received one vial of Anti-D. The patient had an antibody screen three weeks post operatively which was negative.

Severe Acute Anaphylactoid or Anaphylactic Transfusion Reaction

Definition: *Allergic, anaphylactoid and anaphylactic transfusion reactions span a range of symptoms of varying severity. The symptoms encompass simple allergic-type reactions such as urticaria/pruritis associated with or without gastrointestinal discomfort, to more severe reactions such as stridor, wheeze, bronchospasm, laryngeal oedema and hypotension. The onset of intractable hypotension or shock with loss of consciousness is commonly designated as an anaphylactic reaction. In its severest form anaphylaxis can be fatal. (Vamvakas, 2001)*

This category accounted for 23 (13%) of incidents reported during this reporting year. This represents a decrease of 8% on 2002 figures.

Findings:

- There were 23 reports received in total. Nine of the 23 cases (39%), involved children \leq 18yrs of age.

- As in 2002, most A/A (57%) reactions were associated with transfusion of platelets. Of the thirteen reactions associated with platelet transfusions, seven involved pooled platelets and six involved apheresis platelets.
- The number of reported reactions associated with plasma continues to fall with only one case (4%) involving SD plasma.
- Nine (39%) were associated with red cell transfusions. One reaction was associated with red cells where the transfusion was considered inappropriate as the patient had iron deficiency anemia but was haemodynamically stable. (Case 10) This patient then went on to receive a further two units three days later which were also considered unnecessary for the same reason.
- In three cases (Cases 8, 9 and 22), there was failure to prescribe pre-medication cover which had been recommended as a result of previous repeated transfusion reactions. In one case (Case 22), the patient was a known asthmatic. A single

patient who had a previous history of medication allergy was involved in the other two reactions. (Cases 8 and 9). In all three cases, receiving pre-medication cover may have prevented or lessened the severity of the patient's symptoms.

- One case (Case 13), involved transfusion in a day care setting. The patient developed symptoms four hours later at home requiring return to hospital and overnight admission. This highlights the importance of ensuring that all patients transfused in outpatient settings receive post-transfusion information including whom to contact in the event of a transfusion reaction following discharge.
- In most cases, the reactions were not severe and responded quickly to treatment with the patient making a full recovery within hours. However, in one case (Case 16), the patient required adrenaline to control the symptoms. None of the 22 patients required ITU admission as a result of their reaction.
- Eight patients (35%) - seven of them children - were prescribed washed components as a result of A/A reactions.
- The causes of A/A are not always clear. Sixteen (70%) of the patients who suffered A/A transfusion reactions required transfusions for underlying malignant or hematological disease and were on multiple medications, including IV antibiotics and/or chemotherapy. This can make it difficult to be certain if all of these reactions were actually related to transfusion.
- However a number of patients had repeated reactions and/or a previous history of allergy or asthma. In one case (Case 3), the reaction was associated with HLA antibodies in the patient.
- In five cases (Cases 4, 7, 10, 22 and 23), it was unclear if the reaction was actually A/A as there were no skin manifestations. In two of these

cases, (Cases 4 and 22) the patient's symptoms included fever. In Case 7, an elderly female experienced hypotension associated with respiratory symptoms and tachycardia but full investigation of the reaction was not carried out. In Case 10, the patient had rigors and hypertension. In Case 23, the development of oedema in both hands forearms and face had initially been reported as an unusual reaction but in view of the symptoms it was captured as an A/A.

Recommendations

- Protocols and training for the management of severe A/A reactions should be in place in each hospital and all staff involved in transfusion should be familiar with them.
- The importance of only prescribing transfusions that are necessary cannot be over emphasised. Inappropriate transfusions increase donor exposure unnecessarily and can put the patient at risk of a transfusion reaction.
- As iron deficiency produces a chronic anaemia, it does not normally require immediate correction by transfusion. Oral or parenteral iron therapy is effective as first line treatment for patients with iron deficiency anemia (Saxena, 1994). Transfusion therapy for these patients should not be based on laboratory results, but should be based on the clinical status of the patient i.e. patients with symptomatic anemia or where urgent surgical intervention is necessary.
- Where patients are transfused in day care settings, it is important that written post-transfusion information is given to the patient prior to discharge explaining whom to contact and symptoms to look for in case of a reaction following discharge.
- Where patients are receiving shared care, systems must be in place so that all relevant details relating to transfusion such as history of

reaction/allergy and/or premedication requirements can be communicated between centres effectively.

- Washed components for the management of A/A reactions are only appropriate for patients with a history of anaphylactic or severe anaphylactoid transfusion reactions uncontrolled by premedication. A poorly justified requirement for washed components may cause undue delays when transfusions are needed in the future. In addition, washing of platelets can affect platelet yields with loss of platelet numbers and viability from the washing process and poor *in vivo* incremental rises. Before prescribing washed platelets for patients with a history of transfusion reactions to pooled products, a trial of apheresis platelets should be undertaken as patients who react to pooled platelets may often tolerate apheresis platelets. (see Case 19).
- IgA deficiency with anti IgA antibodies can cause severe anaphylactoid reactions and anaphylaxis. Since the transfused product may contain appreciable quantities of IgA, where possible, samples taken pre-transfusion should be used to check for IgA levels.
- Classical allergic or anaphylactoid reactions do not routinely require culture of the unit or pack or serological investigations. However, where atypical symptoms such as fever are present in a suspected A/A reaction or where skin manifestations are absent, it is important to culture the implicated unit/s *and* the patient, to rule out underlying sepsis and/or bacterial infection in the unit and in the case of red cells to undertake sociological tests to exclude incompatibility.

Case No	Age years Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to red cells								
AA Case1 *p	16 M	One unit of red cells	Anaemia Hb 8.7g/dl	Urticaria, hypotension, dyspnoea, restlessness, anxiety, periorbital oedema and skin wheals.	IgA levels normal. Red Cell incompatibility excluded.	Following the first 50mls.	Hydrocortisone and chlorpheniramine IV.	Recovered fully later that day with no complications. Washed cellular components to be transfused in future if required with premedication of chlorpheniramine IV.
AA Case 2 *	34 F	One unit of red cells	Post-operative anaemia Hb 6.6 g/dl.	Dyspnoea, stridor, cyanosis and gastrointestinal symptoms.	Bacterial culture of patient and unit performed – no organisms isolated. IgA levels not done.	Less than 50mls.	Transfusion discontinued. Chlorpheniramine and hydrocortisone IV.	Recovered with no ill effects within four hours. No further transfusion necessary to date. Commenced oral iron therapy.
AA Case 3 *	35 F	One unit of CMV negative and irradiated red cells	Haematological disorder Hb. 9.4g/dl.	Urticaria, dyspnoea, stridor, wheeze, restlessness, anxiety, dizzy, weak, and feeling of impending doom.	IgA levels normal. HLA class 1 antibody present.	Following the first 100mls.	Hydrocortisone and chlorpheniramine IV.	Recovered without complications within a few hours. Subsequent transfusions with pre medication uneventful.
AA Case4 *	71 F	One unit of red cells.	Anaemia Hb. 7g/dl.	Dyspnoea, chills, rigors, periorbital oedema and pyrexia (39°C).	Unit not cultured. Patient cultured -no growth. Red cell incompatibility excluded. IgA levels not done.	Less than 50mls.	Hydrocortisone and chlorpheniramine IV.	Recovered without complications within five hours. Subsequent transfusions with pre medication uneventful.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 21 (CONTINUED) ANAPHYLACTOID/ANAPHYLACTIC TRANSFUSION REACTION (N=23)

Case No	Age years Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to red cells								
AA Case 6	36 F	One unit of red cells	Anaemia of chronic disease, associated with sepsis with Hb 7.9g/dl.	Urticaria of upper and lower limbs, dyspnoea, substernal discomfort and fever.	Both patient and unit cultured negative. Raised IgA levels Red Cell Incompatibility excluded.	100mls transfused over four hours.	Transfusion discontinued. Chlorpheniramine and paracetamol.	Transfusion stopped, recovered with no ill effects within one hour. Prophylactic chlorpheniramine prescribed daily for ongoing rashes and itch. Subsequent transfusion uneventful.
AA Case 7*	89 F	One unit red cells	Post operative anaemia Hb 9.2g/dl.	Patient clammy, with hypotension, dyspnoea, tachypnoea and tachycardia.	Patient or unit not cultured. IgA levels not checked. Transfusion Incompatibility excluded.	Within minutes.	Transfusion discontinued completely. No medication prescribed.	Patient recovered without complications within seven hours.
AA Case 10*	39 M	One unit red cells	Iron deficiency Hb 6.8g/dl.	Rigors and mild hypertension.	Raised IgA levels Unit cultured negative.	Following <50mls of third unit.	Transfusion abandoned following medical review.	Patient recovered fully within minutes. Further two units with pre-medication uneventful but inappropriate.
AA Case 13* *p	10 M	400mls of red cells	Anaemia Hb 6.9g/dl.	Severe urticarial body rash with weeping raised wheals on skin.	None	Four hours following transfusion. Patient at home.	Chlorpheniramine	Admitted to hospital overnight. Recovered fully within 24 hrs Subsequent transfusions uneventful following pre-medication.
AA Case 23*	61 F	Two units of red cells	Post operative blood loss	Oedema of hands, forearms and face.	Antibody screen and DAT negative.	End of second unit.	Frusemide and IV fluids.	Response to diuretic medication and IV fluids not documented.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 21 (CONTINUED) ANAPHYLACTOID/ANAPHYLACTIC TRANSFUSION REACTION (N=23)

Case No	Age years Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to Platelets								
AA Case 8 *	36 F	One unit pooled platelet concentrate	Platelet count 14 x10 ⁹ /L	Urticaria, dyspnoea and chest tightness.	None	Less than 50mls of transfused.	Chlorpheniramine and hydrocortisone.	Recovered immediately following treatment. Subsequent platelet transfusions have been given uneventfully with pre-medication.
AA Case 9 *	36 F	One unit apheresis platelet concentrate	Platelet count 26 x10 ⁹ /L	Urticaria, chills and itch.	None	Following 50-75mls of transfusion.	Transfusion discontinued. Hydrocortisone and chlorpheniramine.	Recovered fully within one hour. Subsequent platelet transfusions using pre-med cover have been given uneventfully.
AA Case 11 *p	17 M	One unit of CMV negative and irradiated apheresis platelet concentrate	Platelet count 10X10 ⁹ /L	Hypotension, tachycardia, urticaria, chest tightness, coughing and falling O ₂ saturation.	IgA levels post transfusion low - 0.37g/L (relates to immunosuppressant therapy received).	When 85mls of platelets had been transfused.	Hydrocortisone and chlorpheniramine.	Patient recovered within ninety minutes without complications. Subsequent transfusions using apheresis platelets and pre- med cover have been uneventful.
AA Case 12 *p	6 M	120mls CMV negative and irradiated apheresis platelet concentrate	Platelet count 11X10 ⁹ /L	Itching, hypertension, dyspnoea restlessness wheeze, nausea and abdominal cramps.	IgA levels normal.	30-35 mins. into transfusion 120mls transfused.	Pre-med cover prior to this transfusion. Temporarily stopped, salbutamol nebuliser given. Remainder of unit then transfused.	Shortness of breath resolved within minutes and rash resolved later that evening. Washed products were recommended for future transfusions and have been transfused uneventfully.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 21 (CONTINUED) ANAPHYLACTOID/ANAPHYLACTIC TRANSFUSION REACTION (N=23)

Case No	Age years Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to red cells								
AA Case 14 *p	2 M	One unit of CMV negative and irradiated pooled platelet concentrate	Platelet count 9X10 ⁹ /L	Urticaria, stridor, wheeze and severe facial hives.	None.	Within two hours of starting transfusion.	Pre-med cover prior to transfusion Chlorpheniramine and salbutamol nebulisers.	Subsequent transfusions with washed platelets have been uneventful.
AA Case 15 *p	6 F	One unit of CMV negative and irradiated apheresis platelet concentrate	Platelet count 8X10 ⁹ /L	Urticarial rash, raised red wheals and blackened eyes.	None.	When more than 100mls had been transfused.	Pre-medication cover prior to transfusion.	Patient recovered fully within 24hrs. Washed platelets have been recommended for future transfusions.
AA Case 16 *p	6 M	One unit CMV negative and irradiated apheresis platelet concentrate.	Platelet count 9X10 ⁹ /L	Urticaria, stridor and wheeze.	Previous IgA levels normal.	Ten minutes following completion of transfusion.	Pre-med cover prior to transfusion Adrenaline and hydrocortisone IV given post transfusion .	Recovered fully within minutes of receiving treatment. Washed platelets have been recommended for future transfusions.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 21 (CONTINUED) ANAPHYLACTOID/ANAPHYLACTIC TRANSFUSION REACTION (N=23)

Case No	Age years	Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to red cells									
AA Case 17	6	M	One unit CMV negative and irradiated pooled platelet concentrate	Platelet count 12x10 ⁹ /L	Urticaria, dyspnoea, stridor and wheeze.	None	Immediately following transfusion.	Pre-med cover hydrocortisone and chlorpheniramine. O ₂ therapy administered and hydrocortisone repeated.	Patient recovered within one hour and discharged two hours later. Patient received one unit of apheresis platelets four months later uneventfully, but had severe anaphylactoid reaction to apheresis platelets on a subsequent transfusion. Patient to receive washed components in future.
AA Case 18	61	M	One unit CMV-negative and irradiated pooled platelet concentrate	Pre planned invasive procedure Platelet count 37x 10 ⁹ /L	Urticaria and hypertension.	Unit and patient cultured - negative. IgA levels post transfusion normal.	Immediately following transfusion.	Chlorpheniramine.	Patient recovered fully immediately following treatment. Subsequent transfusions using apheresis platelets have been uneventful.
AA Case 19	41	M	One unit CMV-negative and irradiated pooled platelet concentrate	Platelet count 25 x 10 ⁹ /L	Urticaria, hypotension, backache and nausea.	Unit cultured negative. Patient not cultured. IgA levels not checked.	Following the first 50-100mls of transfusion.	Chlorpheniramine and hydrocortisone.	Patient recovered fully immediately following treatment. Subsequent transfusions using apheresis platelets have been uneventful.

* Indicated as full case history

*p Included as full case history in Paediatric Chapter

TABLE 21 (CONTINUED) ANAPHYLACTOID/ANAPHYLACTIC TRANSFUSION REACTION (N=23)

Case No	Age years Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to red cells								
AA Case 20	82 M	One unit pooled platelet concentrate	Ventilated post-operatively. Platelet count $60 \times 10^9/L$ pre planned invasive procedure.	Urticaria, dyspnoea, rigors, hypertension and falling urine output. (patient already on dialysis).	Unit cultured negative. Patient not cultured. IgA levels post transfusion normal.	Immediately following transfusion.	Hydrocortisone. Ventilator support increased.	Patient subsequently died from underlying condition.
AA Case 21	27 M	One unit CMV negative and irradiated pooled platelet concentrate	Platelet count $11 \times 10^9/L$.	Urticaria, hypotension, tachycardia and itch.	Unit cultured negative. Patient not cultured. IgA levels pre transfusion normal.	Immediately following transfusion.	Pre-med of chlorpheniramine. Post reaction chlorpheniramine and hydrocortisone.	Patient recovered fully immediately following treatment. Subsequent transfusions using washed platelets have been uneventful.
AA Case 22 *p	14 M	One unit of CMV negative and irradiated pooled platelets.	Known Asthmatic Platelet count $9 \times 10^9 /L$.	Fever $> 1.5^\circ C$, tachycardia, itch, urticarial rash and wheeze.	Unit cultured-negative. Patient not cultured.	200mls transfused.	Should have received pre med of both chlorpheniramine and hydrocortisone- only received chlorpheniramine. Hydrocortisone IV and salbutamol nebuliser given post action.	Recovered fully within 12 hours. Washed platelets have been recommended for future transfusions.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 21 (CONTINUED) ANAPHYLACTOID/ANAPHYLACTIC TRANSFUSION REACTION (N=23)

Case No	Age years Gender	Component	Reason for Transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/Recommendations for future transfusion
Reactions to plasma								
AA Case 5	45 M	SD Plasma	SD Plasma exchange for TTP.	Urticaria associated with buzzing and itching sensation in both ears.	IgA levels within normal limits.	Following ninth unit of SD plasma during plasma exchange procedure.	Procedure abandoned. Hydrocortisone and chlorpheniramine Already on reducing doses of prednisolone.	Recovered with no ill effects, has since received SD plasma during plasma exchange procedures uneventfully, with pre-med. cover.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Anaphylactoid/Anaphylactic Transfusion Reaction (n=23)

Eight cases are described in detail in this chapter. A/A Cases 1, 11, 12, 13, 14, 15, 16, 17 & 22 are detailed in the Paediatric chapter.

Reactions to red cells

AA Case 2

This patient developed a post-operative anaemia Hb 6.6g/dl and required transfusion of one unit of red cells. During the first 20 minutes, following less than 50mls of the transfusion, symptoms of dyspnoea, stridor, cyanosis and gastrointestinal discomfort developed. The transfusion was discontinued completely and IV chlorpheniramine 10 mgs and hydrocortisone 100mgs were given with relief of symptoms. Both patient and unit were cultured - no organisms were isolated. The patient made a full recovery within four hours. IgA levels were not done. No further transfusion has been required to date. Oral iron therapy was commenced on discharge.

AA Case 3

This patient with a haematological disorder, required a transfusion of one unit of CMV negative and irradiated red cells Hb 9.4g/dl. When 120mls of the unit had been transfused, the patient developed symptoms of urticaria, dyspnoea, stridor and wheeze, restlessness, anxiety, dizziness, weakness and a feeling of impending doom. The transfusion was discontinued and hydrocortisone and chlorpheniramine were administered IV. The patient recovered within a few hours without complications. IgA levels were normal. A HLA class 1 antibody was found. Further transfusions were administered successfully following premedication with chlorpheniramine

AA Case 4

This elderly patient, with a malignant haematological disorder and a history of hypertension required a transfusion of one unit of red cells for anaemia Hb 7g/dl. The transfusion was being infused through a

newly inserted peripheral line. When less than 50mls had been transfused, the patient developed symptoms of dyspnoea, pyrexia > 1.5°C, rigors, chills and orbital oedema. The transfusion was discontinued. O₂ was commenced and chlorpheniramine and hydrocortisone were administered IV. The patient recovered from this incident within five hours without complications. ABO incompatibility was excluded. Culture of the patient isolated no organisms but culture of the unit was not performed. Further transfusions were successfully administered without premedication. This patient had no past history of any type of allergic reaction

AA Case 7

This frail, elderly patient required a transfusion of one unit of red cells post operatively Hb 9.2g/dl. The patient had received two units of red cells intraoperatively uneventfully. Within an hour and a half, the patient became clammy and developed symptoms of hypotension, dyspnoea, tachypnoea and tachycardia. The fluid balance chart was missing and there was no written record of the volume that had been transfused. Following medical review, the transfusion was discontinued. No treatment or medication was administered. There is no record of the length of time taken by the patient to recover fully but it is documented in the nursing notes that the patient had 'settled' within seven hours. No chest X ray was performed. The patient had no underlying cardiac or respiratory disease and was not on regular diuretic medication. Neither the patient nor the unit was cultured but ABO incompatibility was excluded. Although it is likely that this reaction was related to the transfusion, it has been difficult to clarify this due to the atypical nature of the symptoms and the lack of investigation post the reaction.

AA Case 10

This patient with chronic iron deficiency anaemia was prescribed three units red cell concentrate for a Hb of 6.8g/dl. This transfusion was based on haematology results taken ten days previously. Oral

iron therapy had also been prescribed but there is a question over patient compliance. The first two units were transfused uneventfully. However following <50mls of the third unit, the patient developed symptoms of rigors and hypertension. Following medical review the transfusion was abandoned, no treatment or medication was necessary and the patient recovered fully within minutes. IgA levels were elevated probably due to underlying liver disease. Following pre medication with hydrocortisone, the patient received a further two units of red cells three days later uneventfully. These transfusions were considered inappropriate as there was no evidence of haemodynamic instability on the day of the first transfusion, or at the time of the subsequent two-unit transfusion.

Reactions to Platelets

AA Cases 8 and 9

This female patient required one unit pooled platelet concentrate for thrombocytopenia. Following less than 50mls of the unit, the patient developed symptoms of urticaria, dyspnoea and chest tightness. The transfusion was discontinued and hydrocortisone and chlorpheniramine were given with relief of symptoms. This patient had a history of medication allergies. As a result, she required routine premedication prior to receiving certain medications and was prescribed chlorpheniramine on an on-going basis. No premedication was prescribed prior to this transfusion. Later that day, this patient was again prescribed one unit of apheresis platelet concentrate. No pre medication was prescribed despite her earlier reaction. Following between 50 and 75mls of this unit, the patient developed symptoms of urticaria, chills and itch. Medical review was again sought, the transfusion was discontinued and hydrocortisone and chlorpheniramine were given IV. The patient recovered fully within minutes of treatment, without complications. Despite this patient's history of medication allergies, routine prophylactic premedication prescribed on an on-going basis and her transfusion reaction earlier that day, she received

no premedication cover prior to either transfusion. Subsequent platelet transfusions have been given uneventfully using premedication cover of hydrocortisone and chlorpheniramine.

AA Case 19

This male patient required transfusion of one unit CMV antibody negative and irradiated pooled platelet concentrate for thrombocytopenia. Following infusion of between 50 –100mls of the unit, the patient developed symptoms of urticaria, hypotension, backache and nausea. Hydrocortisone 100mgs and chlorpheniramine 10mgs were given IV and the patient's symptoms resolved within minutes. The unit was cultured and no organisms were isolated. The patient was not cultured. IgA levels were not checked. Subsequent transfusions using apheresis platelets have been given uneventfully.

AA Case 23

This patient required transfusion of two units of red cells for a postoperative blood loss of - 1140mls. Two units of red cells were issued and transfused. The first unit transfused uneventfully. Towards the end of the second unit symptoms of facial, bilateral hand and forearm oedema developed. Serological investigations post transfusion were normal. The patient suffered no complications as a result of this episode and no further transfusions were required. The case was initially reported as an unusual transfusion reaction, however upon review, it was decided that this reaction should be included in the AA category.

Transfusion Associated Circulatory Overload

Transfusion Associated Circulatory Overload (TACO) is characterised by the development of acute pulmonary oedema secondary to congestive cardiac failure. Signs and symptoms can manifest during, or within some hours of transfusion and can include any or all of the following: dyspnoea, orthopnoea, cyanosis, tachycardia, hypertension and pulmonary and/or pedal oedema. Chest auscultation reveals the presence of rales. (Popovsky, 2001).

TACO accounted for 14 (8%) of the incidents reported during this reporting year. Pulmonary complications due to TACO or TRALI are now among the most frequent causes of life threatening hazards of transfusion. Unfortunately TACO is still an under recognised and under appreciated problem in transfusion practice and can be fatal. It can strike patients of any age and can be treated when recognised early. While adults over 60 and infants are especially susceptible to fluid overload, no transfusion recipient is free from this risk (Popovsky, 2002) and it can be associated with any type of component. Appendix 3 shows the average volume of blood components issued.

Special care should be taken when transfusing patients with diminished cardiac, respiratory or renal function and patients with severe chronic anaemia Hb <5g/dl. Where transfusion is considered essential, patients with significant chronic anaemia should be transfused slowly to avoid acute changes in blood volume, which may precipitate heart failure. (Stack *et al*, 1996). Transfusion should not be required in the vast majority of patients with chronic anaemia due to underlying haematinic deficiencies of iron, B₁₂ or folate. These patients respond quickly to specific replacement therapy. (Saxena *et al*, 2002).

Anaemia is common in patients with moderate to severe heart failure and treatment with transfusion can aggravate the condition. There is encouraging evidence that the anaemia of heart failure, not due to other causes, may be improved by treatment with erythropoietin and iron therapy, which may improve symptoms and reduce the risk of hospitalisation for worsening heart failure. This is currently the subject of a number of randomised control trials. (NHS, Clinical Guideline 5) (Silverberg *et al*, 2001).

TACO causes increased central venous pressure, increased pulmonary blood volume and diminution in lung compliance with resultant secondary congestive failure and pulmonary oedema. (Mollison *et al.*, 1998) While the prevailing view is that the rate of infusion is important in triggering the reaction, there is little data on this important point. (Popovsky, 2002)

The symptoms of TACO usually manifest within several hours of transfusion. Signs and symptoms include dyspnoea, orthopnea, cyanosis, tachycardia, increased blood pressure and pulmonary oedema. Non-specific manifestations include headache, tightness in the chest and dry cough (Popovsky, 2001).

The incidence of TACO has been reported as varying from 1:1000 to 1:3000 red cells transfused depending on age and degree of monitoring of the patients. (Popovsky & Taswell 1996) However in a study of patients undergoing hip or knee arthroplasty, TACO was found in approximately 1% of 382 patients. The underlying common denominator was a positive fluid balance (mean 2.5L) prior to the transfusion. The patients who developed TACO were older (87 vs. 77 years) than those who did not develop this complication. (Popovsky & Taswell 1996, Popovsky 2002)

The incidence of TACO for this reporting year was 1:10,840 red cells and 1:22,171 units of plasma issued.

There has been a reduction in the incidence of TACO associated with plasma transfusions since the first NHO report in 2000. This may be associated with increased education and the issuing of NHO information leaflets from the NHO on indications for use, the associated risks and the recommended rates of infusion. However, in the one case (Case 3) reported this year which was associated with plasma used for warfarin reversal, the transfusion contributed to mortality. This should prevent any complacency and also highlights the need for continuing education.

Additional evidence provided from a recent study demonstrates that the management of patients with markedly prolonged INR values is safe and effective if small doses of vitamin K are administered orally. Findings suggest this results in a more rapid return to safe levels of anticoagulation and reduced risk of bleeding as compared with simple warfarin withdrawal alone. The findings suggest that a 2mg dose of oral vitamin K for patients with an INR value of more than 10.0 is adequate. (Gunther *et al* 2004).

Findings

- 12 of the 14 cases (86%) were associated with the transfusion of red cells.
- One case (Case 3) involved transfusion of eight units of solvent detergent (SD) plasma. Although the patient was very ill before the transfusion, it is likely that the transfusion contributed to mortality.
- One case in a patient with massive bleeding (Case 6) involved a combination of blood products, red cells, pooled platelets, SD plasma and cryoprecipitate.
- Eleven cases (79%) involved elderly patients, the majority of whom were extremely ill pre-transfusion with multiple underlying conditions including cardiovascular insufficiency, malignancy and renal decompensation. In one of these cases (Case 2), the anaemia was due to iron deficiency.
- Seven of the 14 patients did not have an intake and output record for the 12 hours prior to transfusion. (In one of these cases, the case notes were missing).
- Five cases (Cases 3, 4, 6, 7, 13) had a positive fluid balance prior to transfusion. In two of the six cases where there was an intake and output record, the chart was not filled in accurately.
- In six cases (Cases 4, 5, 7, 8, 9 and 14), the patients were receiving regular diuretic cover and in one of these cases (Case 7), the patient also

received a prophylactic diuretic prior to transfusion.

- In two cases (Cases 8 and 10), the patient had received 100mls or less before displaying symptoms of TACO.
- 12 of the 14 cases required supplemental diuretic therapy for relief of symptoms.
- In one case, (Case 8), there is a record of subsequent uneventful transfusions with prophylactic diuretic cover.
- In four cases, TRALI was considered but excluded. One case (Case 13) was submitted as a possible TRALI but on review was moved to the TACO category. In another case, (Case 10), TRALI was excluded following a donor investigation in which granulocyte-specific and anti-lymphocyte antibodies were not detected. In the remaining two cases, (Cases 6 and 12), the possibility of TRALI was considered but excluded on clinical grounds.

Recommendations

- All patients receiving blood components should be assessed carefully but particular attention should be paid to the identification and management of 'high-risk' patients which include:
 - Patients of low body weight,
 - Elderly
 - Infants and children,
 - Physiologically compromised patients, especially with a history of cardiac, respiratory or renal insufficiency or chronic anaemia.
- In susceptible patients, transfusions should be administered slowly (1ml/kg of body weight/hour) (Popovosky, 2001). An accurate intake and output record should be maintained. The risk of overloading the circulation can be minimised by administering a prophylactic diuretic in addition to maintenance diuretic therapy.
- Transfusion should be on a unit-by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component. This assessment should include:
 - A careful estimation of the patient's hydration status prior to transfusion.
 - Thorough review of the patient's fluid balance during transfusion of any blood component.
 - The possible need for 'prophylactic' diuretic therapy.
- It may be prudent to transfuse only one unit in a 24-hour period in high-risk patients. Some subjects take as long as 24 hours to readjust blood volume and the effects of the transfusion of large amounts of blood must always be carefully monitored, particularly in those patients whose venous pressure is already raised before transfusion had begun (Mollison *et al* 1998).
- In view of the need to observe the patient, transfusions should not normally be allowed to continue at night unless the patient has special nursing care. (Mollison, 1998)
- Iron deficiency produces a chronic anaemia that usually does not require immediate correction by transfusion and for which a specific treatment (oral or parenteral iron) is available. Therefore, transfusion therapy in iron-deficient patients should be reserved for those patients who need correction of anaemia immediately. Transfusion therapy should be administered only when the anaemia becomes physiologically destabilising. (Saxena *et al*, 1993).
- SD plasma or FFP is only required for the reversal of over anticoagulation in the presence of major bleeding or emergency surgery as per information leaflet issued by the NHO (Appendix 2).

TABLE 22 TRANSFUSION ASSOCIATED CIRCULATORY OVERLOAD (N=14)

Case Number	Age years Gender	Volume Transfused	Rate of Transfusion	Pre-existing Problems	Symptoms, Signs & Outcome	Comments
TACO Case 1 *	80 M	One unit of red cells	One unit over three hours.	LVF, hypertension and gout. Symptomatic anaemia Hb. 5g/dl due to a GI bleed.	Dyspnoea, chest tightness and felt clammy. Frusemide administered with a good diuretic response. Nebuliser administered. Responded however remained breathless for three days.	Incomplete fluid balance record pre-transfusion. Unit prescribed over four hrs but infused in three. Poor documentation in chart.
TACO Case 2 *	73 F	One unit of red cells	One unit over 4 hours and 20 minutes.	Hypertension, type 2 DM, iron deficiency anaemia, Hb 7.8 g/dl.	Ten minutes post transfusion and 20 mins post oral diuretic, dyspnoea, cyanosis, pulmonary oedema, hypertension and chest tightness, tachycardia, rales on chest exam. No CXR recorded. Treatment IV diuretic, cyclimorph, and O ₂ , symptomatic relief within few hrs.	No documentation of response to diuretic.
TACO Case 4 *	82 F	One unit of red cells and 100mls of the second unit	One unit over four hours.	LVF, chronic anaemia and chronic renal impairment. On regular diuretic.	After 100mls 2nd unit, tachycardia and hypertension. Transfusion discontinued. No CXR, no documentation of chest auscultation. No further diuretic administered. Recovered with no ill effects.	Low weight at risk patient.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 22 (CONTINUED) TRANSFUSION ASSOCIATED CIRCULATORY OVERLOAD (N=14)

Case Number	Age years Gender	Volume Transfused	Rate of Transfusion	Pre-existing Problems	Symptoms, Signs & Outcome	Comments
TACO Case 5 *	85 F	One unit of red cells and 135mls. of the second unit	One unit over four hours.	Significant cardiac history with previous MI, PVD, renal impairment, asthma, Post-op Hb 8.8g/dl. On regular diuretic.	After 135mls of the 2nd unit, dyspnoea, cyanosis, tachycardia, hypertension, rales on chest exam with decreased O ₂ and increased pCO ₂ . CXR showed pulmonary oedema. IV frusemide 120 mg, IV hydrocortisone, IV cyclimorph, combivent nebuliser, O ₂ therapy via venti mask 40% and gelofusine 250mls administered. Recovered with no ill effects within 24 hours.	Low weight at risk patient.
TACO Case 6	57 M	Nine unit of red cells Four units pooled platelets 16 units of SD plasma Two units of cryo-precipitate	75mls per hour over 24-hour period.	Hepatic failure, liver cirrhosis, coagulation disorder, non-insulin dependant DM. Bleeding, post-liver biopsy.	Dyspnoea, pulmonary oedema. CXR showed pulmonary venous hypertension and decreased air entry bilaterally. IV frusemide, O ₂ 80% administered. Patient died of underlying condition.	TRALI considered but excluded.
TACO Case 7 *	53 M	One unit of red cells cells	Over four hours.	Poor respiratory function, sepsis, ascites, CVA, hypertension, malignant haematological disorder, insulin dependant DM, post-operative abdominal surgery. On regular diuretic.	Premed IV frusemide with good diuresis. After 50-100mls, dyspnoea, tachycardia, pulmonary oedema, frothy sputum, rales, and falling O ₂ saturations. No CXR performed, transfusion discontinued. Further dose IV frusemide with good effect. Patient died later unrelated to transfusion.	High-risk patient, received a prophylactic diuretic but still developed TACO.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 22 (CONTINUED) TRANSFUSION ASSOCIATED CIRCULATORY OVERLOAD (N=14)

Case Number	Age years Gender	Volume Transfused	Rate of Transfusion	Pre-existing Problems	Symptoms, Signs & Outcome	Comments
TACO Case 8 *	78 F	Approximately 100mls of red cells transfused over one hour and 15 minutes.	Over four hours.	Multiple medical problems including significant cardiac disease with LVF, previous AAA repair, renal impairment, hypertension, COAD. On diuretic as necessary.	During first 50-100mls, dyspnoea, tachycardia, pulmonary oedema. Transfusion discontinued. IV frusemide administered with good diuretic effect.	High-risk low bodyweight (50 kg).
TACO Case 9	81 M	One unit of red cells		Nephrotic syndrome, LVF.	Dyspnoea. Diuretic administered with good effect.	Medical records missing.
TACO Case 10 *	83 M	100mls unit of red cells	48mls per hour.	Cardiomyopathy, aortic stenosis, AF, COAD, asthma, DM, CVA gastritis, anaemia. On regular diuretic.	After 100mls, dyspnoea, cyanosis, tachycardia, hypertension, falling O ₂ saturations, chest tightness, bilateral wheeze, confusion. Transfusion discontinued. IV frusemide hydrocortisone, IV chlorphenamine, salbutamol nebuliser, O ₂ via mask 60% administered. Diuresis 700mls overnight. Symptoms improved.	High-risk patient, raised JVP and bilateral crepitations on admission. On daily diuretics. No extra diuretic pre transfusion. Investigated for TRALI but excluded.
TACO Case 11 *	77 M	One unit of red cells plus 100mls of second unit of red cells	71mls per hour.	Cardiac surgery, malignant haematological disorder.	First unit transfused uneventfully. After 100mls of the second unit, dyspnoea and chest tightness. Frusemide and O ₂ 40% ventimask administered. Immediate symptom resolution.	High risk elderly compromised patient.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 22 (CONTINUED) TRANSFUSION ASSOCIATED CIRCULATORY OVERLOAD (N=14)

Case Number	Age years Gender	Volume Transfused	Rate of Transfusion	Pre-existing Problems	Symptoms & Outcome	Comments
TACO Case 12 *	70 F	One unit of red cells	Over four hours.	Acute MI, hypertension, DM.	Six hours post transfusion, tachycardia, nausea, hypertension, falling O ₂ saturations, wheeze, pyrexia, and bilateral creps, apprehension. Commenced nasal O ₂ . Transferred ITU, became hypotensive. Frusemide IV, cyclimorph, dobutamine, isorbide dinitrate administered. CXR - pulmonary oedema, left basal effusion. Symptoms resolved within 24 hours.	High-risk, low weight patient, weight 56.6 kg. Intake/output record not maintained pre-transfusion. No diuretic pre-transfusion. TRALI considered but excluded.
TACO Case 13 *	53 M	Two units unit of red cells (had received three units the previous day)	Over four hours each.	Vascular disease, insulin dependant DM, asthma, post-orthopaedic surgery.	After two units units, dyspnoea, falling O ₂ saturation. mild fever, raised JVP bilateral lower limb oedema. O ₂ 35%, frusemide administered, good diuretic response.	Originally investigated as TRALI but excluded.
TACO Case 14 *	84 F	Two unit of red cells (had received one unit the previous day)	Over four hours each.	CCF, renal impairment, DM, anaemia unknown cause. On regular diuretic.	After 100mls 2nd unit, dyspnoea, wheezing, hypertension, sweating chest pain. IV hydrocortisone, nebuliser.	Patient died two to three weeks post transfusion, unrelated to transfusion.
TACO Case 3 *	83 M	Eight units Octaplas	Over eight hours.	Significant cardiac disease, history of malignancy, sepsis of unknown origin and impaired renal function.	Raised INR 11.9. No record of active bleeding. After 5th unit SD plasma O ₂ saturation fell. Patient died 2 hrs following completion of transfusion.	Positive fluid balance 1800mls in 24 hrs pre-transfusion. Patient prescribed 8 units SD plasma. After four units INR=4.5 but a further four units infused. No record of diuretic therapy, poor documentation in medical records.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Transfusion Associated Circulatory Overload (n=14)

Cases Involving Red Cells

We describe 11 cases in detail in this section.

TACO Case 1

This elderly patient with a history of hypertension and significant cardiac disease required a transfusion of red cells for a symptomatic anaemia (excessive fatigue) Hb 5g/dl. The patient was not on any routine diuretic therapy and did not receive any prophylactic diuretics prior to transfusion. Five units of red cells were prescribed over four hours each. The first unit had been transfused over three hours when the patient became clammy and symptoms of chest tightness and dyspnoea developed. The blood pressure remained stable. While the patient had been on an intake and output record, it had not been accurately completed. Frusemide and a combivent nebuliser was administered and a good diuresis of 800mls resulted. No chest x-ray was recorded. The patient recovered but remained breathless for three days following this event.

TACO Case 2

This elderly female was given a transfusion of one unit of red cells for iron deficiency anaemia, Hb 7.8g/dl. The patient had symptoms of tiredness, weakness, dizziness and intermittent back pain. The unit was transfused was completed over four hours twenty minutes and frusemide was administered orally towards the end of the transfusion. Twenty minutes after receiving frusemide and ten minutes post transfusion, the patient developed symptoms of dyspnoea, cyanosis, tachycardia, chest tightness and hypertension. There were audible rales on chest auscultation. The patient was reviewed and frusemide and cyclomorph were administered IV. O₂ therapy at 60% was commenced. No chest x-ray was recorded and no documentation to the response to the diuretic but the patient made a complete recovery within a few hours. The patient's Hb post transfusion was 9.2g/dl. The patient was discharged on oral iron supplements.

TACO Case 4.

This small elderly patient with a significant cardiac history, underlying hypertension, chronic renal impairment and chronic haematological malignancy was transfused with two units of red cells for symptomatic anaemia. Hb 8.1g/dl. The first unit was transfused uneventfully over four hours. During the second unit, when less than 100mls had transfused, tachycardia and hypertension developed and the transfusion was discontinued. The patient was on a regular diuretic and was prescribed further diuretic medication to be given following the second unit. However this diuretic was not administered because the patient was considered "dry" although a positive fluid balance of 230mls was recorded for the twelve hours prior to the transfusions. A chest x-ray was not performed. The symptoms resolved within one hour.

TACO Case 5

This small elderly female patient required a red cell transfusion for post-operative anaemia Hb 8.8 g/dl. This patient had a past medical history of ischaemic heart disease, peripheral vascular disease, asthma and renal impairment. The patient was on maintenance daily diuretic therapy. Twelve hours pre transfusion the patient had an intake of 1050mls but the output was not recorded accurately. Two units of red cells were prescribed over two hours each, but the actual administration rate of transfusion was each unit over four hours. Overnight the first unit was transfused uneventfully, but having received 135mls of the second unit, the patient developed symptoms of dyspnoea, cyanosis, tachycardia, pulmonary oedema and hypertension. The transfusion was immediately discontinued. IV frusemide 80mgs was administered with a poor response. A further 40mgs of frusimide IV was given with effect. The patient also received IV hydrocortisone 100mgs, IV cyclimorph 5mgs, combivent nebuliser 2.5mls and O₂ therapy via venti mask. The patient recovered from this event without complications within 24 hours.

TACO Case 7

This septic patient with multiple medical problems and an underlying malignant haematological disorder, required a post-operative transfusion of one unit of red cells for a symptomatic anaemia - Hb.9.1g/dl. The patient's condition was deteriorating and further surgery was scheduled. The patient had ongoing clinical problems with repeated episodes of pulmonary oedema responsive to frusemide. A clinical decision regarding a continuous frusemide infusion was being considered. A record of the intake and output for the previous 24 hours showed a positive fluid balance of 1453mls. Prior to transfusion, a premedication of IV frusemide 40mgs was administered with an accompanying good diuresis. However, during the first 90 minutes when 50-100mls had been transfused, the patient developed symptoms of tachycardia, dyspnoea, falling O₂ saturation, pulmonary oedema, frothy sputum and rales on auscultation. The transfusion was discontinued and a further dose of IV frusemide 20mgs was administered. The cumulative diuretic response to both doses of frusemide was 3720mls. The patient's condition further deteriorated due to his underlying disease and he subsequently died some days later unrelated to the transfusion.

TACO Case 8

This small elderly female patient with multiple medical problems including ischaemic heart disease, chronic obstructive airways disease and renal impairment was prescribed a transfusion of one unit of red cells over four hours for anaemia Hb 7.1g/dl. The patient was not on regular diuretic therapy, but on this admission, had been administered diuretics as required. After an hour and fifteen minutes when approximately 100mls of red cells had been infused, the patient developed symptoms of dyspnoea, tachycardia and pulmonary oedema. The transfusion was immediately discontinued. IV frusemide 40mgs was administered with immediate effect. Recorded daily weights were taken on this patient and on the day of transfusion was 0.9kg higher than the previous day. The patient recovered with no ill effects. The patient received a further unit of red

cells two days later with premedication of frusemide 40mg with no adverse effects.

TACO Case 10

This elderly male patient with an underlying history of ischaemic cardiomyopathy, aortic stenosis, atrial fibrillation and chronic obstructive pulmonary disease presented with a raised JVP, pedal oedema and bilateral creps on auscultation. Chest x-ray on admission showed gross cardiomegaly with fluid present. The patient was prescribed one unit of red cells for symptomatic anaemia Hb 9.3g/dl. He was taking regular diuretic medication but did not receive any extra diuretic prior to this transfusion. One unit of red cells was prescribed over a period of four to six hours at a rate of 48mls/hour. When approximately 100mls had been transfused, the patient became confused and symptoms of dyspnoea, cyanosis, tachycardia, hypertension, chest tightness, chest pain and bilateral wheeze developed. The O₂ saturation fell and the transfusion was discontinued completely. IV frusemide 40mg, hydrocortisone, chlorpheniramine, salbutamol nebuliser and 60% O₂ were administered. The patient had a diuresis of 700mls overnight and the symptoms improved but never completely resolved due to his underlying cardiac disease. TRALI was considered but excluded following a donor investigation in which granulocyte-specific and anti-lymphocyte antibodies were not detected.

TACO Case 11

This elderly male patient required a transfusion of two units of red cells for anaemia Hb 8.9g/dl. The patient had a history of cardiac surgery one year earlier and an underlying haematological malignancy. One unit of red cells was transfused as prescribed uneventfully at a rate of 71mls an hour. Having received 100mls of the second unit of red cells, the patient developed symptoms of dyspnoea and chest tightness. The transfusion was immediately discontinued. O₂ therapy and IV frusemide 40mgs was administered with immediate effect. The patient recovered with no complications from this event. An intake and output record which

indicated a positive fluid balance of 682mls was only maintained from commencement of the transfusion.

TACO Case 12

This small elderly female patient had a history of diabetes mellitus and hypertension and was on regular beta-blockers. She presented with a subendocardial myocardial infarct and required one unit of red cells for a symptomatic anaemia Hb 8.6g/dl, thought to be due to a leaking diverticulum. The unit was administered over four hours with no diuretic prescribed pre transfusion; intake and output were not recorded. Six hours following completion of the transfusion, the patient became very apprehensive, felt hot and cold and developed symptoms of tachycardia, hypertension, falling O₂ saturations, nausea, wheeze and slight pyrexia, and was commenced on O₂. Bilateral creps were audible on auscultation and a diagnosis of CCF was made. The patient was transferred into ITU for further management. On admission to ITU, her blood pressure had fallen to 90/50. Frusemide, cyclimorph, dobutamine and isosorbide dinitrate were administered and betablockers were withheld. There was a moderate response to the diuretic. A portable chest x ray taken at the time of the reaction showed abnormal changes throughout both lung fields with a diagnosis of pulmonary oedema. Two days following the reaction, the chest X ray showed considerable improvement with a residual left basal effusion. The patient's condition continued to improve and she was discharged from ITU to the ward after two days. Ten days later the patient's chest x-ray was clear. The possibility of TRALI was considered but excluded on clinical grounds.

TACO Case 13

This patient with a history of insulin dependent diabetes and respiratory disease was admitted for elective orthopaedic surgery. He sustained moderate intra-operative blood loss and was transfused three units of red cells uneventfully Hb 6.9g/dl. He subsequently underwent an evacuation of a large haematoma that developed post-operatively. He required a further two units of red cells. He was also

receiving fluid infusions including gelofusion and was in a positive balance of 847mls. The red cells transfused over four hours and following completion of the second unit, he developed a slight rise in temperature, dyspnoea, and falling O₂ saturation 82% on room air. He recovered quite quickly once he was commenced on 35% O₂ treatment. Review showed a mildly elevated JVP, and bilateral lower limb oedema. On examination he was found to have bilateral crepitations over his lung fields. He was administered intravenous diuretics and had a diuresis of more than 400mls with resolution of his symptoms. A chest x-ray 24 hours later showed mild interstitial oedema mainly in the lower lobes and some consolidation medially in the right lower lobe which was thought to be due to localised alveolar oedema. This case was originally reported as a TRALI but this was excluded on the basis of the clinical findings.

TACO Case 14

This elderly patient with underlying renal failure, cardiac failure and anaemia of unknown cause required red cells Hb. 7.9 g/dl. The patient was on regular diuretic therapy pre-transfusion. The intake and output record had not been maintained accurately. One unit of red cells was transfused without incident. On the following day, the patient was prescribed two further units of red cells and a diuretic IV was prescribed for administration following the transfusion. The first unit was transfused over three to four hours. Having received 100 ml of the second unit the patient developed symptoms of dyspnoea, wheezing, chest pain, sweating, hypertension and decreased O₂ saturation. It appears that IV frusemide 40 mg was administered twenty-five minutes prior to this unit being discontinued but there is no documented response to the diuretic. IV hydrocortisone, a nebuliser and O₂ were administered. On O₂, the saturation improved from 84% to 93%. A chest x-ray was performed which showed a diffuse shadowing over both lung fields. The patient remained breathless following the transfusion and died two weeks later due to the underlying condition unrelated to the transfusion.

Cases Involving Plasma

We describe the one case of TACO associated with plasma transfusion in detail.

TACO Case 3

This elderly patient with an underlying malignancy, sepsis, significant cardiac disease and impaired renal function was admitted with an INR of 11.9. There was no record of any active bleeding. Antibiotic therapy had been prescribed for the underlying sepsis but the site of infection had not been determined. There was a positive fluid balance of 1800mls over the 24-hour period pre transfusion. Eight units of SD plasma were prescribed and were administered in less than nine hours (177mls an hour). Following transfusion of four units, the INR was 4.5 but a further four units were infused. The O₂ saturation dropped after the fifth unit and O₂ therapy was commenced at 40%. The patient was not on regular diuretic medication and did not receive any diuretic prior to or during the transfusion. This patient died two hours following completion of the transfusion. The TSO discovered the incident during a routine retrospective audit of transfusion practice.

Delayed Haemolytic Transfusion Reaction

Definition: Delayed haemolytic transfusion reactions are defined, for the purpose of this report, as those occurring more than 24 hours following the transfusion of a blood component. A haemolytic transfusion reaction occurs when antigen-positive red blood cells are transfused to a patient who develops an alloantibody to that antigen. It results in the lysis or accelerated clearance of red blood cells due to immunologic incompatibility between the blood donor and the recipient (Boehlen & Clemeston, 2001)

This category accounted for 5% of incidents reported (9 of 180) Delayed haemolytic reactions, estimated to occur at a frequency of 1:400–1:700 transfusions may be difficult to diagnose and may, therefore, have been underreported in the past. As many of these patients are already very ill, the diagnosis is often overlooked

Typically the picture is of falling Hb four to ten days after a transfusion. In some cases it may be associated with jaundice and rarely renal impairment

although due to the underlying condition in many of these patients, the exact contribution of the delayed haemolytic antibody reaction to the renal impairment is difficult to evaluate.

The pre transfusion antibody screen sample is usually negative for the antibody responsible but the antibodies are subsequently detected on post transfusion samples. These reactions occur where antibodies present due to previous transfusion or pregnancy fall below the detection limits of the pre transfusion antibody screen but are rapidly boosted by a transfusion of red cells that express the corresponding antigen leading to haemolysis of these cells. The antibodies involved typically are Kidd antibodies (Anti-Jk^a, Anti-Jk^b) but other antibodies such as Rh and Kell may also be involved.

Findings

- There were nine cases reported and as of last year we have graded them by severity according to the SHOT criteria.

Group 1 Asymptomatic with 'antibody only' detected (with or without a positive antiglobulin test (DAT) - Three cases (Cases 1, 2 and 4) were classified as group 1 reactions.

Group 2 Evidence of haemolysis measured by falling Hb and positive DAT.

Group 3 Falling Hb with jaundice with or without a positive DAT. There were four cases which were classified as group 3 reactions (Cases 3, 7 8 and 9).

Group 4 As for group 3 but with renal impairment. There were two cases that were classified as group 4 (Case 5 and 6).

- The commonest antibodies implicated were Rh, Duffy and Kidd.
- There were no fatalities associated with the reactions.
- Case 8 demonstrates that in some cases it may be necessary, in an emergency, to transfuse before the antibody has been identified.
- Case 5 illustrates that in cases where there are multiple antibodies it may not always be possible to find fully compatible blood and it may be necessary to issue least incompatible blood.
- One of the group 1 cases (Case 1) represented a report of alloimmunisation after exposure to Rh positive blood rather than a delayed haemolytic reaction.

Recommendations:

- These reactions, which are largely unavoidable, are likely to increase as our patient population, particularly the elderly, receive more transfusions. DHTR should be suspected when there is a falling Hb or jaundice some days post transfusion.

- Careful history taking in relation to transfusion and pregnancies by the requesting physician is important. However, up to 12% of patients do not realise that they have had a transfusion (Busch, 1991) therefore access to and checking of previous transfusion records is essential.
- Use of three cell screening panels, sensitive antibody screening techniques and satisfactory participation in external quality assurance schemes such as the National External Quality Assurance Scheme (NEQAS), should minimise failures to detect weak antibodies.
- As antibodies can develop rapidly, patients requiring repeated transfusions should have a fresh sample submitted within 24-72 hours of a planned transfusions (NBUG, 2002).
- When investigating a DHTR a serum sample should be used for antibody detection as some antibodies, particularly weakly complement binding antibodies, not detectable in plasma specimens may be detected in serum samples (SHOT, 2003).
- A number of fatalities, which were reported in SHOT 2002, associated with DHTR were due to delays in transfusing suitable blood rather than due to the DHTR itself. In the event that a patient has a DHTR, specialist advice should be sought for current management of the patient's condition and future transfusion requirements.
- Consideration should be given to issuing antibody cards to all patients with clinically significant antibodies (NBUG, 2002).
- The possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated.

TABLE 23 DELAYED HAEMOLYTIC TRANSFUSION REACTION (DHTR) (N=9)

Case Number	Age years Gender	Pre-existing condition	Interval between transfusion and onset of symptom/signs	Findings	Outcome
Group 1					
DHTR Case 1	86 M	GI bleed Hb 5.8 g/dl. Transfused with nine units of group O Rh D positive red cells over five days due to supply problems.	No symptoms.	Six months post transfusion of Rh D positive red cells, patient was re-crossmatched and found to have Anti-D and Anti-E.	Has not been transfused since.
DHTR Case 2	71 F	Recurrent pneumothorax and general debility.	None	Anti E detected 6 days post transfusion.	Subsequently transfused with antigen negative blood uneventfully.
DHTR Case 4 *	54 F	Malignancy	After 30mls of blood had infused, fever >1.5°C Transfusion discontinued.	DAT positive and Anti-C & -E detected three days post transfusion.	Subsequently transfused with antigen negative blood uneventfully.
Group 3					
DHTR Case 3	76 M	Post cardiac surgery Hb 6.7g/dl.	Almost immediately post operatively.	Rising bilirubin and LDH, falling haemoglobin, Deteriorating renal function. Anti-E detected on day seven.	Died unrelated to transfusion.
DHTR Case 7 *	78 F	Collapse, seizures and anaemia.	Seven days.	Falling Hb, rising bilirubin. Anti-c, Anti-E and Fy ^b detected.	Recovered without complications.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 23 (CONTINUED) DELAYED HAEMOLYTIC TRANSFUSION REACTION (DHTR) (N=9)

Case Number	Age years Gender	Pre-existing condition	Interval between transfusion and onset of symptom/signs	Findings	Outcome
Group 3					
DHTR Case 8 *	75 M	Collapse, anaemia previous heart surgery.	Eight days post transfusion.	Falling Hb, rising bilirubin and LDH, required further transfusion. Anti-C and Anti-E detected.	Subsequently transfused with antigen negative blood uneventfully.
DHTR Case 9 *	60 M	Hypertension, intraoperative bleeding. Anti Fya detected. Fya negative cells transfused	Four days.	Jaundice, falling Hb, rising bilirubin, positive DAT, anti-Jk ^a detected.	Patient recovered completely within five days.
Group 4					
DHTR Case 5	50 M	Oesophageal varices GI bleed Cirrhosis of the liver. Congenital factor deficiency, Anti-D, anti- Jk ^a , Anti- S, Anti- M antibodies present. D negative, JK ^a negative, S negative, M positive red cells transfused in emergency	Two days.	Falling Hb two days later Rise in bilirubin and LDH 13 days later. Deteriorating renal function.	Recovered without complications.
DHTR Case 6 *	68 M	Emergency perioperative bleeding.	11 days post transfusion.	Falling haemoglobin rising bilirubin. Rising LDH. Anti-c and Anti-E detected. Deteriorating renal function.	Died unrelated to transfusion.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Delayed Haemolytic Transfusion Reaction (n=9)

We describe five cases in detail. In one case (Case 4), reported as a DHTR, the transfusion was stopped as a result of pyrexia which may have been related to the underlying condition or to the presence of Rh antibodies detected three days later.

Group 1

DHTR Case 4

This patient was extremely ill with an underlying malignancy and required three units of red cells for a symptomatic anaemia. Three units of red cells were transfused uneventfully. Within two weeks, three further units were again required for anaemia as a result of continuous minor bleeding Hb 6.1g/dl. The pre transfusion antibody screen was negative. Following 30mls of the first crossmatched unit, the patient's temperature increased > 1.5°C. The transfusion was stopped and the unit discarded. The suspected transfusion reaction was not reported to the laboratory or the TSO. During routine haemovigilance audit three days later, the TSO noticed that only thirty mls had been transfused and the two remaining units were quarantined for investigation. A fresh crossmatch specimen revealed a positive antibody screen with specificity for Anti-C and Anti-E. The DAT was positive for IgG and C3b/C3d. The patient had three further units of antigen negative red cells crossmatched and these were transfused uneventfully.

Group 3

DHTR Case 7

This elderly female patient was admitted for investigation of anaemia associated with collapse and seizures. She had a history of multiple medical problems and had been previously transfused with four units of red cells in 1998. Two units of red cells were crossmatched and transfused. The pre transfusion antibody screen was negative. Seven days post transfusion, the Hb began to fall with an associated rise in bilirubin (10.5 to 30.5µmol/l). The post transfusion antibody screen was positive with a specificity of Anti-c, Anti-E and Anti-Fy^b and the DAT

test was positive for IgG. Anti-c, Anti-E and Anti-Fy^b were identified on the eluate. The patient recovered without complications.

DHTR Case 8

This elderly male patient was admitted following collapse associated with anaemia. He had a history of surgery eight years previously but there was no record of transfusion in this hospital. The pre transfusion antibody screen was negative and six units of blood were crossmatched. Only three of these were compatible and a specimen was sent to the reference laboratory for further investigation. The three compatible units of red cells were prescribed for emergency transfusion and administered uneventfully. Testing of the pre-transfusion sample in the reference laboratory revealed Anti-C and an enzyme only Anti-E. Eight days post transfusion, the Hb began to fall and there was also a rise in serum bilirubin and LDH. Further transfusion was required. A new cross match sample was sent to the reference laboratory for antibody screen and crossmatch. The antibody screen was found to be strongly positive for Anti-C and Anti-E both strongly reacting in IAT. Two compatible antigen negative units were issued to the hospital and one was transfused. The patient recovered from this reaction without complications and required no further transfusions.

DHTR Case 9

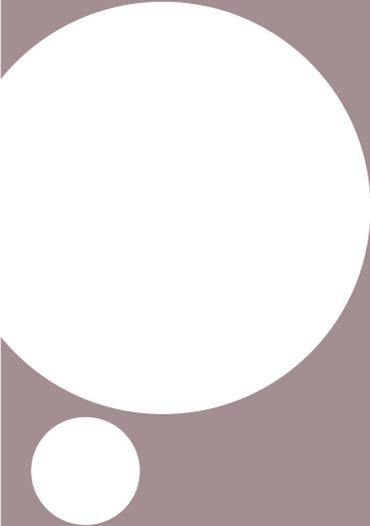
This male patient with a history of hypertension and cardiac disease required four units of red cells for an intraoperative bleed. The patient had a previous transfusion history of two units of autologous and one unit of allogeneic blood for elective surgery seven years ago at a different hospital. The pre transfusion antibody screen was positive with Anti-Fy^b specificity and antigen negative units were selected. These units were transfused uneventfully. However four days post transfusion the patient became jaundiced with falling Hb, a rise in serum bilirubin and a positive DAT. Retesting of the pre transfusion sample was performed with the same result. A new crossmatch specimen was requested

which showed presence of Anti-Jk^a in addition to Anti-Fy^a. No treatment was prescribed, the Hb and serum bilirubin returned to normal within five days and the patient was discharged within the normal postoperative timeframe.

Group 4

DHTR Case 6

This male patient required an emergency transfusion of one unit of blood for a peri-operative bleed. The patient had been previously transfused but the pre-transfusion antibody screen was negative. The patient had a stormy postoperative period as a result of his underlying condition. Eleven days post transfusion it was noted by the laboratory staff that the bilirubin and LDH were raised and the haemoglobin was falling with deteriorating renal function. There was also evidence of DIC which may have been related to the underlying condition rather than the transfusion. A repeat antibody screen was positive with Anti-c and Anti-E specificity. The DAT was also positive for IgG. Anti-c and Anti-E were identified in the eluate. Retrospective testing of the pre transfusion antibody screen was negative. This patient remained extremely unwell post operatively and died as a result of his underlying condition unrelated to transfusion.



Acute Haemolytic and Other Severe Acute Transfusion Reaction

Definition: Acute Transfusion Reactions are defined as those occurring within twenty four hours of transfusion. The major concern in evaluating these reactions is to exclude bacterial contamination of the unit or haemolysis due to incompatible red cells (Heddle & Kelton, 2001).

For the purpose of the NHO report, Acute Haemolytic Transfusion Reactions occurring due to incorrect blood transfused are captured in the 'Incorrect Blood Component Transfused' chapter. Anaphylaxis/Anaphylactoid transfusion reactions are also reported within a separate chapter.

This category accounted for 4% of incidents reported (8 of 180). As these reactions may reflect red cell incompatibility and particularly ABO incompatibility or bacterial infection of the component, both of these possibilities must be excluded. As noted in previous years the direct cause of all these reactions has not been fully established, and in some cases the symptoms were probably related to the patient's underlying condition.

Findings

All eight cases involved the transfusion of red cells. The reactions occurred during transfusion and although in all cases the patients recovered within 24 hours without complications, one case (Case 7) involved a day case patient who required hospitalisation overnight.

- In three cases, the patient had irregular red cell antibodies detected. In two cases (Case 1 and 4) antibodies were detected prior to transfusion and antigen negative blood was selected. In Case 1 no post transfusion serology investigation was undertaken. In the second case (Case 4), red cell incompatibility was ruled out and the reaction was probably due to HLA antibodies. In the third case (Case 3), involving an elderly patient with no apparent previous transfusion history, a weak anti-K^a was detected in the post transfusion sample which had not been detected in the pre-transfusion sample. This was the likely cause of the reaction.
- Although all the reactions involved the development of a fever or rigors, in only five cases (Cases 1, 4, 6, 7 and 8) where both the

patient and the unit were cultured and bacterial contamination definitely excluded as the cause of the symptoms. In one case (Case 5), the reaction on investigation was found to be due to infection in the patient's Hickman line.

- Six of the cases (Cases 1-3 and 5-7) involved transfusions in patients with underlying malignancies. In some of these cases, where no other cause was discovered, the symptoms may have been due to the underlying disease rather than the transfusion.
- One case (Case 8) had been initially reported as a TACO in an elderly patient with underlying cardio-respiratory and chronic renal disease. While there may have been an element of overload, it was decided to capture the reaction within the AHOSTR category on the basis of other symptoms. Red cell incompatibility and bacterial infection were ruled out.

Recommendations:

- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly and the patient observed closely for the first 15 minutes/50mls as severe reactions are most likely to occur within this time (BCSH, 1999).
 - Each hospital must have a policy in place for the management of an acute transfusion reaction. This should include the medical and nursing management of the patient's symptoms and the investigations necessary to complete the transfusion reaction analysis. Following a severe transfusion reaction, the transfusion should be discontinued completely and no further units from this crossmatch should be transfused until an ABO incompatible transfusion has been excluded and the blood has been re-crossmatched.
 - Investigations should include:
 - Re-confirming the identification of the patient and the unit
 - Re-confirming the ABO and Rh D group of the patient and the unit
- Blood samples for:**
- Repeat group, antibody screen and crossmatch to exclude an ABO or red cell incompatible transfusion including a clotted sample for antibody identification using serum
 - full blood count (FBC)
 - direct antiglobulin test (DAT)
 - coagulation screen
 - biochemistry analysis to include serum bilirubin and LDH (NBUG, 2003)
- If at all possible, further transfusions should be delayed until completion of the transfusion reaction work-up.
 - In the event of fever, both the patient and the transfused unit(s) should be cultured to exclude bacterial contamination of the unit
 - Specimens e.g. urine, sputum necessary to exclude other possible sources of infection should also be cultured.
 - A protocol for culturing of the blood component is available by writing to the QA/QC Department of the IBTS. This protocol outlines the procedure to be followed when culturing a unit implicated in a febrile transfusion reaction.
 - Where an antibody is detected in the post transfusion sample taken within 24 hours of the transfusion which was not detected in the pretransfusion sample, the pretransfusion sample should be tested by a different technique and/or referred to a reference laboratory for investigation. It is likely that the antibody was present pretransfusion but was not detected.
 - Since the introduction of leucodepleted products, transfusion reactions associated with HLA antibodies in the patient have become less common. However rarely severe reactions to transfusion may be caused by HLA antibodies despite leucodepletion of the product and particularly in the case of repeated reactions, HLA antibody investigations should be undertaken.

TABLE 24 ACUTE HAEMOLYTIC OR OTHER SEVERE TRANSFUSION REACTION (N=8)

Case No	Component Prescribed	Age years Gender	Underlying condition	Volume transfused/onset	Symptoms/Signs	Investigations	Treatment & Outcome
AHOSTR Case 1 * *p	One unit of antigen negative red cells.	14 F	Haematological malignancy Anti-E prior to transfusion.	< 200mls	Fever rise > 1.5°C, chills/rigors and hypotension.	Patient and unit cultured—no growth. Red cell incompatibility not excluded.	Transfusion discontinued completely and paracetamol given with effect. Recovered with no ill effects.
AHOSTR Case 2	Two units of red cells.	45 M	Haematological malignancy.	During transfusion of the second unit.	Fever rise > 1.5°C hypotension.	Neither patient nor unit cultured. Red cell incompatibility excluded.	Transfusion completed. Paracetamol and frusemide administered. No further complications as a result of this transfusion. Patient died of underlying condition.
AHOSTR Case 3 *	One unit red cells.	70 M	Ischaemic Heart Disease and malignancy.	>100mls	Fever, chills, rigors restlessness, anxiety, feeling of impending doom and chest pain.	Raised bilirubin, positive DAT, weak anti K detected post transfusion.	Transfusion discontinued, paracetamol administered. Recovered with no ill effects.
AHOSTR Case 4 *	Three units of antigen negative red cells.	65 F	GIT disease Anti-E and anti-Le ^a .	Symptoms developed during third unit.	Fever rise >1.5°C, chills, rigors, dyspnoea and back pain.	Both patient and unit cultured – no growth. DAT positive post transfusion -no red cell incompatibility detected.	Transfusion discontinued. O ₂ , paracetamol and salbutamol nebuliser given. Recovered with no ill effects.
AHOSTR Case 5	One unit of red cells.	27 M	Haematological malignancy.	> 100mls	Fever, chills, anxiety, hypertension.	Unit cultured- no growth. Gram negative bacilli isolated from Hickman line Red cell incompatibility excluded.	Hydrocortisone and chlorpheniramine. Recovered with no ill effects.

* Included as full case history

*p Included as full case history in Paediatric Chapter

TABLE 24 (CONTINUED) ACUTE HAEMOLYTIC OR OTHER SEVERE TRANSFUSION REACTION (N=8)

Case No	Component Prescribed	Age years Gender	Underlying condition	Volume transfused/onset	Symptoms/Signs	Investigations	Treatment & Outcome
AHOSTR Case 6	One unit of Red cells	83 F	Haematological malignancy.	50-99mls	Fever rise > 1.5°C, chills/rigors, nausea and vomiting.	Patient and unit cultured - no growth. Red cell incompatibility excluded.	Chlorpheniramine IV hydrocortisone 100mg IV Cyclizine 50mg IV Patient recovered with no ill effects.
AHOSTR Case 7	Two units of red cells	49 M	Suspected malignancy.	>100mls.	Chills/rigors	Patient and unit cultured -no growth. Red cell incompatibility excluded.	Transfusion discontinued and no treatment given. Day case patient needed overnight admission.
AHOSTR Case 8*	Group Rh D Red cells	84	Chronic cardio respiratory disease and chronic renal failure.	90mls	Dyspnoea, hypertension, falling O ₂ sats, pyrexia, rigors and became agitated.	Patient, unit and peripheral line cultures negative. Red cell incompatibility excluded.	Frusemide and IV hydrocortisone administered. Recovered with no ill effects.

* Included as full case history

*p Included as full case history in Paediatric Chapter

Acute Haemolytic or Other Severe Transfusion Reactions (n=8)

We describe four cases in detail

AHOSTR Case 1

This young patient with a malignant haematological disorder required one unit of red cells for anaemia Hb 7g/dl. The patient grouped as O Rh D positive with an Anti E antibody and an autoantibody reactive in enzyme only. The DAT was negative. Antigen negative blood was crossmatched and issued. When less than 200mls had been transfused, the patient developed fever with chills/rigors and hypotension. The transfusion was discontinued completely and paracetamol was given. A full recovery was made within approximately 1-2 hours. The patient was cultured and no organisms were isolated but no repeat serology was done post transfusion reaction as per hospital policy. As a result of this failure to complete reaction investigations, the management of adverse transfusion reactions has been highlighted at existing educational sessions and laboratory policy on the investigations of adverse reactions to transfusion is being reviewed.

AHOSTR Case 3

This elderly male patient with a history of ischaemic heart disease and malignancy required a transfusion of one unit of red cells for anaemia Hb 8.3g/dl. This patient gave no previous history of transfusion and the pre transfusion antibody screen was negative. Following transfusion of 100mls, the patient developed symptoms of fever, chills, rigors, restlessness, anxiety, chest pain and feeling of impending doom. The transfusion was immediately discontinued and paracetamol given. The patient recovered uneventfully from the symptoms within 24 hours and required no further transfusion. Post transfusion investigations showed a weakly positive DAT, a positive antibody screen and a raised bilirubin.

AHOSTR Case 4

This patient with anaemia secondary to GIT disease Hb 7.2 g/d required transfusion of three units of red cells. The patient's serum contained Anti-E and Anti-Le^a. Three units of antigen negative red cells were issued. During the third unit, when 140mls had transfused, symptoms of fever (38.9°C) chills, rigors, back pain and dyspnoea developed. The transfusion

was discontinued and O₂, paracetamol and salbutamol by nebuliser were given. The patient recovered within one hour. Bacteriological culture of the patient and the third unit isolated no organisms. There was no evidence of red cell incompatibility on retesting of the pre and post transfusion samples although the DAT result on the post transfusion clotted sample was positive (IgG). The serum bilirubin was not measured. There was no increase in Hb after transfusion of two and a half units of red cells but this was probably due to active bleeding. Strong HLA antibodies were subsequently detected which may have been responsible for the symptoms, which subsided quickly. This patient was subsequently managed by intravenous iron infusions instead of transfusion.

AHOSTR Case 8

This elderly male patient with underlying cardio-respiratory disease, chronic anaemia, and chronic renal failure required a transfusion of one unit of red cells for a symptomatic anaemia Hb 10g/dl. The patient had been transfused with five units of red cells over the previous week uneventfully. The patient received his regular diuretic medication that morning but did not receive a premedication of a diuretic prior to the transfusion. The unit was prescribed over 4 hours. The patient's intake and output were not being recorded. Two hours into the transfusion, having received 90mls, the patient developed symptoms of dyspnoea, hypertension, falling O₂ saturations, pyrexia (39.2°C) rigors and agitation. The transfusion was discontinued and hydrocortisone and frusemide IV were administered. There is no record of the response to the diuretic but the patient's symptoms resolved within three hours. The patient suffered no complications as a result of this incident and has received further transfusions successfully. Investigations of the reaction excluded ABO incompatibility and the post transfusion antibody screen was negative. Cultures of the patient, peripheral line and unit were negative. This reaction may have been complicated by transfusion overload but in view of the high fever and rigors it was decided to include the reaction in the AHOSTR category.

Transfusion Related Acute Lung Injury

Definition: Transfusion Related Acute Lung Injury (TRALI) is a clinical combination of acute respiratory distress, hypotension, fever and rigors associated with bilateral pulmonary oedema with no evidence of cardiac failure or fluid overload. Symptoms typically begin within 1-2 hours of transfusion and always within 6 hours (Popovsky, 2001)

Introduction

This category accounted for 1% (1 out of 180) incidents reported during this period. Two reports were submitted and on analysis one fatal case was considered to be definitely attributable to TRALI. In a second case reported, the diagnosis of TRALI was considered extremely unlikely and this case was re-categorised as a TACO incident.

It is very difficult to distinguish TRALI from other causes of acute lung injury which also cause dyspnoea, hypoxia and chest x-ray white out by interstitial and alveolar infiltrates. Patients may also present with hypo/hypertension. Symptoms generally begin within six hours of transfusion and in the vast majority the patient outcome is good. However, as systems are put in place to tackle fatal outcomes from other adverse events, TRALI is slowly coming to increased prominence. In 2003 the most common

cause of transfusion related fatalities reported to the FDA in the USA was TRALI.

The true incidence is unknown and may range from 1:5000 to 1:100,000 units of plasma containing blood components transfused. Under reporting and the lack of prospective data complicate the issue further. However, it is important to recognise that TACO is much more common than TRALI and where there is evidence of fluid overload or cardiac failure, the diagnosis is very unlikely to be TRALI (NHO, 2002).

The presence of white cell antibodies (including HLA class I and II antibodies, granulocyte-specific antibodies and anti-monocyte antibodies) has been reported to be associated in about 80% of cases and correspondence between the donor antibody and patient antigen is found in up to 50% of these. There are, however, a number of cases where no antibody is found. It has been proposed that non-immunologic mechanisms may play a part in causing TRALI whereby two insults to the lung are necessary, the first one being a predisposing event such as trauma or sepsis and the second transfusion of a biologically active substance such as lipids found in stored cellular blood products.

It is important that the condition is recognised promptly. Timely intervention with O₂ or mechanical

ventilation if necessary and other support measures are fundamental to a successful outcome.

Findings

- There were two cases reported to the NHO throughout this period. One involved the transfusion of an apheresis platelet concentrate and one involved transfusion of a 16-day-old red cell concentrate.
- In Case 1, as was pointed out in the case history, it was not possible to perform HLA typing of the patient nor was cross-match carried out between the patient's cells and the donor's serum. However, based on the close temporal association of symptom onset with the transfusion, the clinical picture and the post-mortem features, it was felt that this fatality was very likely to be due to TRALI. The donor was found to have Class 1 HLA IgG antibodies and has been permanently deferred.
- The second case was notified as a TRALI on account of the temporal association of symptom onset with the transfusion and because the symptoms resolved rapidly on commencing O₂ treatment. On review of the case however, there was evidence of fluid overload, the JVP was found to be mildly raised and the patient also had bilateral lower limb oedema. A diagnosis of TRALI has therefore been considered highly unlikely. This case has been transferred to the TACO chapter as TACO Case 13.

Recommendations

- Whilst in both cases blood components were transfused for appropriate reasons, it is important to underline the need for vigilance in the appropriate use of blood, as transfusion related adverse reactions can be associated with fatalities.
- It is important that hospital staff be made more aware of this complication of transfusion in order for it to be recognised and dealt with in an appropriate fashion. This would also facilitate prompt investigation and case review. The NHO

information leaflet on differential diagnosis of TRALI is included in Appendix 4

- The IBTS has put in place a number of measures with a view to minimising the risk from TRALI namely avoiding the use of plasma from female donors both for suspension of pooled platelets and as FFP and in early 2004 to defer new and lapsed female plateletpheresis donors with a history of pregnancy. As part of the vCJD Policy, SD Plasma has become the standard plasma product. To date, SD treated plasma has not been convincingly implicated in TRALI.

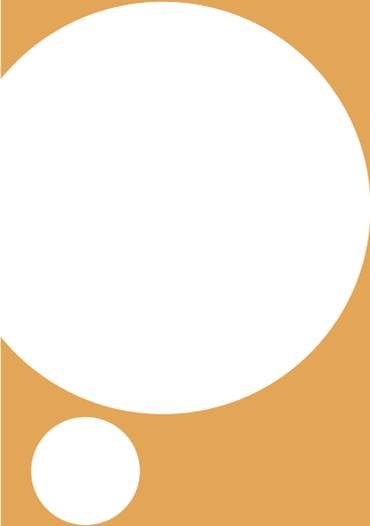
Transfusion Related Acute Lung Injury (TRALI) (n=1)

TRALI Case 1

An elderly male patient who was newly diagnosed with a malignant haematological disorder was admitted for his first dose of chemotherapy. He had no previous history of cardiovascular disease; a physical examination showed no evidence of lower limb oedema or raised JVP and his lung fields were normal. The ECG showed normal sinus rhythm. One hour after receiving his chemotherapy, (Daunorubicin and Vincristine) he was transfused with one unit of platelets. 15 minutes after the transfusion he developed acute shortness of breath, vomiting, frothing, dizziness and clamminess. He became cyanotic, hypotensive (60/48mmHg) tachycardic, and tachypnoeic with O₂ saturation on room air 74%. He suffered a cardiac arrest and resuscitation was attempted but was unsuccessful. The autopsy showed a normal heart with no evidence of fibrosis or recent ischaemia. It also showed severe pulmonary oedema bilaterally. Petechial haemorrhages were present on the surface of the lungs and there was no evidence of pulmonary embolism. There was focal infiltration of the lungs by the malignant haematological cells. Blood samples from the donor of the implicated apheresis platelet concentrate showed the presence of HLA Class 1 IgG antibodies and on this basis the donor has been permanently deferred. It was not possible to perform HLA typing on the patient nor was it possible to perform cross-match between the patient's white cells and the donor's.

TABLE 25 TRANSFUSION RELATED ACUTE LUNG INJURY (TRALI) (N= 1)

Case Number	Age years Gender	Component and number of units transfused	Reason for transfusion	Symptoms	Patient Investigations	Treatment	Donor Investigations	Comments
TRALI Case 1	77 M	One unit of apheresis platelet concentrate	Thrombocytopenia secondary to malignant haematological disorder.	Profound hypotension, dyspnoea, cyanosis and falling O ₂ saturation.	O ₂ saturation 74%. No chest x-ray performed. Electrocardiograph normal sinus rhythm.	100% nasal O ₂ and intravenous adrenaline.	One donor involved HLA class 1 antibody detected.	Patient died two hours following the completion of transfusion.



Suspected Transfusion Transmitted Infection

This category accounted for 2% of incidents reported (4 of 180) in 2003. The NHO collects and investigates reports of all suspected transfusion-transmitted viral infections relating to blood components which have been transfused after the introduction of mandatory testing for that virus. Viral infections which are not covered by mandatory testing, e.g. Hepatitis A virus, CMV and Parvovirus, but are reported to the NHO and suspected to be associated with a blood transfusion during the current reporting year will be recorded as an NHO incident and investigated appropriately. The NHO also collects and investigates reports of transfusion-transmitted bacterial and parasitic infections.

The onset of symptoms related to a transfusion-transmitted viral infection may occur several weeks to years after the date of transfusion. Bacterial or parasitic infections are usually associated with acute symptoms and come to clinical attention soon after transfusion. Viral diseases however, may not be associated with any symptoms until some years later. Therefore, reports received within this category are

not necessarily the result of components transfused during this reporting year.

Infections presenting weeks, months or years after a transfusion are termed post-transfusion infections. These may indeed be due to the transfusion of an infected or contaminated unit, but equally, infection may have been acquired from another source. Investigation of markers of infection in an implicated donation, or in subsequent samples from the donors of implicated donations, can confirm transfusion as the probable cause of infection, or identify the need to investigate other possible sources (SHOT, 1999). Such investigations may involve microbiological testing of many donors and may take many months to complete.

A post transfusion infection is confirmed as transfusion-transmitted once investigations are complete and the following criteria are fulfilled: (SHOT, 1999)

- The recipient had evidence of infection following the transfusion, with no evidence of infection prior to the transfusion

and, either

- A donor who had evidence of the same transmissible infection donated at least one component received by the infected recipient

or

- At least one component received by the infected recipient was shown to have been contaminated with the same infectious agent .

Much concern has been voiced in recent years regarding the risk of transfusion-transmitted infection and much quality assurance effort has been directed towards appropriate testing and handling of blood after collection. There is very good evidence that with continuous improvements in the donor selection/testing procedures and manufacturing processes used in Ireland, the risk of transfusion-transmitted infection is very small. The current estimated risk for HIV and HCV is less than 1:4,000,000 components transfused, (O’Riordan, 1999). These residual risk estimates are based on serological testing and nucleic acid amplification testing (NAT) for HCV and HIV.

Even prior to the introduction of NAT testing the risk for Hepatitis C for screened blood was 1:500,000 which is estimated to be less than the risk of infection from nosocomial sources. (Ross *et al*, 2000, Gerberding *et al*, 2003).

The risk for HBV has been estimated at approximately 1:200,000 since the introduction of testing for antibody to Hepatitis B core in January 2002 (O’Riordan 2002 personal communication). Hepatitis B infection is not uncommon in the community and in up to 40% of cases no risk such as sexual exposure, intravenous drug abuse or transfusion is present. Evidence of past cleared

infection in blood donors, a highly selected population was found in 0.17% i.e. 17 in 10,000 donors in the first year of testing. In many of these cases, nosocomial risks in the past may be responsible. Such cleared infection does not pose a risk to recipients and in a number of countries, such individuals are acceptable as donors. In Ireland, we introduced core antibody testing in 2002 to reduce the possible risk of donors donating before HBV infection was fully cleared i.e. in the second window period when HbsAg is no longer detectable in blood but before an adequate (>100miu/l) antiHbs antibody is found. Because hepatitis B core antibodies are a mandatory test, donors with cleared infection found reactive for the marker are also deferred.

Investigations into suspected transfusion transmitted infections are difficult. They can involve considerable upset to donors who often have to be recalled and offered testing and they are resource intensive. Where pre-transfusion samples are available, these samples can provide significant help in investigation. Patients such as haematology patients who will require ongoing transfusion should be offered testing before therapy and at regular intervals with storage of samples wherever possible for further testing if necessary.

The risk of receiving an incorrect blood component is in fact much greater than the risk of receiving a transfusion-transmitted infection. Over the seven year period since the United Kingdom Serious Hazards of Transfusion (SHOT) began reporting, confirmed reports of TTI accounted for 2.2% of incidents in comparison to reports in the IBCT category, which accounted for almost 63.9% (SHOT, 2003)

One case (Case 1–2002) of Hepatitis B remains outstanding from NHO Annual Report 2002 where it has not been yet been possible to undertake viral sequence investigations.

Findings

- Four incidents, which fit the criteria of suspected transfusion-transmitted infection, were reported to the NHO during this reporting year.
- There were two reports of suspected HBV infection, one of HCV and one of HIV.
- In all cases, transfusion was excluded as the likely cause.

We report the details on the four suspected cases.

TTI Case 1

This patient was found to have chronic HBV infection in May 2003 having had a number of transfusions between March 2002 and May 2003 all of which screened negative for Hepatitis B surface antigen and anti Hepatitis B core antibody. The patient had not been previously tested for hepatitis B but a stored sample from December 2002 was tested and showed similar findings. Investigation of the nine donors whose units had been transfused between March and December 2002 were investigated. Eight of the donors had returned or were recalled and tested negative for HBV markers of infection. The final donor could not be contacted but the archive sample of the implicated donation was tested for hepatitis B DNA and anti-Hb core antibody and was found to be negative. It is therefore very unlikely that transfusion was the cause of the patient's chronic hepatitis B

TTI Case 2

This patient, a EU non-national, had had transfusion in their country of origin prior to coming to Ireland. The patient had three units of blood in Ireland between July 2002 and April 2003. She was found to be HIV positive in July 2003 not having been previously tested. The three donors were investigated and found to HIV negative on repeat testing, and have been excluded as the cause of the patients HIV.

TTI Case 3

This patient who had four units of blood in 1994 was tested and found to have evidence of hepatitis C in 2003. She had not been previously been tested. The four donors have retested and had been found to be negative.

TTI Case 4

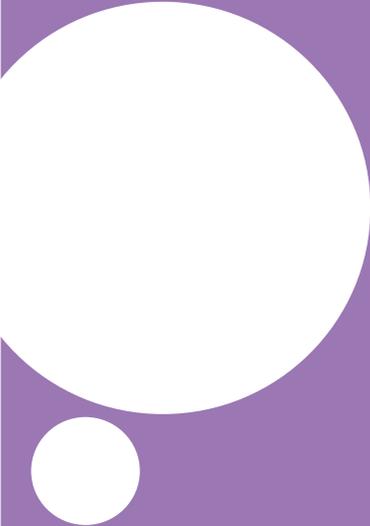
This patient with a haematological malignancy received a total of 41 blood components between May 2001 and October 2001. He was found to have evidence of chronic Hepatitis B in October 2003. A sample for Hepatitis B surface antigen was negative in June 2001 before therapy but full hepatitis B markers had been not been done and the sample was no longer available for retesting.

All but one donor has either returned to donate or been recalled. One donor was found on recall to have evidence of past cleared hepatitis B infection (core antibody positive and surface antibody level > 1000 miu/L). Testing of an archive of a donation in 1999 prior to the implicated transfusion showed core antibody and the same high surface antibody levels of > 1000miu/l indicating that the infection had been cleared prior to the implicated transfusion in 2001. It is therefore very unlikely that this donor was the cause of the patient's Hepatitis B infection. The final donor who did not return was tested on an archive for HBV DNA and anti Hepatitis B core antibody and found to be negative. It is therefore very unlikely that transfusion was the cause.

TABLE 26 SUSPECTED TRANSFUSION TRANSMITTED INFECTION (TTI) (N=4)

Case Number	Gender	Year of Transfusion	Adult or Child	Viral Market	No. of donors	Outcome
TTI Case 1 *	F	2002	Adult	Suspected HBV	9	Transfusion excluded as the source of the infection.
TTI Case 2 *	F	2001-2003	Child	Suspected HIV	3	Transfusion excluded as the source of the infection.
TTI Case 3 *	F	1994	Adult	Suspected HCV	4	Transfusion excluded as the source of the infection.
TTI Case 4 *	M	2001/2002	Adult	Suspected HBV	41	Transfusion excluded as the source of the infection.

* Included as full case history



Pre-Deposit Autologous Donor Incidents

Definition: An adverse or unforeseen event which is experienced by the donor during or following a pre-deposit autologous donation procedure. (SHOT, 2001)

Adverse incidents or reactions during the donation procedure are collected in this section. Incidents occurring during the transfusion of autologous blood are captured elsewhere in this report under the relevant category.

These adverse reactions account for 3% of the total incidents reported (6 out of 180).

Autologous blood transfusion is an option for suitable patients where transfusion is anticipated during surgery (BCSH, 1993). Pre-deposit autologous donation (PAD) involves the collection and storage of up to five units of autologous blood during the pre-operative period. The technique increased in popularity during the 1980s as a result of public concern regarding transfusion safety.

One popular area of application for PAD has been in the field of elective orthopedic surgery. Ten years ago, the average estimated blood loss for total hip replacement (THR) averaged between 900 and 1800mls. Today the average blood loss has been reduced to 500ml (Billotte *et al*, 2002). Thus advancements in anaesthesia and surgical technique, in addition to appropriate pre-operative assessment and reduced transfusion thresholds, have reduced the need for transfusion in such patients. Billote *et al* (2002) showed that pre-operative autologous donation increased the likelihood of transfusion at the time of surgery or led to wastage.

Most donors tolerate the donation procedure without incident, but adverse reactions occur occasionally (Brecher *et al*, 2002). The most common reaction is vasovagal in nature. (Yomtovian and Praprotnik, 2001). However, severe reactions are up to 12 times more likely in autologous donors than in allogenic donors. (Popovsky *et al*, 1995). The benefits to the patient of autologous transfusion include elimination of the risk of transmission of infectious diseases, alloimmunization

and other adverse immunological effects of allogeneic transfusion (Politis and Richardson, 2001). However Linden and Kruskall (1997) point out that while autologous blood is considered safer than allogeneic blood, it is not without risk. Bacterial contamination, febrile non-haemolytic reactions and allergic reactions have all been reported following autologous transfusion. (Goldman *et al*, 2002).

The use of PAD blood has declined with the increasing safety of blood transfusion for the main transfusion transmitted viruses HIV, Hepatitis B & C. However other transfusion transmitted infection agents are emerging including West Nile Virus and vCJD. Although for a long time considered a theoretical risk, a case of vCJD in a transfusion recipient was reported in the UK in late 2003 (Llewelyn *et al*. 2004). The patient had received a transfusion from a donor who subsequently developed vCJD. Although this patient could also have acquired vCJD from dietary exposure, the findings strongly suggest that vCJD is transmissible by blood. The reported finding of abnormal prions at post mortem in the spleen of a second recipient who died of unrelated causes but who had received a unit of blood from a donor who developed vCJD supports the likely transmission of vCJD through transfusion (Peden *et al*, 2004).

These cases may lead to the re-evaluation of the need to provide autologous transfusion. However the disadvantages associated with PAD such as the necessity for a definite date for surgery, increased likelihood of receiving a transfusion, additional cost and the fact that it is still open to the risk of error, volume overload and bacterial contamination suggests that other forms of autologous transfusion in particular intraoperative cell salvage may be more useful. Increased usage of such systems can help reduce the requirement for allogeneic transfusion. (BCSH, 1993). Guidelines for perioperative haemodilution and cell salvage have been issued by the BCSH in 1997.

Regulatory aspects

Hospitals that collect pre-deposit autologous blood will now be considered blood establishments¹ and as such subject to the same scrutiny as a blood transfusion service under Article 29 of the new European Directive 2002/98/EC due to come into effect on 8th February 2005.

More detailed requirements covering autologous donations are listed in Commission Directive 2004/33/EC which addresses technical requirements for blood donors including autologous donors. It covers information to be given to donors, and storage, transport and distribution requirements.

In particular Article 7.2 states that autologous donations must be clearly identified and kept separate from allogeneic donations.

The information, which must be given to autologous donors, is covered in Annex II. These Directives can be downloaded from <http://europa.eu.int>.

Findings:

- Four of the six incidents involved PAD for orthopaedic surgery, two of which were total hip replacement revisions. The remaining two incidents were associated with PAD prior to plastic surgery.
- Symptoms reported were vasovagal in nature and ranged from feeling sleepy, light headed, or nauseous, to actually fainting. Onset of symptoms varied from during donation to up to five hours post donation.
- All of the donations took place in an outpatient setting. All but one of the incidents occurred to donors donating for the first time. The remaining donor had donated a unit previously without incident.

¹ Blood establishment has been defined: "Any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose and their processing, storage and distribution when intended for transfusion.

- The donors involved in these incidents had no underlying medical conditions that would contraindicate PAD. All were female and four were below the age of 40. All weighed over 50kg. The predonation Hb level was over 12g/dl in all cases
- Simultaneous volume replacement did not take place during any of the donations. However in two cases, IV fluids were transfused to two donors who experienced symptoms during or shortly after donation while still in the clinic.
- All donors recovered without complications or hospitalisation but none went on to donate again.
- After the adverse reaction had resolved in two cases, the donors admitted to having a fear of "needles".
- The blood collected was transfused in only two out of the six cases. In one case (Case 3) where the adverse reaction occurred on the second donation, neither unit was transfused. In another case, the unit was not transfused as the planned surgery was cancelled.
- It is important PAD is only used for procedures where blood transfusion is likely to be needed. Hospitals should have up to date Maximum Surgical Blood Ordering Schedules (MSBOS) to identify procedures likely to require transfusion and the decision to take an autologous unit should be based on this. Donors should not be exposed to the risks of donation if the blood is unlikely to be required.
- Patients in a PAD programme, particularly those patients who donate more than one unit, may be more likely to require transfusion intra- or post-operatively. This increased likelihood brings with it increased risks, as autologous transfusion holds the same risks as allogeneic transfusion in terms of errors at the time of administration. (Goldman *et al*, 2002).

Recommendations

- PAD clinics must have in place procedures to deal with donor reactions. All serious reactions should be documented and reported to the NHO.
- Particular attention at pre-donation assessment should be paid to first time donors, as these are more likely to have reactions. Popovsky *et al* (1995) also identified an increased risk of adverse reactions in low weight female donors. At pre-donation assessment, attention should also be paid to psychological factors such as fear of needles which may predispose the donor to an adverse reaction.

TABLE 27 PRE-DEPOSIT AUTOLOGOUS DONATION (N=6)

Case Number	Age years Gender	Weight Kgs	Hb g/dl	Procedure	Current medication	No. donations planned	Reaction/ donation history	Complication	Comments	PAD unit transfused
PAD Case 1 *	39 F	70	14.3	Breast reduction.	None	1	On 1st	Bradycardia, hypotension, temporary loss of consciousness at end of donation.	Past history of fainting. Recovered with no complications.	No
PAD Case 2 *	17 F	59	13.8	Periacetabular osteotomy.	None	1	On 1st	Nausea, light-headedness immediately post donation.	Past history of fainting witnessing injection, needle phobia. Recovered with no complications.	No
PAD Case 3 *	52 F	>50	14.1	Revision THR.	Oral analgesia	2	On 2nd, 1st uneventful	Nausea light-headedness, fainting five hrs post donation.	Fault occurred on a hot crowded train. Recovered with no complications.	No
PAD Case 4 *	34 F	>50	13.6	Revision THR.	Oral iron	2	On 1st	Hypotension, fatigue, 20mins post donation.	500mls IV Fluids administered. Recovered with no complications.	No (surgery cancelled)
PAD Case 5 *	17 F	>50	12.2	Second stage spinal fusion.	Oral iron	3	On 1st	Delayed fainting 2 hrs. 45 mins post donation.	Recovered with no complications.	Yes
PAD Case 6 *	62 F	60	13.2	Breast Reconstruction.	Oral iron	2	On 1st	Pallor, light-headedness, nausea, four mins into donation.	1L IV fluids administered. Recovered with no complications.	Yes (partial unit)

* Included as full case history

*p Included as full case history in Paediatric Chapter

Pre-Deposit Autologous Donation Incident (PAD) (n=6)

PAD Case 1

This female patient was pre-donating one unit of blood for elective plastic surgery. She was not on any medication and had never donated blood previously. Between 400-450mls of blood were collected. Towards the end of the donation, she developed symptoms of bradycardia, hypotension and experienced a temporary loss of consciousness. Following medical review and a rest period of 50 minutes, she was discharged. Further questioning revealed that she was frightened of needles and prone to fainting. Although this was covered by the pre assessment questionnaire, she did not alert the nurse to this fact until the procedure had begun. No further attempt at pre-deposit donation was made. The autologous unit was suitable for transfusion, however, the patient's haemoglobin postoperatively did not warrant blood. The estimated blood loss for this procedure is between 500-700mls.

PAD Case 2

This young female patient was pre-donating one unit of blood for elective orthopaedic surgery. She was not on any medication and had no record of previous donations. The amount collected was 537mls. Immediately following donation, she developed symptoms of nausea and light-headedness. Following medical review and a rest period of 30 minutes, she was discharged. Further questioning revealed that she was "frightened of needles" and had fainted while witnessing an injection previously. She had been asked about this, but the nurse undertaking the procedure was not alerted to this until after the event. No further attempt at pre-deposit donation was made. The autologous unit was suitable for transfusion, but was not required.

PAD Case 3

This female patient attended a pre-donation clinic to pre deposit her second unit of blood prior to elective surgery. She was on oral analgesia twice daily. Although she had a past history of bronchitis, she was fit at the time of donation. Five hundred and forty one mls of blood were collected. She left the donation suite following a rest period of 30 minutes. She subsequently had a long train journey during very

warm weather and the train was very crowded. Approximately five and a half hours following donation, she became light-headed, nauseated and fainted despite taking frequent fluid as recommended. Both donated units were suitable for transfusion but neither was required at the time of surgery.

PAD Case 4

This female patient was scheduled to pre-donate two autologous units of blood for elective surgery. The amount of blood collected was 543mls. Twenty minutes following donation, she became hypotensive and complained of fatigue. Following medical assessment, 500mls of normal saline was administered. After this, she recovered and was discharged. She did not donate again. Although the unit was suitable for donation, it was not used as the planned surgery was cancelled.

PAD Case 5

This young female patient was scheduled to pre-donate three units of blood prior to elective surgery. The first donation took place uneventfully and 450mls of whole blood were collected. She rested for 30 minutes following donation and left the hospital. Two hours and forty-five minutes later, she fainted. It was an extremely hot day and she had not taken any fluids since she left the clinic. The symptoms resolved following oral fluids and a further rest period of twenty minutes. No further attempts were made at donation. The patient received one unit of autologous blood immediately post operatively and did not require allogeneic transfusion. The haemoglobin prior to discharge was 10.4g/dl.

PAD Case 6

This elderly female patient was scheduled to pre-donate two units of blood prior to elective surgery. She had no significant previous medical history. Four minutes into the donation when 355mls had been collected, she felt faint with symptoms of light-headedness, nausea and appeared pale. The donation procedure was discontinued at this point. She received one litre of IV fluids and recovered with no ill effects after a rest period of one hour at the donation clinic. The second pre-donation episode was cancelled. Post operatively the patient's Hb was 7.5gm/dl and she received the pre-donated unit. No allogeneic units were required. Prior to discharge home her Hb was 9.8gm/dl.

Paediatric Incidents

Paediatric patients form an important sub-group of transfusion patients. We have therefore summarised the findings of the 26 paediatric cases in Tables 28-32. We have collected all the individual case histories in the AA and AHOSTR categories in this section and the IBCT incidents of particular relevance to paediatric rather than general hospital practice. The remaining incidents are described in their respective chapters. For the purpose of this year's report, we have raised the age to which the definition of paediatric refers to from 15 to 18 years.

Findings

IBCT

There were 13 incidents reported in the IBCT category. The types of errors were similar to those found in the adult patients involving all parts of the transfusion chain.

There were five level 1 cases (Cases 13, 23, 27, 37 and 52).

- Four of these cases (Cases 13, 27, 37 and 52) involved failure to prescribe or issue the correct product.

- In two cases of these cases, Uniplas* was issued instead of group specific SD plasma (Case 13 and 27).
- In one case, the crossmatched label was put on the wrong pack and blood issued was uncrossmatched (Case 23).
- One case involved collection of blood components where the wrong component was collected from the satellite fridge (Case 37).
- The final case involved the wrong Recombinant Concentrate prescribed (Case 52).

There were seven level 2 incidents (Cases 1, 8, 44, 65, 35, 89 and 110).

- Three cases involved failure to prescribe CMV negative and/or irradiated product (Cases 1, 8 and 44). In two of these, (Cases 1 and 8) patients had congenital immunodeficiencies and should have received irradiated products.
- Two cases involved problems with medical devices involving an infusion pump in one case (Case 65)

and a syringe used without a filter in the second. (Case 35)

- In one case, a unit was left out of storage for over one hour before being returned to the fridge and then removed and transfused (Case 89).
- One case (Case 110) involved an inappropriately large dose of platelets.
- The one level 3 incident (Case 61) involved units transferred between hospitals.
- None of the incidents were associated with complications.

Reactions

- The most common reaction reported was in the A/A category with nine cases.
- Seven of these involved platelet concentrates and two involved red cells.
- In one case (case 13), the patient who had been transfused in a day care ward had a reaction at home and required overnight admission.
- Further transfusion was managed by premedication in one case (Case 13) and by premedication and platelet apheresis in a second case (Case 11).
- In one case (Case 17), however, the patient suffered a reaction despite having received premedication cover and platelet apheresis.
- Seven cases required/will require washed components for further transfusions. (Case 1, 12, 14, 15, 16, 17 and 22). All but one (Case 12) had a history of previous reactions.
- There was one AHOSTR where the patient had a red cell antibody pre-transfusion but no post reaction investigation was undertaken. (AHOSTR Case 1).

- Two cases (PAD Cases 2 and 5) involved reactions associated with pre-autologous donations. These cases are described in the PAD chapter.

- One case (TTI case 4) was an investigation for Suspected Transfusion Transmitted Infection which was excluded. This case is described in the TTI chapter.

Recommendations:

- On call staff not routinely working in the transfusion laboratory must receive on-going training on the correct products to be issued for neonates.
- It is important to ensure that the patient has a patent IV cannula and that all documentation is correct prior to collection of the unit. Should there be a delay in the commencement of the transfusion, it is necessary to return the unit to controlled storage within thirty minutes and inform the laboratory to insure the unit is being returned to the appropriate fridge.
- Medical staff must be aware of guidelines for prescribing irradiated products in paediatric patients.
- Alert stickers should be placed on charts where patients have special requirements e.g. irradiated/CMV negative components.
- A/A reactions are distressing for both the patient and the clinical team and washed components may be indicated for serious repeated reactions. However, poorly justified requirements for washed components may cause undue delays when transfusions are needed in the future. In addition, washing of platelets can affect platelet yields with loss of platelet numbers and viability from the washing process and poor *in vivo* incremental rises. Before prescribing washed platelets for patients with a history of transfusion reactions to pooled products, apheresis platelets (which are associated with a lower rate of reactions) with premedication cover should be tried first.

TABLE 28 IBCT PAEDIATRIC INCIDENTS:

Level	Case Number	Age years	Volume of Incorrect Blood Component or Product Transfused	Symptoms & Outcome	Cause of Error
1	IBCT Case 13 *p	2 wks	18mls of Uniplas given.	No complications as a result of this transfusion.	Wrong component issued on call. Medical scientist thought Uniplas was the product of choice for neonates.
1	IBCT Case 27 *p	1 day	Less than 50mls of Uniplas	No complications as a result of this transfusion.	Medical scientist thought Uniplas was the product of choice for neonates.
1	IBCT Case 37 *p	3 days	32mls of red cells	No complications as a result of this transfusion.	Emergency uncrossmatched group O Rh D negative red cells for adult use collected from satellite fridge and transfused instead of group O Rh D negative paedipack for emergency neonatal use.
1	IBCT Case 23 *	9 mths	One unit of red cells	No complications as a result of this transfusion.	Label for crossmatched unit attached in error to an uncrossmatched but group compatible unit. Error identified by laboratory staff when checking stock and noted that a unit which was logged out of the fridge as transfused was in fact still in stock.
2	IBCT Case 1 *p	2 mths	Three units of SAG-M red cells. Seven aliquots of paedipack red cells	No complications as a result of this transfusion.	Failure to request and/or prescribe irradiated cellular components for this patient.
2	IBCT Case 8 *p	7 days	Three units of SAG-M red cells. Two units of platelet concentrate apheresis and five aliquots of paedipack red cells	No complications as a result of this transfusion.	Failure to request and/or prescribe irradiated cellular components for this patient.

* Included in this chapter

*p Included as full case history in appropriate Chapters

TABLE 28 (CONTINUED) IBCT PAEDIATRIC INCIDENTS:

Level	Case Number	Age years	Volume of Incorrect Blood Component or Product	Transfused Symptoms & Outcome	Cause of Error
2	IBCT Case 35 *	1 day	11mls red cells	No complications as a result of this transfusion.	Transfusion given via a syringe without integral 170-260 micron filter in place.
2	IBCT Case 44 *p	1 day	45mls red cells	No complications as a result of this transfusion.	CMV negative red cells not selected although available in laboratory.
2	IBCT Case 65 *p	5 mths	One unit of platelets for neonatal use.	No incremental rise following transfusion. Infant required further transfusion to increase platelet count to acceptable levels.	Platelet transfusion given via an electronic infusion device, contravening hospital policy.
2	IBCT Case 89 *p	6	One unit of CMV negative and irradiated red cells.	No complications as a result of this transfusion.	Unit out of fridge for one hour then returned to fridge for twenty minutes then removed and transfused.
2	IBCT Case 110 *p	4	Two units of CMV negative and irradiated apheresis platelets.	No complications as a result of this transfusion.	300mls of platelets prescribed pre-operatively platelet count $19 \times 10^9/L$ Platelet count post transfusion of 200mls unit was $118 \times 10^9/L$ but patient was transfused with a further unit of platelets. Platelet count $155 \times 10^9/L$.
3	IBCT Case 61 *	17	Two units of red cells.	There were no complications to this transfusion.	Two units transfused came from a different hospital and had accompanied the patient on transfer.
1	IBCT Case 52 *p	16	8000 iu of Refacto	No complications to this incorrect administration of Refacto.	Refacto was prescribed instead of Recombinate for a patient with high responding inhibitors. It was highlighted on the computer system that this patient normally receives Recombinate or Novoseven. Laboratory staff questioned request but were asked to issue the product.

* Included in this chapter

*p Included as full case history in appropriate Chapters

TABLE 29 A/A PAEDIATRIC INCIDENTS:

Case Number	Age years Gender	Component	Reason for Transfusion	Symptoms	Stage Transfusion Reaction developed	Investigations	Treatment	Sequelae/Recommendations For future transfusion
AA Case 1 *p	16 M	One unit of red cells.	Anaemia Hb 8.7g/dl	Urticaria, hypotension, dyspnoea, restlessness, anxiety, periorbital, oedema & wheals on body.	Following the first 50mls.	IgA levels normal. Transfusion incompatibility excluded.	Hydrocortisone and chlorpheniramine.	Recovered fully later that day. There were no complications to this transfusion. Further transfusion will require pre med. of IV chlorpheniramine and washed cellular components.
AA Case 11 *p	17 M	One unit of apheresis platelet concentrate.	Platelet count $10 \times 10^9 / L$	Hypotension, tachycardia, urticaria, chest tightness, coughing and falling O ₂ saturation.	When 85mls of platelets had been transfused.	IgA levels post transfusion low - 0.37g/L (related to immunosuppressant therapy received).	Hydrocortisone and chlorpheniramine.	Patient recovered within ninety minutes without complications. Subsequent transfusions using apheresis platelets and pre-med cover have been uneventful.
AA Case 12 *p	6 M	120mls CMV negative and irradiated apheresis platelet concentrate.	Platelet count $11 \times 10^9 / L$	Itching, hypertension, dyspnoea restlessness wheeze, nausea and abdominal cramps.	Following 120mls. 30 –35 mins. After commencing transfusion.	IgA levels normal.	Pre-med. cover of hydrocortisone & chlorpheniramine given. Transfusion temporarily stopped, salbutamol nebuliser given & remainder of unit then transfused.	Shortness of breath resolved within minutes and rash resolved later that evening. Washed products were recommended for future transfusions and these have been transfused uneventfully.
AA Case 13 *p	10 M	400mls of CMV-negative and irradiated red cells.	Hb 6.9g/dl	Severe urticarial body rash with weeping raised wheals.	Four hours following transfusion when patient was at home.	None	Chlorpheniramine.	Admitted to hospital overnight. Recovered fully within 24hrs. Subsequent transfusions were uneventful following pre-med. cover with chlorpheniramine.

*p Included as full case history in this Chapters

TABLE 29 (CONTINUED) A/A PAEDIATRIC INCIDENTS:

Case Number	Age years Gender	Component	Reason for Transfusion	Symptoms	Stage Transfusion Reaction developed	Investigations	Treatment	Sequelae/Recommendations For future transfusion
AA Case 14. *p	2 M	One unit of CMV negative and irradiated pooled platelet concentrate.	Platelet count 9 X 10 ⁹ /L	Urticaria, stridor, wheeze and severe facial wheals.	Within two hours of starting transfusion.	None	Pre-med. cover of hydrocortisone & chlorpheniramine given. Chlorpheniramine IV and salbutamol nebulisers administered.	Subsequent transfusions with washed platelets have been given uneventfully.
AA Case 15. *p	6 F	One unit of CMV negative and irradiated apheresis platelet concentrate	Platelet count 8 X 10 ⁹ /L	Urticarial rash, raised red wheals and blackened eyes.	When more than 100ms had been transfused.	None	No treatment. Pre-med. cover of hydrocortisone & chlorpheniramine given	Patient recovered fully within 24hrs. Washed platelets required for future transfusions.
AA Case 16 *p	6 M	One unit CMV negative and irradiated apheresis platelet concentrate.	Platelet count 9X10 ⁹ /L	Urticaria, stridor and wheeze.	Ten minutes following completion of transfusion.	Previous IgA levels normal.	Pre-med cover prior to transfusion. Adrenaline and hydrocortisone IV given post reaction.	Recovered fully within minutes of receiving treatment. Washed platelets recommended for future transfusions.
AA Case 17 *p	6 M	One unit pooled platelet concentrate.	Platelet count 12x10 ⁹ /L	Urticaria, dyspnoea, stridor and wheeze.	Immediately following transfusion.	None	Pre-med. cover of hydrocortisone and chlorpheniramine given. O ₂ therapy administered and hydrocortisone 50mgs IV repeated.	Patient recovered within one hour, discharged home two hours later. Patient went on to receive apheresis platelets four months later uneventfully but experienced a severe anaphylactic reaction to apheresis platelets subsequently. Washed components recommended for further transfusions.

*p Included as full case history in this Chapters

TABLE 29 (CONTINUED) A/A PAEDIATRIC INCIDENTS:

Case Number	Age years Gender	Component	Reason for Transfusion	Symptoms	Stage Transfusion Reaction developed	Investigations	Treatment	Sequelae/Recommendations For future transfusion
AA Case 22. *p	14 M	One unit of CMV negative and irradiated pooled platelets.	Known Asthmatic. Platelet count $9 \times 10^9/L$	Fever > 1.5°C, tachycardia, itch, urticarial rash and wheeze.	When 200mls. had been transfused.	Unit cultured - no organism isolated. Patient not cultured. IgA levels not checked.	Should have received pre med. of both chlorpheniramine and hydrocortisone but only received chlorpheniramine. Hydrocortisone IV & salbutamol nebuliser given post reaction	Recovered fully within 12hrs. Washed platelets recommended for future transfusions.

TABLE 30 AHOSTR PAEDIATRIC INCIDENTS

Case Number	Age years Gender	Component Prescribed	Volume Transfused	Symptoms	Investigations	Treatment & Outcome
AHOSTR Case 1 *p	14 F	One unit of antigen negative red cells for anaemia of malignancy. Anti-E prior to transfusion.	Less than 200mls of red cells.	Fever rise of > 1.5°C, chills/rigors and hypotension.	Patient cultured – no growth. Red cell incompatibility excluded.	Transfusion discontinued. Paracetamol given. Recovered with no ill effects.

TABLE 31 TTI PAEDIATRIC INCIDENTS:

Case Number	Gender	Year of Transfusion	Viral Marker	Number of donors	Outcome
TTI Case 2 *	F	2001, 2003	Suspected HIV	3	Transfusion excluded.

*p Included as full case history in this Chapter

* Included as case history in TTI chapter

TABLE 32 PAD PAEDIATRIC INCIDENTS

Case Number	Age years Gender	Weight	Hb Level	Procedure	Current medication	Number of donations planned	History of donations	Complication	Comments
PAD Case 2 *	17 F	59 kgs	13.8g/dl	Periacetabular osteotomy.	None.	1	1st.	Nausea and light headed immediately following donation.	Donor had previous history of fainting witnessing an injection and a fear of needles. Unit not transfused.
PAD Case 5 *	17 F	>50kgs	12.2g/dl.	Second stage spinal fusion.	Oral iron daily	3	1st	Delayed faint 2 hours and 45 mins after leaving the donation session.	There were no complications to this transfusion. Unit transfused

* Included as full case history in PAD chapter

IBCT Paediatric Incidents 2003 (n=13)

We describe a number of these cases in detail

Wrong component issued

Uniplas issued instead of group specific SD plasma

Level 1 IBCT Case 13

This infant, with an abnormal coagulation screen unresponsive to vitamin K, required a transfusion of SD treated plasma. Eighteen mls of SD plasma was prescribed (weight 1.17 kg). A medical scientist who does not regularly work in the transfusion laboratory processed the request on call. Uniplas was issued although the baby's group was known and group specific SD plasma was available. The scientist thought Uniplas was the product of choice for neonates. The error was not identified during the pre-transfusion checking procedure. The error was discovered by the TSO during retrospective audit of blood component/product usage.

Level 1 IBCT Case 27

This premature baby with an abnormal coagulation screen – APTT 77.1 seconds - required an emergency transfusion of solvent detergent (SD) plasma. The pre-transfusion sample was processed on call. In error, Uniplas was issued to this baby although the baby was known to be group A. The historical grouping record was checked confirming the group of the baby, but the medical scientist issuing the product, who normally works in the transfusion laboratory, thought Uniplas was the product of choice for neonates. The error was identified during routine retrospective audit by the TSO.

Failure to transfuse red cells suitable for neonatal use

Level 1 IBCT Case 37

This group A Rh D positive baby, with a pulmonary haemorrhage required an emergency transfusion in the neonatal intensive care unit Hb 9.2 g/dl. Thirty

two mls of group O Rh D negative emergency red cells, in paedipack form for neonatal use, were required. One unit of group O Rh D negative red cells for adult use was collected from the satellite fridge in error and 32mls were transfused from this pack. Transfusion laboratory staff identified the error when checking stock in satellite fridge. The use of emergency adult red cells was then investigated. In this hospital, emergency group O Rh D negative red cells for adult use are always CMV negative. However the donor would not have fulfilled the screening criteria for neonatal transfusion.

Label on uncrossmatched unit

Level 1 IBCT Case 23

This case is reported in the IBCT chapter

Failure to provide irradiated or CMV negative product

Level 2 IBCT Case 1

This infant with a congenital immune deficiency required a transfusion peri-operatively with three units of SAG-M red cells, seven aliquots of a paedipack and two units of apheresis platelet concentrate. All neonatal blood used in this hospital is CMV negative, but the prescription and request did not state the need for irradiated cellular components. The error was not identified either during laboratory processing or during the bedside checking procedures. The laboratory staff discovered the error when subsequent post-operative requests for blood stated the need for irradiated cellular components.

Level 2 IBCT Case 8

The infant, with a congenital immune deficiency, was transfused with three units of SAG-M red cells, five aliquots of a paedipack and two units of platelet concentrate during the peri-operative period. Transfusion policy within this hospital states that all neonatal blood is CMV negative, but the prescription and request did not state the need for

irradiated cellular components. The error was not identified either during laboratory processing or the bedside checking procedures. The TSO discovered the error during routine surveillance.

Level 2 IBCT Case 44

This day-old group B Rh D negative male infant suffered a haemorrhage post delivery, Hb 14.4g/dl. One unit of CMV negative red cell concentrate was prescribed. The on call medical scientist informed the prescribing paediatrician that there were no group compatible CMV negative red cells available in the laboratory and that they would need to be ordered from the IBTS. The paediatrician wished to transfuse without delay resulting in an emergency transfusion of 45mls of non-CMV negative O Rh D negative red cells. The on call medical scientist did not regularly work in the transfusion laboratory. The following day during a routine audit, transfusion staff discovered that Group B, Rh D negative CMV negative red cells had been available in the blood fridge.

Problems with infusion pump

Level 2 IBCT Case 65

This septic baby required a platelet transfusion for thrombocytopenia – platelet count $21 \times 10^9/L$. The unit was transfused via a blood administration set using an electronic infusion device which was not suitable for platelets. The error was discovered when the laboratory staff questioned the lack of a platelet increment. The baby required a further unit of platelets. As there was underlying sepsis the failure of the platelet count to rise may have been due to this rather than the use of the infusion pump.

Level 2 IBCT Case 35

As this case occurred in an adult centre it is reported in the IBCT chapter.

Unnecessary Component Transfused

Level 2 Case 110 IBCT

This young child with an underlying malignancy required a transfusion of CMV negative irradiated

platelets pre operatively for a platelet count of $19 \times 10^9/L$. The prescription for platelets was calculated using a hospital guideline of 10-20ml/kg. The child weighed 16 kg and 300mls of apheresis platelets were prescribed. However the first unit of platelets contained only 198ml and a second unit of platelets was then administered. The child's platelet count post transfusion of the first unit was $118 \times 10^9/L$ and a decision was made by the clinical team to transfuse a second unit. Following transfusion of the second unit the platelet count was $155 \times 10^9/L$. This was discovered during a routine haemovigilance audit the following day. Following discussion with the consultant haematologist, it was felt that the second unit exposed the child unnecessarily to a second donor. As a result of this incident, changes have been made within the hospital policy so that where greater than 200ml transfusion is required, a repeat platelet count post transfusion may show that a single unit of platelets is adequate.

Red cells out of controlled storage

Level 2 IBCT Case 89

This young child required a transfusion of one unit of CMV negative irradiated red cells for anaemia associated with a malignant haematological disorder. One unit of red cells was collected by the porter and brought to the ward for transfusion. During the final bedside check, it was noted that the patient's unique blood transfusion sticker in use in this hospital was missing from the hospital ID band. This transfusion sticker serves as an additional check in conjunction with the other three identifiers. As per hospital policy the transfusion was abandoned. As the child was being nursed in isolation the staff spent considerable time searching for the sticker. The porter was then notified by clinical staff to return the unit of blood to the fridge. By the time this occurred, the unit had been out of controlled storage for over one hour. The unique ID transfusion sticker was subsequently located by nursing staff and reapplied to the patient's hospital ID band. (This would not be normal practice but the other three identifiers were correct and the child was being

nursed in isolation). The child who was a bit mischievous admitted to removing the sticker himself. The porter was then contacted again to collect the unit of red cells from the laboratory fridge and the transfusion commenced, ninety minutes from the time the unit was initially removed from the fridge. The unit was transfused uneventfully. The event was discovered during a routine audit of transfusions at this hospital.

Units transfused crossmatched elsewhere

Level 3 IBCT Case 61

This case is reported in the IBCT chapter.

Wrong Factor Concentrate

Level 1 IBCT Case 52

This young man with Factor VIII deficiency and high responding inhibitors required factor concentrate for two consecutive days over a weekend. He normally received Recombinate but in error a member of the haematology team prescribed Refacto. The on call laboratory scientist processing the request was warned by the computer system that this patient normally received Recombinate and questioned the medical team. As the primary care team had prescribed the product and the on-call medical officer was not a member of this team, he/she decided to proceed with the administration of the incorrect product. The error was discovered following review of all on-call work on the next normal working day. The hospital plans to introduce stickers which can be placed on the front of each patient's chart indicating the clotting factor deficiency and which factor concentrate the patient is to receive.

AA Paediatric Reaction Incidents (N=9)

AA Case 1

This teenage patient with a haematological disorder required one unit of red cells for Hb of 8.7/dl in the day ward. The patient had a history of urticarial reaction to red cells within the previous few months. IgA levels were normal. On this occasion,

desferroxamine was administered alongside the transfusion, of red cells. Following the first 50mls of transfusion the patient developed symptoms of urticaria, hypotension, dyspnoea, restlessness, anxiety, periorbital oedema and wheals on body. The transfusion was discontinued and chlorpheniramine and hydrocortisone were given IV. The patient recovered fully within hours and was discharged home later that day. Future transfusions will be managed with chlorpheniramine premedication and washed cellular components.

AA Case 11

This adolescent patient suffered a relapse of a malignant haematological disorder and required one unit of apheresed platelets for thrombocytopenia. When approximately 85mls of platelets had been transfused, the patient developed symptoms of hypotension, urticaria, chest tightness, coughing and falling O₂ saturation. The transfusion was discontinued immediately. Chlorpheniramine and hydrocortisone were administered and the patient recovered from this episode within 90 minutes. IgA levels were performed, but although the result was low - 0.37g/L, this related to the immunosuppressant therapy rather than a true IgA deficiency. Further transfusions were administered uneventfully following premedication with chlorpheniramine and the use of apheresed platelets.

AA Case 12

This young child who was receiving shared care for a malignant haematological disorder, required one unit of CMV negative irradiated apheresis platelets for thrombocytopenia. Premedication cover of hydrocortisone and chlorpheniramine was given prior to transfusion. Following 120mls of platelets over 30-35 minutes, the child developed symptoms of itching, hypertension, dyspnoea, restlessness, wheeze, abdominal cramps and nausea. The transfusion was discontinued temporarily and a salbutamol nebuliser was administered. The child's respiratory symptoms resolved within minutes and the remainder of the transfusion was then given uneventfully. IgA levels were within normal limits.

The rash resolved completely later that evening. The child's primary care centre was contacted and following specialist advice, it was decided that washed products should be used for future transfusions. Subsequent transfusions using washed products have been uneventful.

AA Case 13

This young child required a transfusion of CMV negative irradiated red cells for anaemia of malignancy. Previous transfusions had been uneventful. The transfusion was completed in the day ward and the child discharged home. Four hours later, the child returned to the hospital with an all over urticarial rash and weeping, raised red wheals. Chlorpheniramine was administered PO. The child remained in hospital overnight and had recovered fully by the following day. Premedication cover of chlorpheniramine was recommended prior to future transfusions. Subsequent transfusions following this regime have been successful.

AA Case 14

This male infant required CMV negative irradiated platelets for thrombocytopenia associated with a malignant haematological condition. The child had a history of one previous reaction to platelets. As a result, he was receiving a premedication of chlorpheniramine prior to each transfusion. Within two hours of commencing the transfusion, he developed symptoms of an urticarial rash including severe facial hives associated with stridor and wheeze. The transfusion was discontinued. Chlorpheniramine IV and salbutamol nebuliser were administered and he recovered from this incident within 24 hours. Subsequent transfusions using washed platelets have been uneventful.

AA Case 15

This young child required CMV negative irradiated apheresed platelets for thrombocytopenia associated with malignancy. She had a history of two previous reactions to platelets and one reaction to red cells. Premedication of chlorpheniramine and hydrocortisone was administered prior to this transfusion. However, within 20 minutes of

commencing the transfusion when greater than 100mls had been transfused, she developed symptoms of an urticarial rash with raised red wheals and blackened eyes. The transfusion was discontinued completely. No medication or treatment was administered and the child recovered from this incident within 24 hours. This patient will receive washed platelets for any future transfusions.

AA Case 16

This young child required a transfusion of apheresed CMV negative irradiated platelets for thrombocytopenia associated with a malignant haematological disorder. He had a history of three previous reactions to pooled platelets. As a result, apheresed platelets were prescribed and premedication of chlorpheniramine and hydrocortisone was administered prior to this transfusion. Within 10 minutes of completing the transfusion, the child developed symptoms of urticaria, stridor and wheeze. Adrenaline and hydrocortisone were administered IV and the child recovered immediately. Future transfusions will be carried out using washed platelets.

AA Case 17

This young male child required platelet transfusion for thrombocytopenia secondary to a malignant haematological disorder. As a result of a previous allergic reaction to platelets, premedication of hydrocortisone and chlorpheniramine was given. Immediately following transfusion of one unit pooled platelet concentrate, he developed symptoms of urticaria, dyspnoea, stridor and wheeze. O₂ therapy was commenced and a further dose of hydrocortisone 50mgs was given. The patient recovered fully within one hour and was discharged home two hours later. A subsequent transfusion four months later using apheresis platelets and premedication cover was uneventful. However, this patient went on to experience an anaphylactic reaction following his most recent platelet transfusion, despite pre-medication cover and the use of apheresis platelets. If this patient requires any further transfusion, washed components will be prescribed.

AA Case 22

This young male patient required transfusion of one unit of CMV negative irradiated pooled platelet concentrate. He had previously experienced a reaction to platelets. He was also a known asthmatic and as a result, should have received premedication of hydrocortisone and chlorpheniramine prior to transfusion. However chlorpheniramine only was given pre transfusion. Following infusion of 200mls of this unit, the patient developed symptoms of tachycardia, itch, urticarial rash, wheeze and an associated temperature rise of >1.5°C. The transfusion was abandoned and hydrocortisone IV and salbutamol nebuliser were given. The patient recovered fully within 12hrs. Bacteriological culture of the pack was negative. Following discussion between the supply centre and the patient's consultant, a decision has been made to use washed products for future transfusions.

AHOSTR Paediatric Incidents (N=1)

AHOSTR Case 1

This case is also reported in the AHOSTR chapter. This young patient with a malignant haematological disorder required one unit of red cells for anaemia - Hb 7g/dl. The patient grouped as O Rh D positive with an Anti E antibody and an autoantibody reactive in enzyme only. The DAT was negative. Antigen negative blood was crossmatched and issued. During transfusion, when less than 200mls had been transfused, the patient developed symptoms of fever >1.5°C with chills/rigors and hypotension. The transfusion was discontinued completely and paracetamol was given. A full recovery was made within approximately 1-2 hours. The patient was cultured and no organisms were isolated but no repeat serology was done post transfusion reaction as per hospital policy. As a result of this failure to complete reaction investigations, the management of adverse transfusion reactions has been highlighted at existing educational sessions and laboratory policy on the investigations of transfusion reactions is being reviewed.

PAD (N=2)/TTI (N=1) Paediatric Incidents

The PAD Paediatric incidents (Cases 2 and 5) and TTI Paediatric Incident (Case 2) are reported in their respective chapters.

The Near Miss Project

Definition of a Transfusion Related Near Miss Event: "Any error which might have occurred, but didn't, because it was detected and corrected before administration took place"
Adapted by NHO 2002

A three-year research project looking at Near Miss Events in transfusion commenced in November 2002. During the first year, most of the focus has been on setting up the project and carrying out training in all of the ten sites involved.

The first fully trained site commenced 'live' reporting in May 2003, with seven sites joining on a site-by-site basis between May and December 2003. The remaining two sites completed training and went 'live' with reporting from January 2004.

The events are being processed and analysed using the Medical Event Reporting System for Transfusion Medicine (MERS-TM)

The MERS-TM system analyses events slightly differently to the way the NHO analyses actual errors

or reactions. The main focus is the Root Cause Analysis (RCA). MERS-TM breaks down root causes into either System (both organisational and managerial) or Human failures. It can highlight to each individual site trends in error, high-risk steps in the work process and high-risk areas. This allows the focus for improvement and resources to be concentrated in these particular areas first.

The reporting is anonymised and confidential with each site contributing data under unique hospital codes. The establishment of a 'non punitive' reporting culture which has full support of both management and stakeholders along with the enthusiasm and hard work of the TSOs from each site have been key factors in the successful implementation of the project.

The following data analysis is based on a relatively small number of events as the project is still in its infancy. However, there are some areas where trends are already significant and should be monitored carefully.

The following is aggregate data for 2003 from the sites that have contributed to the project to date. Each site is given individual feedback on their data analysis by the project co-ordinator as definite trends or high-risk events/areas emerge.

There were 84 low risk events, 31 medium risk events and 15 high-risk events reported in 2003.

Findings

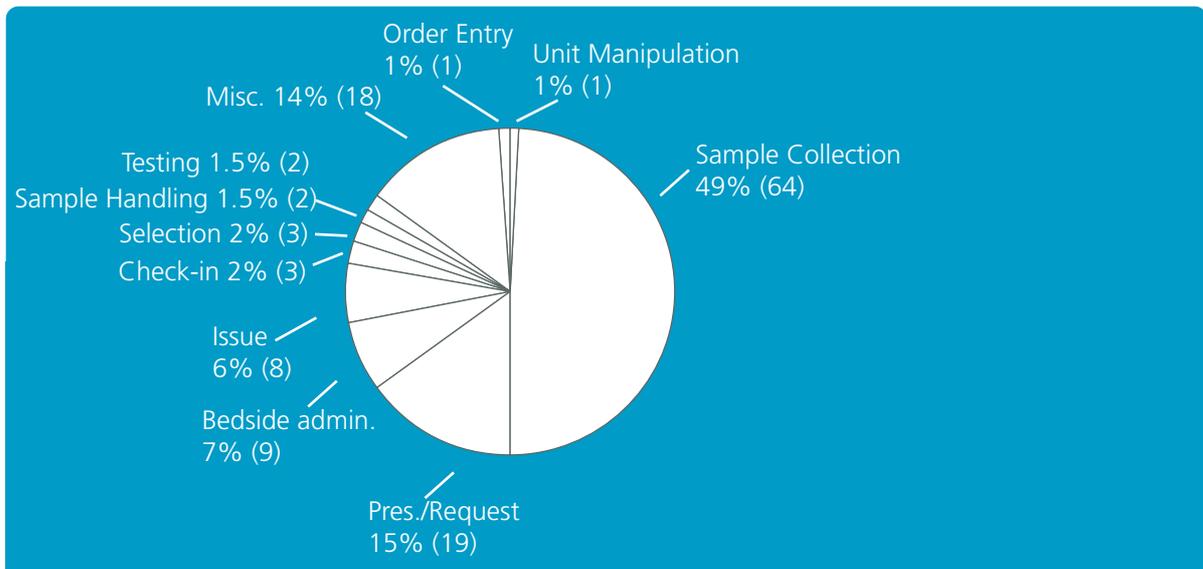
Total Number of Near Miss Events Reported May – December 2003

A total of 130 Near Miss Events were reported between May and December 2003. A further ten reports were received but could not be processed due to either insufficient information provided on the form, or the event did not fit the criteria for a Near Miss Event according to the NHO definition.

Step in the Work Process Where Near Miss Events are First Occurring

Sample Collection is the step in the work process most frequently associated with Near Miss events occurring, with 64 events (48%) first occurring at this step. This is followed by the Prescription/ Request step, where 19 events (15%) first occurred.

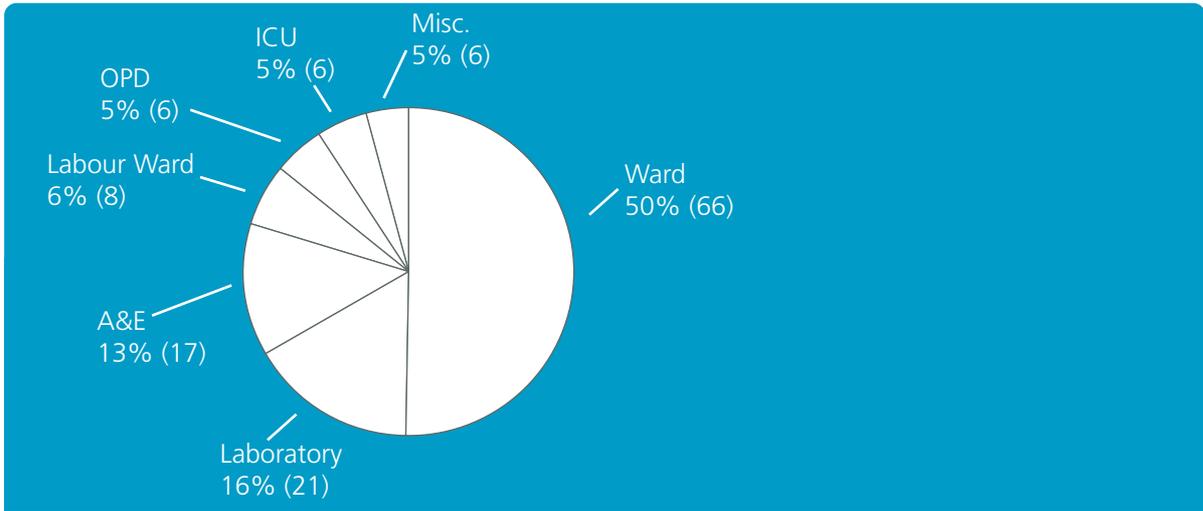
Figure 4 Occurrence Information (First Site of Error) N=130



Distribution of Events by Clinical area

The majority of Near Miss Events 66 (51%) occurred in wards. Laboratory and Accident and Emergency Departments were also areas which featured significantly in events reported.

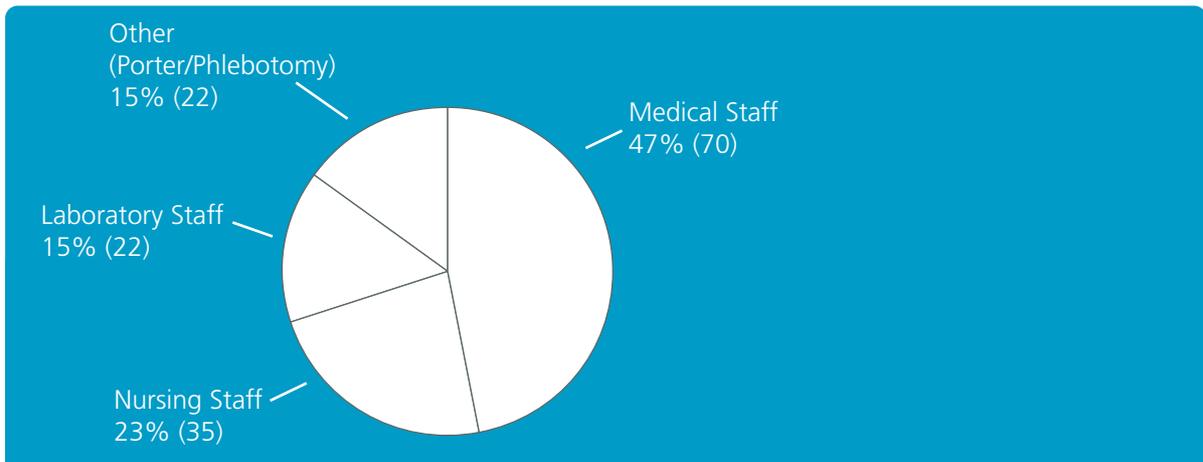
Figure 5 Areas where Events are Occuring (N-130)



Who Is Involved in Near Miss Events?

Medical staff were most frequently involved in Near Miss events - 70 events (47%). This was followed by nursing staff who were involved in 35 events (23%). Laboratory and other grades of staff (phlebotomy and portering) were involved in 22 events (15%) each. It should be noted that many events involved errors by more than one grade of staff.

Figure 6 Who is Involved in Near Miss Events



Patients Requiring Repeat Samples as a Result of Near Miss Events

Of the 130 events reported, 77 (59%) required the patient to be re-sampled. Where delays occur in re-sampling, the patient's transfusion can be delayed. In addition, patients (including neonates and children) have to be sampled twice, often causing distress and leading to extra workload for both the sampler and the laboratory.

ROOT CAUSES - WHAT DO THEY MEAN?

Where root cause analysis is carried out on an event using MERS-TM the root cause/causes will be shown as either 'system' or 'human' failure or a combination of both. Most events involve more than one type of failure and therefore will have more than one root cause.

Following root cause analysis of the 130 reported events, the most frequent root causes seen involve 'Human Failures' (human error).

Human Failures

Human slips were the most common type of human error seen. The main reasons cited for these slips were tiredness, distraction and / or busy workload. Examples of events involving human slips were errors relating to unique identifiers on samples, transcription errors and forgetting to complete tasks.

The second most significant root cause seen was failure to adhere to policies/procedures and/or failure to verify patient/product details.

Examples of events involving these root causes are failure to check patient's ID band or product information, remote or pre labelling of samples or requests and failure to adhere to SOPs correctly.

Lack of knowledge by all grades of staff involved in the transfusion chain and failure to communicate effectively were also root causes seen in a smaller

number of events. Although these root causes were seen far less frequently than other types of human failures, they were significant, as a lack of knowledge about either policies/procedures or clinical issues and poor communication were frequently associated with high risk events.

System Failures

The most frequent system failure seen was poorly designed or absent policies/procedures within an organisation. Examples of events involving this root cause are absence of policies such as laboratory sample acceptance/rejection policies, maximum surgical blood ordering schedules (MSBOS) and policies / procedures which are flawed, out of date or confusing.

System failures at management level were also a significant root cause. These events relate to inadequate staffing levels, cross call cover in the laboratories and lack of training for new or inexperienced staff. Organisational/professional culture was also found to be a root cause in some cases. Examples found involving these types of events were the reluctance of medical staff to attend haemovigilance training as it was not seen as significant to their work, portering staff who were reluctant to use newly introduced collection slips and unwritten rules being applied to work practices.

Technical design faults were also found to have contributed to some events. These were faults such as hospital computer systems not being fully linked to laboratory computer systems, which led to a failure to carry any updated information across from one system to the other. In other cases, poorly designed systems allowed warnings be overridden too easily where special requirements such as CMV negative and irradiated products were required. Also highlighted, were faults in technical equipment such as label printers.

There were also a small number of events, caused by material defects such as poorly designed labels or

forms which led to staff using them incorrectly and poor quality of materials i.e. adhesive failures leading to stickers falling off or becoming smudged and illegible.

Other Root Causes

In some cases the failures, either system or human, were beyond the control of the investigating organisation. This would include events such as errors made involving the blood supplier or errors made by another centre, which were picked up in the reporting site.

A further category of root cause, which has been seen in small numbers, is 'patient related factors'. These types of events involve errors made due to the patient giving false or wrong information to a hospital i.e. in relation to their name or date of birth or patients who remove their own ID bands.

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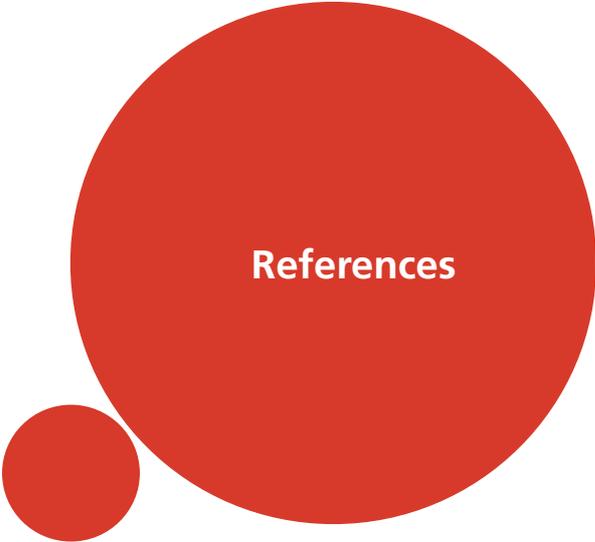
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04/406/NMD

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Dear Doctor

BLOOD TRANSFUSION GUIDELINES, INDICATIONS AND TRANSMISSION OF vCJD

The National Blood Users Group, chaired by Professor John Bonnar, is circulating a copy of its Guidelines for the Administration of Blood and Blood Components to all medical practitioners in Ireland. Along with these you will also find a copy of the earlier Guidelines for Transfusion of Red Blood Cells in Surgical Patients, first issued in 2001.

The therapeutic use of blood and blood components is, as you know, an integral and essential part of many aspects of medicine and surgery. Used appropriately, blood is life saving or life-enhancing. Used inappropriately, it is at worst lethal, at best a careless waste of a limited resource. Many of the risks associated with transfusion are caused by errors in the process of ordering or administering blood and almost all the errors can be avoided if proper procedures are followed. It is only by constant adherence to procedures that errors can be fully prevented.

Transfusion always carries a risk of causing an adverse event. Some of the risks, such as ABO mismatch are well characterised and preventable; some such as immunomodulation less so. In addition it is difficult to demonstrate benefit in many patient groups who may be transfused, particularly in patients with moderate degrees of anaemia in association with surgery, trauma, or sepsis.

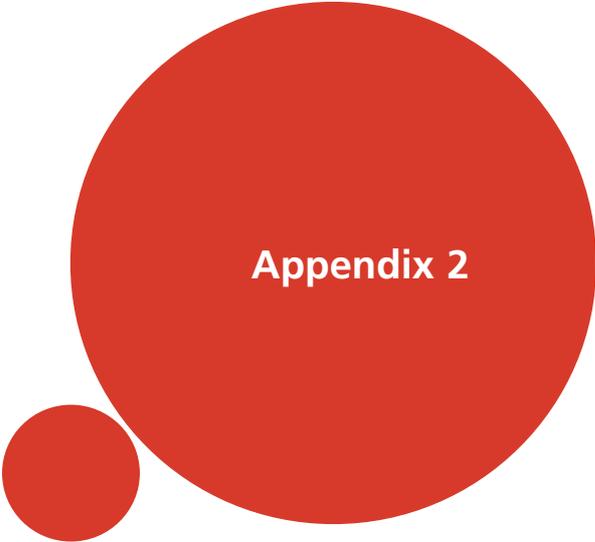
Transfusion of infectious disease still occurs with transfusion. For HIV and Hepatitis C the risk is very small, due mainly to the combination of highly effective testing and a low prevalence in the donor population.

Recent reports of transfusion transmission of vCJD in the UK gives cause for renewed concern. The risk in Ireland is likely to be much lower but cannot be accurately quantified. No one has yet developed vCJD in Ireland from eating infected food here. Nevertheless it is important to take the possibility of disease transmission, however remote it may turn out to be, into account when ordering a blood transfusion. Does the patient really require a blood transfusion? Are there alternative therapies that would be equally effective? Such therapies might include simply withholding transfusion or use of haematinics in relevant circumstances.

It is important to remember that the risk of transfusion of vCJD, or of any infection, is also directly related to the number of units of blood or blood component that the patient receives. Blood should always be transfused on a unit by unit basis to achieve the desired therapeutic effect.

Yours sincerely

Dr William Murphy MD, FRCPEdin, FRCPath
National Medical Director



Appendix 2

Solvent Detergent (SD) Plasma

This leaflet is an up-date of the FFP information leaflet issued in March 2000. We wish to remind you that there remains a risk of Transfusion Associated Circulatory Overload following the administration of Solvent Detergent Plasma.

Points to note

- In 2001, the National Haemovigilance Office (NHO) received 16 (11%) reports of Transfusion Associated Circulatory Overload (TACO). Six (37.5%) of these were associated with Fresh Frozen Plasma (FFP).
- Occasional severe anaphylactoid reactions have been reported in association with FFP, especially with rapid infusion rates. During 2001 the NHO received 35 reports of severe acute anaphylactoid reactions, 11 (30.5%) of which were associated with FFP. Anaphylactic or anaphylactoid reactions due to hypersensitivity to infused plasma proteins or anti-IgA following the transfusion of Solvent Detergent Plasma (SDP) are rare (<1: 1000),¹ and are likely to be of the same order as for FFP.
- The dosage of SDP depends upon the clinical situation and underlying disorder, but 12-15mls/Kg is a generally accepted starting dose. It is important to monitor the response both clinically and with measurement of prothrombin time (PT), partial thromboplastin time (PTT) or specific factor assays.²
- The statement on both the label and the product insert recommends that 'the thawed product should be used immediately'. This must be interpreted in such a way as to minimise the risk of volume overload. The infusion of SDP should begin as soon as clinical circumstances permit after thawing. British guidelines recommend that each unit of plasma be transfused to an uncompromised adult over 30 minutes.³ Generally, the thawed product should be transfused within four hours of thawing. Coagulation factor replacement in the massively haemorrhaging patient may require faster infusion rates.
- The patient who is elderly, very small and/or cardiac or respiratory compromised deserves special mention. There is a significant risk of volume overload leading to respiratory distress with severe morbidity/mortality especially using rapid infusion rates. In the non-bleeding situation, transfusion rates for this group of patients should not exceed 2-4mls/kg per hour.⁴

- Each unit of SDP contains a standard volume of 200mls, in contrast to a unit of FFP, which contains 220-300mls. This smaller volume may need to be considered when calculating doses.

Table 1. Suggested times for infusion in the non-bleeding patient.

In general SDP can be considered as equivalent, volume for volume, to FFP. If a slower transfusion rate is needed, the plasma can be thawed in divided doses.

Patient Weight	Units Required	Rate of Transfusion per hr
20 kg	1 unit	40mls – 80mls
30 kg	2 units	60mls – 120mls
40 kg	3 units	80mls – 160mls
50 kg	3 units	100mls – 200mls
60 kg	4 units	120mls – 240mls

Firm indications for giving plasma⁵:

Plasma therapy should only be given where there is a clear clinical indication and where the expected benefit outweighs the inherent risks. Firm indications for giving plasma include:

- The correction of haemostatic disorders where no other more suitable therapy exists or is available
 - Emergency warfarin reversal where prothrombin complex concentrates are unavailable (As in Table 2)
 - Haemostatic failure associated with major blood loss
 - Liver disease, either in the presence of haemorrhage, or prior to an elective procedure
 - Acute Disseminated Intravascular Coagulation
 - Replacement of single factor plasma deficiencies where no licensed virally-inactivated or recombinant single factor concentrate is available e.g. factor V deficiency (currently) and acetyl cholinesterase deficiency
- The treatment of choice in thrombotic thrombocytopenic purpura (TTP) in conjunction with plasma exchange

SDP is only required for the reversal of over anticoagulation in the presence of major bleeding. Generally it should not be used in patients scheduled for elective invasive procedures as these situations are best managed using Vitamin K and withdrawal of Warfarin.

Table 2. Recommendations for management of bleeding and excessive anticoagulation⁶

INR* 3 - 6 (target INR 2.5) INR 4-6 (target INR 3.5) no bleeding or minor bleeding	1. Reduce warfarin dose or stop 2. Restart warfarin when INR < 5.0
INR 6 - 8; no bleeding or minor bleeding	1. Stop warfarin 2. Restart when INR < 5.0
INR > 8.0, no bleeding or minor bleeding	1. Stop warfarin 2. Restart warfarin when INR < 5.0 3. If other risk factors for bleeding exist**, give 1-2.5 mg of vitamin K IV or orally
Life threatening bleeding	1. Stop warfarin 2. Give 5mg of vitamin K IV 3. Give prothrombin complex concentrate*** 25- 50 iu/kg or SDP 12-15mls/kg

Notes: *INR = International Normalised Ratio **Age of patient > 70 and/or Previous history of bleeding ***Unlicensed product

Managing Anticoagulation in the Perioperative Period

Elective invasive procedure: Stop anticoagulant for three days prior to surgery

Emergency invasive procedure: Where surgery cannot be postponed, reverse anticoagulant with low dose Vitamin K as above.⁶

In emergency situations, Vitamin K should be given IV, which will reduce the INR within 4 hours, with complete reversal to the therapeutic range within 24 hours. In less urgent situations, it can be given orally. As Vitamin K tablets are only available as 10 mgs, the intravenous solution of Vitamin K can be given orally and is effective. Only 1mg is required to reduce the INR from >4.5 to a target of 2.0-3.07 within 24 hrs.^{6, 8, 9}

SD Plasma is not indicated in treatment of:

- Hypovolaemic shock
- Selected nutritional deficiencies
- Correction of immunodeficiency
- Replacement fluid in plasmapheresis with the exception of TTP

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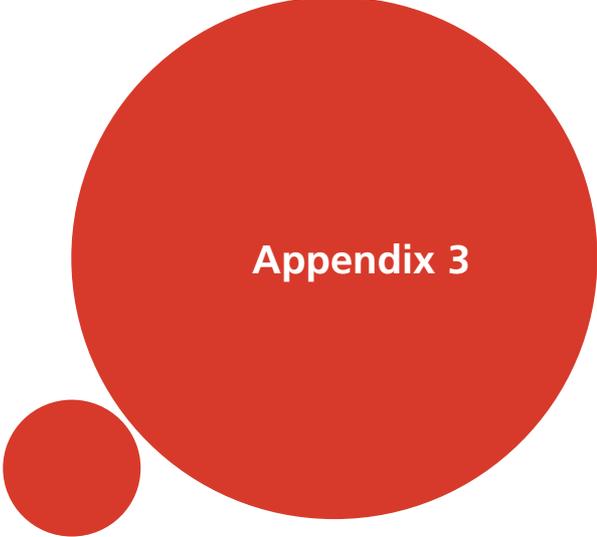
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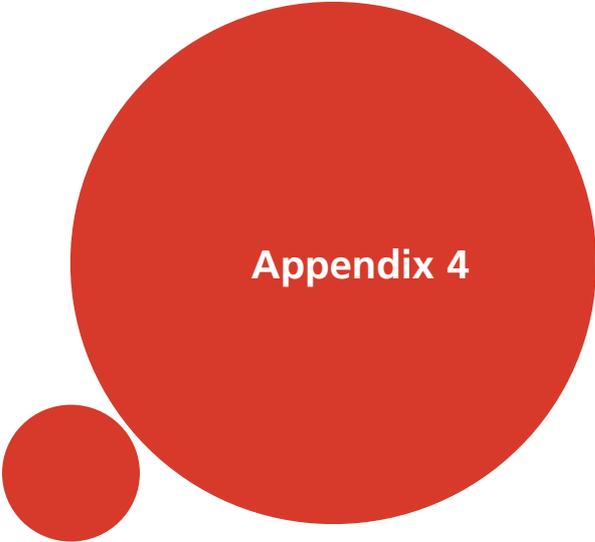
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Appendix 3

AVERAGE VOLUME OF BLOOD / COMPONENTS ISSUED IBTS 2003

Product	Average Volume Issued
Red cell concentrate	284mls.
Solvent detergent (SD) Plasma	200mls.
Fresh Frozen Plasma	260mls.
Platelets Pooled	330mls.
Platelets Apheresis	240mls.



Appendix 4

Transfusion-Related Acute Lung Injury (TRALI)

As we have recently received some reports of serious adverse transfusion reactions, which were suspected to be TRALI, we are forwarding some up-dated information for your notice board.

Presentation

TRALI generally manifests itself as acute respiratory distress, fever, and hypotension (hypertension is present in 15% of cases) during or after transfusion with associated bilateral pulmonary oedema, and with no evidence of cardiac compromise or acute volume overload. Symptoms typically begin within 1-2 hours of transfusion and are usually present by 4-6 hours. Chest X-rays classically demonstrate white-out by interstitial and alveolar infiltrates, but in the first few hours a patchy pattern may be observed. The incidence of TRALI is about 1:5000 transfusions, but this may be significantly under diagnosed.

Implicated Products

TRALI has been more frequently described in transfusions containing significant amounts of plasma i.e. fresh frozen plasma (FFP) and platelets, but it has also been associated with cryoprecipitate, red cell transfusions and intravenous immunoglobulin.

Solvent detergent plasma (SD plasma) has not been implicated in TRALI probably because of the pooling process involved during manufacture.

Pathophysiology

TRALI is thought to result from the presence of anti-HLA and/or anti-granulocyte antibodies mainly in the plasma of multiparous female donors, or less commonly in the plasma of donors who have received previous transfusions. One or both of these antibody types have been found in 89% of TRALI cases, although there have been documented cases where there were no associated antibodies. It has been hypothesised that white cell-antibody interaction causes activation and sequestration of white cells in the pulmonary microvasculature. The granulocyte metabolic products released give rise to endothelial injury, leading to increased endothelial permeability and consequent exudation of fluid and protein.

National Haemovigilance Office (NHO) Annual Report 2001

During 2001, the NHO received three reports of suspected TRALI. Two of these reports, which involved the transfusion of red cells, have been confirmed as TRALI. The third, which is still under investigation, is related to the transfusion of two units of FFP.

Differential Diagnosis

- The symptoms of *transfusion associated circulatory overload* usually begin within several hours of the transfusion of any type of component or product. There may be other symptoms of cardiac insufficiency. Often there is pre-existing cardiovascular or respiratory disease.
- The respiratory distress and cyanosis of *anaphylactic transfusion reactions* is related to bronchospasm and laryngeal oedema, not to pulmonary oedema. Furthermore, cutaneous manifestations are common and typically involve the trunk, face and neck. Fever, generally, is not a manifestation of anaphylactic transfusion reactions.
- While fever and hypotension are frequent symptoms of *bacterial contamination*, respiratory distress is not as frequently observed. The onset of symptoms is usually within 1-2 hours of commencing the transfusion. Although platelets are most frequently implicated due to their ambient storage conditions, red cell transfusions may also be associated with this complication.
- TRALI is clinically indistinguishable from *acute respiratory distress syndrome (ARDS)*. ARDS should be considered if the presentation is over 12 hours post transfusion, or if the condition fails to resolve within 72 - 96 hours. This should also be considered in patients with clinical disorders associated with ARDS e.g. pneumonia, sepsis, aspiration of gastric contents and severe trauma.

Treatment

TRALI is associated with significant patient morbidity and the mortality rate may be as high as 25%. Generally patients will require O₂ support, with approximately 70% requiring mechanical ventilation. In about 80 percent of cases the pulmonary infiltrates evident on radiography resolve almost completely within 96 hours and arterial blood gases return to baseline values during this period. It is generally agreed that ventilatory assistance (O₂ and in severe cases mechanical ventilation) and fluid replacement (0.9% NaCl) are indicated for the treatment of TRALI. Diuretics are contraindicated. Pressor agents are occasionally required to control fluid replacement resistant hypotension. No significant role has been determined, as yet, for the use of corticosteroids.

Recommendations

1. Be alert that any respiratory distress occurring during, or within six hours following, blood or blood component transfusion could potentially be TRALI. Discontinue the transfusion immediately, begin O₂ and supportive therapy.
2. Patient samples required for follow-up investigations include: 10mls in EDTA tube and 10mls in plain tube. Please contact the NHO for advice re same.
3. Notify the Blood Centre that supplied the blood component of the unit numbers of the components used.
4. Report TRALI as a serious adverse reaction to transfusion to the NHO.

DIFFERENTIAL DIAGNOSIS

	Fever	BP	Pulse	Clinical features	Onset	Investigation
TRALI	▲	▲▼	▼	Bilateral Pulmonary Oedema	During / up to 1-6 hours after	Granulocyte serology
Circulatory Overload	-	▲	▲	Cardiac Failure Pulmonary Oedema Positive Fluid Balance	During/after	ECG, cardiac enzymes, ECHO
Anaphyactoid reaction	-	▼▼	▲	Rash Dyspnoea	Immediate occurring up to 2 hours	IgA Levels
Bacterial infection	▲	▼▼	▲	Endotoxic Shock	During or 1-4 hours after	Blood cultures of patient and blood component
ARDS	▲	▲▼	▲	Bilateral Pulmonary Oedema	Consider if onset later than 6 hours	Investigations for underlying conditions

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