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List of Abbreviations

AA  Severe Acute Anaphylactoid/Anaphylactic Reaction
AAA  Abdominal Aortic Aneurysm
AABB  American Association of Blood Banks
A&E  Accident and Emergency
AHOSTR  Acute Haemolytic or Other Severe Acute Transfusion Reaction
ARDS  Adult Respiratory Distress Syndrome
BCSH  British Committee for Standards in Haematology
BNP  B-natriuretic Peptide
CMV  Cytomegalovirus
CVA  Cerebrovascular Accident
CXR  Chest X-ray
DAT  Direct Antiglobulin Test
DHTTR  Delayed Haemolytic Transfusion Reaction
DIC  Disseminated Intravascular Coagulation
DNP  Did Not Progress
DOB  Date of Birth
DVT  Deep Venous Thrombosis
ECG  Electrocardiograph
EU  European Union
FBC  Full Blood Count
FFP  Fresh Frozen Plasma
GMP  Good Manufacturing Practice
Hb  Haemoglobin
HBV  Hepatitis B Virus
HCV  Hepatitis C Virus
HIV  Human Immunodeficiency Virus
HVO  Haemovigilance Officers
IBCT  Incorrect Blood Component Transfused
IBTS  Irish Blood Transfusion Service
ID band  Identity band
IgA  Immunoglobulin A
IgG  Immunoglobulin G
IgM  Immunoglobulin M
IMB  Irish Medicines Board
INR  International Normalised Ratio
ITP  Immune Thrombocytopenic Purpura
IV  Intravenous
LDH  Lactate Dehydrogenase
LIS  Labarotory Information Systems
LVF  Left Ventricular Failure
MERS-TM  Medical Event Reporting System for Transfusion Medicine.
MRN  Medical Record Number
NBUG  National Blood Users Group
NAT  Nucleic Acid Amplification Testing
NCHCD  National Centre for Hereditary Coagulation Disorders
NHO  National Haemovigilance Office
OPD  Out Patient Department
PAD  Pre-deposit Autologous Donation
PAS  Patient Administration System
PCC  Prothrombin Complex Concentrate
PCR  Polymerase Chain Reaction
PNH  Paroxysmal Nocturnal Haemoglobinuria
PTP  Post Transfusion Purpura
RCA  Root Cause Analysis
Rh  Rhesus
RTA  Road Traffic Accident
SD Plasma  Solvent Detergent Plasma
SHOT  Serious Hazards of Transfusion
SOP  Standard Operating Procedure
STTI  Suspected Transfusion Transmitted Infection
TACO  Transfusion Associated Circulatory Overload
TA-GvHD  Transfusion Associated Graft-versus-Host Disease
TRALI  Transfusion Related Acute Lung Injury
TTP  Thrombotic Thrombocytopenic Purpura
vCJD  variant Creutzfeldt Jacob Disease
We have changed the format of the NHO Annual Report for 2005, the sixth full year of NHO reporting. We have done this for a number of reasons; notably that previous reports have provided a detailed assessment of reactions and adverse events reported, but required a large input of time from all members of the NHO. This together with the introduction of EU Directive 2002/98/EC which made reporting of serious adverse reactions and events mandatory from November, 2005 led us to focus on supporting hospital haemovigilance and expanding our educational remit in 2006.

Visits to hospitals by the NHO Team members have been made a priority for 2006. In addition a new educational initiative has been undertaken with Dublin City University (DCU) for individuals interested in haemovigilance practice. The first two professional development modules "Understanding and Management of Blood Transfusions in a Haemovigilance Context" and "Haemovigilance: Blood Transfusion Nursing" were successfully completed in the academic year 2005/2006 and will continue for the next two years. We should like express our thanks both to the NHO staff supporting these modules and the lecturers from the hospitals and IBTS who have contributed enthusiastically to the success of these modules.

The NHO gratefully acknowledges the work of Haemovigilance Officers (HVOs) Medical Laboratory Scientists and Consultant Haematologists/Pathologists and other hospital Consultants in ensuring the success of the haemovigilance programme.

The advice of the Medical Director and staff of the Irish Medicines Board (IMB) – the Competent Authority, is also appreciated, as is the expertise of the staff of the IMB’s Pharmacovigilance Department.

The Near Miss Project funded by IBTS was completed during 2005 and the NHO would like to thank all the hospital staff in the ten participating hospital sites who contributed to ensuring the success of the project. It is hoped that the information on near miss events in Irish hospitals generated by the project will be valuable in improving patient safety. We would also like to thank the IBTS Chief Executive Mr. Andrew Kelly, National Medical Director, Dr. William Murphy and the staff of the IBTS. Their efforts in recruiting voluntary blood donors and maintaining high standards in blood processing and distribution are the backbone of the national haemovigilance scheme. A special thank you and best wishes to Dr. Stefan Laspina who acted as NHO Director from January to July 2005, we wish him well with his new responsibilities in Malta.
As in the past, the Incorrect Blood Component Transfused (IBCT) is the highest category reported, but of note in this year’s report are the numbers of unnecessary transfusions reported compared to previous years. This we feel reflects increased awareness and reporting rather than a real increase but focuses attention on the need to audit clinical transfusion practice. While the risk of transmission of the known viruses HIV, HCV and HBV are now extremely small, the emergence of other infectious diseases such as variant Crutzfeldt Jacob Disease (vCJD) and West Nile Virus (WNV) as new transfusion risks emphasises the need to avoid unnecessary transfusions. As previously reported, in June 2005 an Irish blood donor was subsequently diagnosed with vCJD, indicating that vCJD is potentially in the blood supply.

We hope that you find this slimmed down version of the NHO Annual Report useful in your practice. In compliance with the Official Languages Act 2003 copies of this report are also available in the Irish language.

Your feedback will be welcome.

Dr. Emer Lawlor,
Director NHO
The National Haemovigilance Office in IBTS was set up in 1999 to collect confidential anonymised reports of transfusion associated severe adverse reactions and events from healthcare professionals.

**The remit of the NHO is to:**
- Receive, collate and follow up reports from hospitals and general practitioners of adverse reactions/events connected with transfusion 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 TSO and as appropriate to medical, nursing and technical staff.
- Provide medical, scientific and nursing analyses 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 four and a half fulltime equivalent HVOs, a Programme Administrator and Assistant Administrator.
Definition of Terms used in Haemovigilance

**Serious Adverse Event:**
Any untoward occurrence associated with the collecting, testing, processing, storage and distribution of blood and blood components that might lead to
- Death or
- Life-threatening, disabling or incapacitating conditions for patients or
- which results in, or prolongs, hospitalisation or morbidity

**Serious Adverse Reaction:**
An unintended response in the patient associated with the collection or transfusion of blood and blood component that is
- Fatal
- Life-threatening, disabling or incapacitating or
- which results in, or prolongs hospitalisation or morbidity

EU Directive 2002/98/EC was transposed into Irish law on 8th November, 2005, by European Communities (Quality and Safety of Blood and Blood Components), Regulations 2005 SI 360/2005. Reporting of serious reactions which may be attributed to the quality and safety of blood components has become mandatory as have serious adverse events relating to the testing, storage and distribution of blood and blood components.

Irish Medicines Board
The IMB and NHO representatives had regular case review meetings during 2005 to discuss reported incidents. As and from 8th November 2005, the IMB has become the Competent Authority for implementation of all aspects of the EU Blood Directive, including haemovigilance.

Education, promotion & developments
The NHO Annual Conference entitled “Haemovigilance – The Challenge of the European Directive” was held in Cork in October, 2005, with a special workshop arranged the day before the main conference for HVOs. The workshop examined the future of Haemovigilance in Ireland under the headings of traceability and the EU Directive, the role and career of the HVO and the education of blood users. Guest speaker at the workshop was Ms. Catherine Howell, Transfusion Liaison Nurse Manager National Blood Service (NBS) whose presentation entitled ‘Handmade in England’ shared the experience of UK Haemovigilance Officers.

The Conference was officially opened by Dr. Elizabeth Keane, IBTS Board Member. The NHO Annual Report 2004 was presented by Dr. Stefan Laspina and Dr. Emer Lawlor. The keynote address ‘Using Haemovigilance Data’ was given by Dr. Dorothy Stainsby, Serious Hazards of Transfusion (SHOT) – UK

Other presentations included:
- 759 Chances to Learn - Ms. Derval Lundy, HVO NHO (Near Miss Project)
- Clinical Transfusion Practice - Ms. Marina Cronin, HVO Adelaide and Meath Hospital, Tallaght
- Managing Problems at the Sharp End - Dr. Dafydd Thomas, Consultant in Anaesthesia and Intensive Care, Swansea National Health Service Trust, United Kingdom
- Blood Safety and Quality Regulations - Ms Joan Jones, Manager Hospital Transfusion Practitioners, Welsh Blood Service
- Blood Inventory Management - Ms. Judith Chapman, Blood Stocks Management Scheme, London NBS
- Laboratory Events - Don Mullahy, Senior Medical Scientist IBTS
- Complex Transfusion Problems - Dr. Joan Fitzgerald, Consultant Haematologist IBTS
The winning poster competition entry was submitted by Rosemary Hannigan, HVO Letterkenny General Hospital with her poster entitled ‘Exploiting Data’. Dr. Dorothy Stainsby acted as adjudicator for the poster competition.

Near Miss Research Project
The three year Near Miss Project based on the MERS TM Reporting System (Kaplan et al 2002) undertaken in ten hospital sites between 2003 –2005 finished in October 2005 and completed collection of near miss incidents in May 2005 to allow data analysis. An abstract entitled Transfusion Related Near Miss Events in Ireland was accepted for full oral presentation as a finalist at the Irish Society for Quality and Safety in Healthcare (ISQSH) National Conference and Quality in Healthcare Awards 2005 as part of 10th Annual ISQSH Conference in Dublin in October 2005. In addition, an oral presentation on the Near Miss Project, won the best presentation at the Haematology Association of Ireland Annual Conference in Belfast in November 2005. A paper on the results of the project has been accepted for publication and is in press.

Education, Promotion and Developments
The NHO continues to support the development of hospital in-service training programmes by working closely with hospital based HVO. Support is also provided in transfusion education for nursing and laboratory science students.
All newly appointed hospital based HVO attend an induction training programme at the NBC including an introduction to Good Manufacturing Practice (GMP) and an overview of the IBTS manufacturing processes at the NBC. Nationwide networking among HVO is also promoted by regular correspondence through telephone/e-mail communication and personal visits.

The NHO News, an information newsletter circulated to all HVO, provides an informal forum for the reporting of work carried out within the NHO and individual hospitals, and includes local education and training initiatives and social events which may be of interest to other HVO. Details of events of national and international interest are also reported. During 2005, five editions of this newsletter were published with new features including a ‘Hot Topics’ notice board, facilitating HVO interaction and communication on areas of interest together with an occasional item featuring transfusion medicine updates.

Information on haemovigilance can be directly accessed on the IBTS website @ www.ibts.org. (Haemovigilance pages)
Hospital Annual Report Forms

Eighty three hospitals transfusing blood were circulated with the Annual Report Form. (Nil to Report Form) All 83 (100%) submitted a completed form with the numbers of components transfused in the hospital and the number of incidents submitted. Forty-nine (59%) hospitals reported that they had submitted a transfusion reaction or event during 2005. A further 34 (41%) of hospitals indicated that they had not reported any adverse events or incidents in 2005.

Denominator data

During 2005 a total of 186,482 components were issued by IBTS. A breakdown by components issued is given in Table 1.

Table 1 Blood and Blood Components Issued by IBTS 2005

<table>
<thead>
<tr>
<th>Component</th>
<th>No. Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Cells &amp; Whole Blood</td>
<td>139,314</td>
</tr>
<tr>
<td>Platelets – therapeutic doses</td>
<td>19,777</td>
</tr>
<tr>
<td>Frozen Plasma</td>
<td>746</td>
</tr>
<tr>
<td>SD Plasma</td>
<td>24,880</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>1,765</td>
</tr>
<tr>
<td><strong>Total components issued</strong></td>
<td><strong>186,482</strong></td>
</tr>
</tbody>
</table>

Serious Adverse Reaction and Serious Adverse Event Reports

In total 266 incidents were accepted for this report. An additional 31 reports did not fulfil the criteria for a haemovigilance event, as on further investigation it was found that the reaction or adverse event was not related to transfusion. These reports were classified as ‘Did Not Progress’ (DNP).

Serious Adverse Reaction and Serious Adverse Event Reports 2005

The number of serious adverse reactions and events continues to increase with 266 reports in 2005 versus 214 in 2004, an increase of 52 (24%).

The breakdown of serious adverse reactions and events in 2005 compared to previous years is given in Table 2.
Serious Adverse Transfusion Reactions

A total of 93 Reactions were reported in 2005. The breakdown by category is given in Figure 2. The incidence of reactions by component type is set out in Table 3 below.

Table 2 Breakdown of NHO incidents (2000-2005) (n=1044)

<table>
<thead>
<tr>
<th>YEAR</th>
<th>IBCT (no of cases)</th>
<th>AA (units)</th>
<th>TACO (units)</th>
<th>DHR (units)</th>
<th>STTI (no of cases)</th>
<th>TRALI (no of cases)</th>
<th>PAD (no of cases)</th>
<th>Unusual (no of cases)</th>
<th>AHOSTR (no of cases)</th>
<th>TOTAL (no of cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>31</td>
<td>22</td>
<td>8</td>
<td>2</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>14</td>
<td>85</td>
</tr>
<tr>
<td>2001</td>
<td>69</td>
<td>35</td>
<td>16</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>12</td>
<td>144</td>
</tr>
<tr>
<td>2002</td>
<td>87</td>
<td>31</td>
<td>10</td>
<td>9</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>-</td>
<td>8</td>
<td>155</td>
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<tr>
<td>2003</td>
<td>115</td>
<td>23</td>
<td>14</td>
<td>9</td>
<td>4</td>
<td>1</td>
<td>6</td>
<td>-</td>
<td>8</td>
<td>180</td>
</tr>
<tr>
<td>2004</td>
<td>126</td>
<td>35</td>
<td>15</td>
<td>4</td>
<td>3</td>
<td>-</td>
<td>7</td>
<td>-</td>
<td>24</td>
<td>214</td>
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<td>2005</td>
<td>173</td>
<td>22</td>
<td>25</td>
<td>5</td>
<td>6</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>32</td>
<td>266</td>
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<tr>
<td>TOTAL</td>
<td>601</td>
<td>168</td>
<td>88</td>
<td>30</td>
<td>25</td>
<td>6</td>
<td>24</td>
<td>4</td>
<td>98</td>
<td>1044</td>
</tr>
</tbody>
</table>

% 57% 16% 9% 3% 3% 0.6% 2% 0.4% 9% 100%

Table 3 Incidence of AHOSTR, AA, DHR and TACO by component type 2005

<table>
<thead>
<tr>
<th>Category (no of cases)</th>
<th>RCC (units) (139,314)</th>
<th>Platelets (19,777)</th>
<th>Plasma SD Plasma &amp; FFP (25,626)</th>
<th>Cryoprecipitate (1,765)</th>
<th>Total Components incl. SD Plasma (186,482)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHOSTR (32)</td>
<td>1:5358 (26)</td>
<td>1:3955 (5)</td>
<td>0</td>
<td>0</td>
<td>1:5828</td>
</tr>
<tr>
<td>AA (22)</td>
<td>1:13,931 (10)</td>
<td>1:2197 (9)</td>
<td>0</td>
<td>0</td>
<td>1:8476</td>
</tr>
<tr>
<td>DHR (5)</td>
<td>1:27,863 (5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1:37,296</td>
</tr>
<tr>
<td>TACO (25)</td>
<td>1:7332 (19)</td>
<td>0</td>
<td>1:6407 (4)</td>
<td>0</td>
<td>1:7459</td>
</tr>
</tbody>
</table>

1 Multiple components implicated in reaction: AHOSTR • 1, AA • 1, DHR • 1 TACO • 2.

PAD incidents are not included as denominator data is not available. STTI and TRALI not included as there were no confirmed cases in these categories in 2005.
Acute Transfusion Reactions

These can be divided into Acute Haemolytic and other Transfusion Reactions (AHOSTR) and Acute Allergic and Anaphylactic Reactions (AA).

Acute Haemolytic and Other Severe Transfusion Reactions (AHOSTR)

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)

During the reporting year 2005, 32 reports of AHOSTR were reported. Twenty nine (91%) of the patients experiencing AHOSTR reactions were adults, the majority of these being elderly (>70 years). There were only three reactions that occurred in paediatric patients. Twenty six reports involved red cells, five involved platelets (two involved pooled platelets, two involved apheresis platelets and in one case, both pooled and apheresis platelets were implicated). One report involved both red cells and platelets. No AHOSTR reactions were reported with SD plasma.

There was one haemolytic reaction. This was associated with apheresis platelets given to a patient with Paroxysmal Nocturnal Haemoglobinuria (PNH) where HLA matched platelets of the patient’s ABO group were not available leading to the transfusion of ABO incompatible plasma.

Blood cultures from the patient were undertaken in 19 cases (59%) and from the pack in 13 cases (41%), Cultures of both pack and patient were performed in only 11 cases (34%). In eight cases, initial cultures of patient (5 cases), or pack (3 cases), showed bacterial growth but this was not confirmed by finding the same organism in the patient or the pack in any case. Contamination during culturing was suspected in some of these cases, and in the five patients who had positive blood cultures, the reactions were probably due to the patient’s underlying condition, as three had probable underlying sepsis and one had end stage malignancy. In the fifth case, the blood cultures were not taken until 48 hours after the reaction.

These reactions, therefore, fall into the category of febrile non-haemolytic reactions which, although considered not serious, can be uncomfortable for the patient and may recur on further transfusions. While in many of the cases the patient was acutely unwell, in the 20 cases where time to recovery information was provided, 13 (65%) recovered fully within 12 hours. Four (20%) patients took over 24 hours to recover. On review of these four cases, it is likely that these reactions were due to the patient’s underlying condition rather than related to the transfusion. Two patients subsequently died due to their underlying condition, unrelated to transfusion.

In two of the cases involving reactions to apheresis platelets the transfusion was also considered unnecessary, as it was given for an erroneously low platelet count based on a telephone message in one case and in the second case, the prescriber had not checked the most recent platelet count prior to transfusion.

The number of reactions reported in this category continues to rise - eight in 2003, 20 in 2004 and 32 in 2005. Part of this rise probably reflects better reporting and reaction classification, but it is notable that the increase in this type of reaction appears to be confined to red cell components.
Acute Severe Allergic and Anaphylactic Reactions (AA)

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 and Pineda, 2001)

There were 22 AA reactions reported, of which ten were associated with red cells and nine with platelet concentrates (six with pooled and three with apheresis platelets). Three cases involved both red cells and platelets. There were no reports of AA associated with SD plasma. IgA levels were reported in only nine cases, but in one of the nine cases, a patient with repeated reactions was found to be IgA deficient with anti IgA antibodies. See detailed case report below.

Reaction Case Report 1: Patient with repeated allergic/anaphylactic reactions

This female patient was transfused for bleeding post surgical procedure. Five minutes into the transfusion, stridor and cyanosis developed. The transfusion was stopped. Fifteen minutes later, the patient was semi comatose with a BP of 97/50. She was treated with IV fluids, hydrocortisone and chlorpheniramine. A clinical diagnosis of possible pulmonary embolus was made and heparin started 1 hour 10 minutes after the transfusion. She remained hypotensive, but her blood pressure recovered over the next four hours.

A second unit of red cells was then commenced. Five minutes later, the patient complained of strange sensations, nausea, headache, palpitations and tingling. There was no change in her blood pressure. The transfusion was stopped. Three hours later her condition had improved and she made a complete recovery within 48 hours.

The pre and post transfusion serological investigations were negative but subsequently a sample was referred for investigation to the transfusion centre because of her history and a reaction of her serum with one cell on a red cell antibody investigation panel. Based on the history, the sample was referred to the Transfusion Centre, Sheffield NBS, where IgA deficiency with anti IgA antibodies was confirmed.

Because of the increased numbers of Acute Transfusion Reactions notably of the AHOSTR type reported with red cells, we reviewed the red cell AHOSTR and AA reactions by the type of blood bag into which the unit had been bled. Analysis of the rates associated showed an increased incidence of reactions with one type of blood bag used to collect whole blood. This may reflect the slightly increased amount of plasma left in the bag after processing.

Recommendations

Acute Haemolytic or Other Severe Transfusion Reactions

- 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/50 mls as severe reactions are most likely to occur within this time. (British Committee for Standards in Haematology (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.

• Where antibody is detected in the post transfusion sample taken within 24 hours of the transfusion, which was not detected in the pre-transfusion sample, the pre-transfusion sample should be tested by a different technique and/or referred to a reference laboratory for investigation, as it is likely that the antibody was present pre-transfusion but was not detected.

• It is essential to carry out adequate serological investigations in patients with multiple antibodies who present with an acute reaction.

• If possible, further transfusions should be delayed until completion of the transfusion reaction work-up.

• In AHOSTR, particularly where there is fever and chills/rigors, both the patient and the transfused unit(s) should be cultured to exclude bacterial contamination of the unit. This is particularly important when the reaction occurs with platelet transfusion as platelet concentrates are stored at room temperature and the incidence of bacterial contamination is highest in platelet concentrates.

• A protocol for culturing of the blood component is available by writing to the Quality Assurance/Quality Control Department of the IBTS. This protocol outlines the procedure to be followed when culturing a unit implicated in a febrile transfusion reaction which can be modified for hospital use. Culturing the outside of the blood pack is unnecessary.

• Specimens e.g. urine, sputum, necessary to exclude other possible sources of infection should also be cultured if indicated.

Acute Severe Allergic and Anaphylactic Reactions

• Even mild allergic reactions should be reported to the hospital blood bank and haemovigilance officer as subsequent reactions may be more severe.

• Most allergic transfusion reactions respond to chlorpheniramine. Steroids should be reserved for the more severe reactions.

• Prophylaxis with antihistamine should be considered if there is a previous history of allergy or repeated reactions.

• Protocols and training for the management of severe AA reactions should be in place in each hospital and all staff involved in transfusion should be familiar with them. The National Blood Users Group (NBUG) has produced recommendations for the Management of an Acute Transfusion Reaction (NBUG 2004) (See Appendix 1)

• Patients who have experienced a severe allergic/anaphylactic reaction during a blood
component transfusion should have a label placed on their chart alerting clinical staff to their history of transfusion reactions to ensure that appropriate pre-medication is given prior to future transfusions.

- Where patients are receiving shared care, systems must be in place so that relevant details relating to transfusion such as history of reaction/allergy and/or pre-medication requirements can be communicated between centres effectively.

- IgA deficiency (<0.05mg/dl) with anti IgA antibodies can cause severe allergic/anaphylactic reactions. IgA levels should be checked in patients with severe or repeated allergic/anaphylactic reactions. Since the transfused product may contain appreciable quantities of IgA, where possible, samples taken pre-transfusion should be used to check IgA levels.

- If anti IgA antibodies are present, these patients will require special transfusion management including the use of saline washed cellular components for future transfusions.

- Washed components for the management of AA reactions are only appropriate for patients with a history of anaphylactic or severe allergic transfusion reactions uncontrolled by pre-medication, as a 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.

- Classical allergic or anaphylactic reactions do not routinely require culture of the unit/pack or serological investigations. However, where atypical symptoms such as fever are present in a suspected AA reaction, or where skin manifestations are absent, it is important to culture both 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 serological tests to exclude incompatibility.

**Delayed Haemolytic Reactions (DHTR)**

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. (Davenport 2001)

- These can be graded by severity according to the SHOT criteria (SHOT, 1999)

  **Group 1:**
  Asymptomatic with 'antibody only' detected (with or without a positive antiglobulin test (DAT)

  **Group 2:**
  Evidence of haemolysis measured by falling haemoglobin and positive DAT.

  **Group 3:**
  Falling Hb with jaundice with or without a positive DAT.

  **Group 4:**
  As for Group 3, but with renal impairment.
Five incidents were reported in this category accounting for 2% of all incidents reported

Three showed no evidence of haemolysis and were classified as serological reactions only (Group 1). Two showed evidence of haemolysis and were classified as Group 3. The antibodies involved were anti-Fy^a^ in three cases and multiple antibodies in one case. In one case, although the patient had evidence of haemolysis, no antibodies were detected and the exact mechanism could not be determined. All patients recovered without sequelae.

**Recommendations**

- It is likely that there is under-diagnosis or under-reporting of this condition. It is essential that any patient presenting with any signs of haemolysis or a positive DAT some days after a transfusion should be investigated for a DHTR. The successful diagnosis also depends on accurate history taking and eliciting a history of recent transfusion.

- Consideration should be given to issuing antibody cards to patients with clinically significant antibodies (NBUG 2002) and the possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated. (Lariat and Fisher 2005)

**Table 4  Details of Delayed Haemolytic Transfusion Reactions Reported (n=5)**

<table>
<thead>
<tr>
<th>Case No</th>
<th>Age &amp; Gender</th>
<th>Pre-existing condition</th>
<th>Interval between transfusion and onset of symptoms/signs</th>
<th>Findings</th>
<th>Antibody</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>Elderly (70+) M</td>
<td>AAA repair</td>
<td>Transfused over previous 3 months</td>
<td>No evidence of haemolysis</td>
<td>Anti Fy^a^ detected</td>
<td>No clinical sequelae</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 2</td>
<td>Adult (21-69) M</td>
<td>Malignancy Massive Transfusion</td>
<td>5 weeks</td>
<td>Positive DCT no fall in haemoglobin or increase in bilirubin</td>
<td>Anti-D Anti L^u^ Anti K Anti Jk^a^</td>
<td>No clinical sequelae</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 3</td>
<td>Elderly (70+) F</td>
<td>Malignancy</td>
<td>2 weeks</td>
<td>Positive DAT no fall in haemoglobin or increase in bilirubin</td>
<td>Anti Fy^a^ detected</td>
<td>No clinical sequelae</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 4</td>
<td>Elderly (70+) M</td>
<td>Retro-peritoneal bleed</td>
<td>3 weeks</td>
<td>Raised bilirubin lowered haptoglobin raised LDH</td>
<td>Anti Fy^a^ detected</td>
<td>Recovered with no ill effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 5</td>
<td>Elderly (70+) M</td>
<td>Left knee replacement</td>
<td>1 week</td>
<td>Jaundice raised LDH lowered haptoglobins</td>
<td>No antibody detected</td>
<td>Recovered with no ill effects</td>
</tr>
</tbody>
</table>
Respiratory Complications of Transfusion

Transfusion Related Acute Lung Injury (TRALI)
Transfusion-related acute lung injury (TRALI) is an acute lung injury unrelated to circulatory overload occurring within six hours of a transfusion (Toy et al 2005).

TRALI is one of the leading causes of transfusion related mortality.

The NHO has adopted the Canadian Conference definitions which divides TRALI into TRALI and Possible TRALI (Kleinman et al 2004)

TRALI is characterised by the following
• Acute onset of symptoms
• Hypoxemia \( \text{SpO}_2 < 90\% \) on room air or other evidence of hypoxemia
• Bilateral infiltrates on frontal chest X-ray
• No evidence of circulatory overload
• No pre-existing acute lung injury (ALI) before transfusion or during or within six hours of transfusion
• No alternative risk factors for Acute Lung Injury present

Possible TRALI
• ALI as above
• No pre-existing ALI before transfusion or during or within six hours of transfusion
• Alternative risk factors for Acute Lung Injury present

Symptoms of fever, hypotension or hypertension are present in some cases but are not sufficiently specific to be included in the definition of TRALI or possible TRALI.

Three cases were initially reported to the NHO as possible TRALI and a fourth case (Case 4) sent in by the reporting hospital as a TACO was reviewed as a possible TRALI by the NHO. On investigation, one of the cases (Case 3) was considered circulatory overload unrelated to blood transfusion and in a second case (Case 4), where the patient died, the reaction was found to be due to the underlying illness and unrelated to transfusion. Both these reactions were excluded from further evaluation as DNP. TACO was considered the mostly likely diagnosis in the two remaining patients who are covered in the TACO section. There were therefore no cases fitting the criteria of TRALI in 2005.

Table 5: Reports received as possible TRALI 2005 (N=4)

<table>
<thead>
<tr>
<th>Case No</th>
<th>Product</th>
<th>No of donors</th>
<th>Gender</th>
<th>Investigations</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 units of RCC 7 units of octaplas 2 cryo.</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Reclassified as TACO</td>
</tr>
<tr>
<td>2</td>
<td>2 units of RCC</td>
<td>2 donors</td>
<td>1 female donor 1 male not investigated</td>
<td>Donor WCC antibodies negative.</td>
<td>Reclassified as TACO</td>
</tr>
<tr>
<td>3</td>
<td>1 unit of pooled platelets</td>
<td></td>
<td></td>
<td></td>
<td>DNP Overload not related to transfusion</td>
</tr>
<tr>
<td>4</td>
<td>18 units of RCC 12 units of FFP 2 units of Platelets</td>
<td></td>
<td></td>
<td></td>
<td>DNP Reaction related to underlying condition TACO and TRALI excluded</td>
</tr>
</tbody>
</table>

N/A Not Applicable
Recommendations

• Although there were no cases confirmed as TRALI in 2005, it is important to emphasise the ongoing need to use blood components appropriately, as TRALI has been identified as the most important cause of transfusion related mortality and morbidity to the UK SHOT scheme (Stainsby et al 2006).

• The NHO scheme collects reports of TRALI and TACO and it can often be difficult to differentiate between them. Clinical evaluation of pre and post transfusion fluid balance and pre and post transfusion B-natriuretic peptide (BNP) levels may be helpful in differentiating TACO from TRALI (Zhou et al 2005).

• 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 deferring new and lapsed female plateletpheresis donors with a history of pregnancy. Moreover, 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 Associated Circulatory Overload (TACO)

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).

There were 25 reports of TACO. This is an increased number of reports compared to previous years. Nineteen were associated with red cells, four associated with plasma and two with multiple blood products. One of the reactions associated with red cells was originally submitted as TRALI as was one of the cases associated with multiple blood components. Thirteen of the patients were males and twelve were female. Eighteen of the patients were over 70 years of age. Twenty one (80%) had underlying cardiac disease.

Only one patient, a young woman treated with multiple blood components for massive obstetric haemorrhage had no history, apart from asthma which had not required treatment, of underlying disease. This case was originally submitted as a possible TRALI, but the patient was in marked positive fluid balance (6 litres) and the X-ray showed bilateral pleural effusions in addition to pulmonary edema.

Four patients who received SD plasma for the correction of an abnormal INR, - only one of whom had evidence of bleeding - developed TACO. Two of these patients were due to undergo procedures. Only two of the four patients had been given Vitamin K to correct the INR.

Twelve patients developed TACO after a single unit transfusion. The patient’s weight was available in only 14 patients and fluid balance information was available in only nine patients. Time of onset of symptoms was given in 15 cases and was between 10 minutes after starting the transfusion to 18 hours later with a mean onset of 4 hours.

Diagnosis was based on clinical findings in 16 cases, in a further 9 cases an X-ray was performed.
The commonest symptom and signs were dyspnoea and falling $O_2$ saturations. Tachycardia was present in nine cases and hypertension in only six cases. The two patients with hypotension had massive bleeding. (Figure 3).

Ten (40%) of the patients had been on regular diuretics. Only three patients received a diuretic immediately pre-transfusion; only two of these were patients on regular diuretics. One further patient received a diuretic during the transfusion. One case who received multiple components for treatment of post chemotherapy anaemia and thrombocytopenia was possibly in fluid overload before the transfusion.

Twenty one patients (84%) received a diuretic post transfusion.

Seventeen patients recovered fully. Time to recovery was given in only 13 patients but recovery was complete by 24 hours in eight patients. Two patients required ongoing cardiac support and four patients died later of their underlying condition unrelated to transfusion. One of the patients given SD plasma to correct an abnormal INR developed TACO and subsequently died. This was a severely ill patient with underlying liver disease but the transfusion was considered unnecessary as the patient was not bleeding. The death was considered possibly related to the transfusion.
Recommendations

- All patients should be assessed pre-transfusion to assess their risk of developing TACO. Particular attention should be paid to the identification and management of ‘high-risk’ patients who include:
  - Patients of low body weight
  - Elderly patients
  - Infants and children
  - Physiologically compromised patients, especially with a history of cardiac, respiratory or renal insufficiency or chronic anaemia.
  - At risk patients should be transfused slowly at a rate of 1ml/kg/hour (Popovsky 2001) and close attention should be paid to the patient’s fluid balance status not only during the transfusion but also in the 24 hour period prior to transfusion. Single unit transfusions can result in TACO and therefore should be monitored as closely as multiple unit transfusions.
  - 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 and cardiac 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
  - The risk of TACO can be reduced by the administration of pre-transfusion diuretics. This may also be necessary for those on regular diuretic therapy.
  - In very low weight/at-risk patients, it may be advisable to transfuse units with an interval of 24 hours between each unit, in combination with pre-transfusion diuretics. Some patients take as long as 24 hours to readjust blood volume particularly in those patients whose venous pressure is raised pre-transfusion. (Mollison et al 1997)

Suspected Transfusion Transmitted infection

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 which 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 is less than 1 per 4 million components transfused, and for HCV is less than 1 per 4 million components transfused (O’Riordan, personal communication). 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, 2004, 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 antibody is a mandatory test, donors with cleared infection found reactive for the marker are also deferred.
Investigations into suspected transfusion transmitted viral 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.

Bacterial infection remains a rare but serious complication of transfusion, particularly associated with platelets which are stored at 20°C (Stainsby et al, 2006). The IBTS has introduced bacterial screening of all platelets before issue and the diversion of the first aliquot of the blood donation into the blood testing pouch which are measures which have been shown to reduce the risk of bacterial contamination (McDonald 2006).

The risk of receiving an incorrect blood component is in fact much greater than the risk of receiving a transfusion-transmitted infection. Over the eight year period since the United Kingdom Serious Hazards of Transfusion (SHOT) began reporting, confirmed reports of TTI accounted for 1.8% of incidents in comparison to reports in the IBCT category, which accounted for 70% (Stainsby et al 2006)

**Findings**

Seven initial reports of suspected TTI were received; three hepatitis B infections, two HIV infections, one suspected bacterial infection and one parasitic infection. On preliminary investigation of one of the HBV cases (Case 7) the patient had been diagnosed as having Hepatitis B many years before and no further donor investigations were undertaken. This report has been categorised as a DNP. The remaining six cases were accepted for further evaluation. After evaluation, transfusion transmitted infection was excluded in all cases.

Two cases of suspected HIV were investigated. In one case of HIV (Case 6) where the donors had all tested negative for HIV by serology and PCR at the time of donation, there was clinical evidence that the patient had already been infected before the transfusion and no further donor investigations were undertaken. In the second case (Case 3) of HIV all four donors were investigated and transfusion was excluded as the source of infection.

In the two Hepatitis B cases (Cases 1 and 2) investigated, testing of archived patient samples showed evidence of infection prior to a number of the transfusions and reduced the extent of donor investigations necessary. Transfusion was excluded as the source in both cases.

One case (Case 5) of a possible bacterial infection associated with red cells was reported. The patient, who was neutropenic following chemotherapy for an underlying haematological malignancy, was transfused as a day ward patient, became ill at home some hours later and was admitted with Serratia Marcescens septicaemia the following day. The blood bag was no longer available for culture but the FFP from that unit showed no growth and following review, transfusion was considered unlikely to be the source of the infection.

The final case (Case 6) involved possible transfusion transmitted parasitic disease. Toxoplasma gondii is an intracellular parasite which is present in white cells of infected individuals. The infection is commonly passed by the oral route but can rarely be transmitted by transfusion in immunocompromised hosts. It is associated with mild infections except in the immunocompromised or if it occurs pre-natally. If transmitted pre-natally, it can be associated with
IgM antitoxoplasma antibody was detected in a neonate who was found to have had two red cell transfusions, one of which was a whole blood exchange transfusion shortly after birth. Both of the donors were recalled. One of the donors was found to have serological evidence of recent resolving toxoplasmosis infection. The donor had been well at the time of donation but developed respiratory symptoms subsequently. As all units are leucodepleted during processing the risk of transmitting toxoplasmosis through leucodepleted blood is low. The infant showed no evidence of illness or infection and suffered no sequelae. Further investigations including Polymerase Chain Reaction (PCR) testing for Toxoplasma DNA showed no evidence of active infection in the baby and it was concluded that the antibody detected was a passively transferred antibody as a result of the exchange transfusion.

Table 6  Suspected Transfusion Transmitted Infection

<table>
<thead>
<tr>
<th>STTI Case No:</th>
<th>Date of Incident</th>
<th>Age &amp; Gender</th>
<th>Infectious Agent</th>
<th>Donors Implicated</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>2002 2005</td>
<td>Adult M</td>
<td>Hepatitis B</td>
<td>3</td>
<td>Donors investigated Transfusion excluded</td>
</tr>
<tr>
<td>Case 2</td>
<td>2005</td>
<td>Adult F</td>
<td>Hepatitis B</td>
<td>11</td>
<td>Donors investigated Transfusion excluded</td>
</tr>
<tr>
<td>Case 3</td>
<td>2000</td>
<td>Adult M</td>
<td>HIV</td>
<td>4</td>
<td>Donors investigated Transfusion excluded</td>
</tr>
<tr>
<td>Case 4</td>
<td>2004</td>
<td>Adult F</td>
<td>HIV</td>
<td>3</td>
<td>Clinical evidence of infection before transfusion Transfusion excluded</td>
</tr>
<tr>
<td>Case 5</td>
<td>2005</td>
<td>Elderly F</td>
<td>Serratia Marcescens</td>
<td>1</td>
<td>FFP from donation cultured negative Transfusion considered unlikely</td>
</tr>
<tr>
<td>Case 6</td>
<td>2005</td>
<td>Neonate F</td>
<td>Toxoplasmosis</td>
<td>2</td>
<td>Passive transfer of donor antibody. Active infection excluded</td>
</tr>
<tr>
<td>Case 7</td>
<td>2005</td>
<td>Adult M</td>
<td>Hepatitis B</td>
<td>30+</td>
<td>Laboratory evidence of infection before transfusion Transfusion not implicated DNP</td>
</tr>
</tbody>
</table>
Pre-deposit Autologous Donation

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

Pre-deposit autologous blood donation (PAD) is undertaken in a small number of hospitals and in the IBTS. All units involved in autologous transfusion are designated blood establishments under EU Directive 2002/98/EC. Three reactions associated with PAD donation all of which were in patients undergoing orthopaedic surgery were reported. See Table 7. All of the donors were females and two of the three donors were adolescents. None of the reactions were severe and the patients recovered without complications. The pre-deposited autologous blood was used around the time of operation in two of the three cases.

Table 7 Pre-deposit Autologous Donation

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Gender</th>
<th>Weight kg</th>
<th>Hb g/dl</th>
<th>Planned Procedure</th>
<th>No of planned donations</th>
<th>Reaction Donation History</th>
<th>Complications</th>
<th>PAD unit(s) transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAD 1</td>
<td>Adult</td>
<td>F</td>
<td>68 kgs</td>
<td>12.4</td>
<td>Orthopaedic surgery</td>
<td>1</td>
<td>Blood donor</td>
<td>Nausea and headache following day</td>
<td>Unit transfused</td>
</tr>
<tr>
<td>PAD 2</td>
<td>Adolescent</td>
<td>F</td>
<td>49 kgs</td>
<td>13</td>
<td>Orthopaedic surgery</td>
<td>2</td>
<td>Had donated 1st unit. Reaction occurred at end of 2nd unit</td>
<td>Pallor, light-headedness, hypotension</td>
<td>Both units transfused</td>
</tr>
<tr>
<td>PAD 3</td>
<td>Adolescent</td>
<td>F</td>
<td>55 kgs</td>
<td>14.9</td>
<td>Orthopaedic surgery</td>
<td>2</td>
<td>Reaction occurred at end of 1st unit. 2nd unit taken 1 week later without problem</td>
<td>Felt weak, pallor, sweating</td>
<td>Neither unit transfused</td>
</tr>
</tbody>
</table>
Serious Adverse Events

Incorrect Blood Component Transfused (IBCT)

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, 1996).

This category accounted for 65% of incidents reported in 2005, (173 of 266), an increase of 47 (37%) from 2004. The Site of First Error indicates the stage in the transfusion chain where the IBCT first occurred.

Introduction

Adverse events are classified as follows

Level 1
Events with the real potential for permanent injury or to be life threatening.
In 2005 there were 65 reports (37%) which were classified as Level 1 incidents.

Level 2
Events that are very unlikely to cause permanent harm or have the potential for minimal or transient harm.
In 2005 there were 48 reports (28%) which were classified as Level 2 incidents.

Level 3
Events with no realistic potential for harm.
In 2005 there were 60 reports (35%) which were classified as Level 3 incidents.

Findings
There were ten cases in this category.

Pre-transfusion Sampling Error
- One case was due to a bedside sampling error where a patient was transfused on the basis of a low Haemoglobin (Hb). The Hb and group and crossmatch sample were taken from the wrong patient. The transfusion went ahead in spite of concerns that the Hb, which was being repeated, was not correct. Fortunately, by chance, both patients were of the same blood group so the patient suffered no ill effects. See IBCT case report 1 page 26.

Laboratory problems
- Seven of the ten errors originated in the laboratory, five occurring on-call, three involving massive transfusions.

ABO Rh typing problems
- In one case, two units of ABO incompatible red
cells were transfused during massive haemorrhage when emergency ABO grouping tubes were read in the wrong sequence. The patient was incorrectly grouped as B Rh D negative but on confirmatory typing shortly afterwards was found to be group O Rh D positive. See IBCT case report 2 page 26.

- One case involved the issue of group O SD plasma and O red cells to a group A neonate out of hours. The grouping by microtitre plate technology was performed correctly but the results were recorded incorrectly.

- Two cases involved Rh D typing errors. In one case, a postmenopausal female patient was transfused with Rh D positive cells although she had been correctly grouped as Rh D negative on the automated grouping machine. Both medical scientists checking the results manually on the sample misinterpreted the result and changed the result on the computer to Rh D positive. In the second case, during a massive transfusion the on-call medical scientist read the Rh D group incorrectly and the male patient, who was Rh D positive, received Rh D negative cells unnecessarily.

- In a further case, an issuing error during massive haemorrhage led to a group B positive patient who was correctly switched to group O red cells, receiving group O positive plasma instead of continuing to receive group B plasma.

Communication Failures

- Three cases involved failures in communication between the transfusion centre and the hospital laboratory, between the transfusion laboratory staff and on-call laboratory staff, or between the ward and the laboratory. These led to the issue of a wrong component.

- In one of these cases unwashed group O Rh D positive platelets were issued by the transfusion centre for a group A Rh positive neonate.

- In the second case, where there was a shortage of group specific SD plasma due to a misunderstanding by laboratory on-call staff, the patient received cryo poor plasma instead of SD plasma of another group which was the recommended alternative product.

- The final case involved communication between the ward and the laboratory where SD plasma instead of platelets were given to a patient where there was no written order to the laboratory and the prescription was not checked before administration.

Supply problem

- One case was a supply issue in the hospital where a group A patient who required four units of plasma was given two units of group O SD plasma in addition to two units of group A SD plasma because there was insufficient group A SD plasma. Where plasma of the same group is not available, AB plasma or B plasma should be used wherever possible to avoid possibility of haemolysis from anti A or B haemolysins in group O plasma. Group O plasma should be reserved for group O patients only. The patient, however, suffered no sequelae as group O SD plasma is a pooled product with low haemolysin titres. (BCSH guidelines 2004)

- There were no fatalities or major morbidity associated with any of these transfusions.
Detailed case reports

**IBCT Case Report 1:**
**Wrong patient transfused**
A transfusion dependent male patient needed a FBC to check his Hb level. A Hb result of 5.9g/dl was telephoned back to the clinical area but the medical scientist who processed the FBC sample was familiar with the patient’s usual Hb level and noted that this low result was unusual and informed the clinical area of this. The treating physician decided to repeat the Hb but also prescribed two units of red cells. The repeat specimen result was Hb 8.3g/dl but by the time this was available, the first unit had already commenced.

On investigation it was established that the phlebotomist had taken the samples from the wrong patient. The correct patient identification procedure was not performed as the patient was not asked to identify himself nor was the ID wristband checked. A total of 300mls of red cells had been transfused to the wrong patient. Fortunately this patient happened to be the same blood group as the patient from whom the sample had been taken and had no complications as a result of this unnecessary transfusion.

**IBCT Case Report 2:**
**Transfusion of ABO incompatible red cells during massive transfusion**
This young male patient required a massive transfusion during the on-call period. The specimen was grouped using a quick spin method and the result was interpreted as group B Rh D negative and two units of B Rh D negative cells were issued. Both units were transfused immediately. However during the confirmatory second ABO group, the group was found to be O Rh D positive. The clinical staff were notified and the patient subsequently received a large number of group O Rh D positive components to cover emergency surgery. There was no evidence of an acute haemolytic reaction but his bilirubin post-transfusion was 59 mmol/l. He went on to make a full recovery.

Investigation of the error revealed that the tubes had been read from the rack in the wrong sequence leading to a wrong blood group determination. The laboratory scientist covering the on-call period did not normally work in transfusion but regularly covered the on-call rota.

**Recommendations**
- Pre-transfusion blood sampling is a critical step in the blood transfusion process and failure to ask the patient to identify themselves and to check the details against the patients wristband can lead to a patient being transfused with blood which may be ABO incompatible.
- Patients must have a wristband in place before samples for transfusion are taken or blood is administered.
- Pre-transfusion samples must be labelled at the bedside using the wristband details. Pre-labelled tubes or addressograph labelled tubes are not acceptable.
- Prior to administration, the prescription should be checked and the details on the unit must be checked against the patient’s wristband at the
bedside and wherever possible, the patient should be asked to identify themselves. Remote checking is an unacceptable and dangerous practice.

- Electronic forms of patient and blood component/product identification are now available and are recommended as they provide the highest degree of security. As these systems are currently not in place in most hospitals, manual bedside identification procedures at sampling and administration remain the gold standard and must be strictly adhered to (NBUG, 2004).

- Wherever possible, written or electronic blood/blood component transfusion requests are preferred. In the event of telephone orders, hospitals should have a policy regarding the information required to ensure the right product and patient are identified (NBUG, 2004).

- A check must be performed on the component and on the identification documentation to ensure that the correct component is selected at the site of collection.

- Where possible blood grouping should be read electronically with electronic transmission of results rather than manual entry into the computer.

- Editing/changing data, particularly test results, on computer systems should be strictly controlled. Access to this function should be reserved at supervisory level at a minimum.

- As far as possible, an uninterrupted working environment should be maintained during the crossmatch and issue of units, to avoid distraction which may lead to errors.

- There is evidence that the risk of error is increased in emergency/massive transfusion setting (BCSH 2006c, Stainsby et al, 2006).

- Hospitals should have a massive transfusion protocol in place specifically designed for their hospital taking into account local factors such as ready availability of blood and blood components. (NBUG 2002). This is particularly important in obstetric haemorrhage. The protocol should be activated periodically to ensure that flaws are identified, and staff, - including on-call staff - are familiar with it. Providing blood for massive haemorrhage puts a considerable strain on the laboratory on-call staff, particularly if they do not routinely work in blood transfusion.

Unnecessary Transfusions
Findings
Forty transfusions which were considered unnecessary were reported making up 23% of IBCT cases reported. These were as a result of either decisions based on incorrect or outdated laboratory results, or transfusions based on errors in clinical decision making. Ten of the transfusions involved red cells, 19 involved plasma and 11 involved platelets.

Unnecessary Transfusion due to sample problems
- There were four unnecessary red cell transfusions associated with incorrect results due to problems with the samples. In three cases blood samples were probably taken from an arm with a drip running and in one case there were clots in the sample. These are in addition to the case described earlier, where a patient who did not need a transfusion was transfused on the basis of another patient’s Hb result.

- In a further case in an emergency setting, the patient was given platelets on the basis of a platelet count performed on a haemodiluted sample which the laboratory had queried and which had been repeated and found to be normal.
Unnecessary Transfusion based on old results
• There were five reports of unnecessary transfusions based on old Hb results. Two of the transfusions were erroneously prescribed on the basis of results which were actually the pre-transfusion Hb levels for which the patients had already received a red cell transfusion.

• A further case was based on paper laboratory results which were a month old as the doctor had no access to the laboratory computer. In another case user difficulty in accessing the laboratory computer records led to a Hb from the wrong date being selected. A further case was based on a written incorrect Hb level in a nursing note in the patient’s chart.

Laboratory Processing Errors
• Error in reconstituting a reagent causing an incorrect coagulation screen result led to a patient receiving an unnecessary plasma transfusion.

• Two patients received platelet transfusions as a result of incorrect platelet counts, possibly associated with clots in the samples not detected at the time of processing in the laboratory. Both these events involved on-call medical scientists who did not normally work in haematology and did not request repeat samples to confirm the low platelet counts.

Errors in clinical decision making

Unnecessary use of SD Plasma
Eighteen reports of unnecessary plasma transfusions due to errors in clinical decision making were received.

Associated with Warfarin Reversal
• Fourteen were associated with use of SD plasma to reverse warfarin anticoagulation.

• Ten of these were for warfarin reversal pre-procedure or surgery where either warfarin or warfarin discontinuation and Vitamin K administration would have been sufficient.

• In two of these cases failure to use Vitamin K was due to a concern about the possibility of difficulty in re-anticoagulating the patient.

• In two of the remaining four cases, there was either no bleeding or minor bleeding and discontinuation of warfarin administration and/or Vitamin K administration would, again, have been sufficient.

• The two remaining cases involved the use of plasma instead of/as well as prothrombin complex concentrate (PCC). In one of these cases, the patient had a suspected Cerebrovascular Accident (CVA) with an INR of 7.9 and PCC, which was available from the laboratory was considered the treatment of choice. In the second case, the haematology team had treated the patient who was bleeding with PCC but the following day the patient was given a plasma infusion where, if further treatment had been required, PCC would have been the treatment of choice.

Associated with other conditions
• In four cases, plasma usage was inappropriate either because no treatment was required, as the prothrombin time was normal or only slightly prolonged, or vitamin K was the appropriate therapy.

• In one case, where the patient was already extremely ill, the transfusion of plasma was associated with circulatory overload which may have contributed to mortality. (This case is in addition to the case collected in the TACO section where a severely ill patient with underlying liver disease given SD plasma to correct an abnormal INR developed TACO and subsequently died. In this case also the transfusion was considered unnecessary as the patient was not bleeding and
death was considered possibly related to the transfusion).

Platelets

- Eight case reports involved the inappropriate use of platelets.

- Four involved platelets used in patients with Immune Thrombocytopenic Purpura (ITP). Three reports involved the same patient who received a number of units of platelets perioperatively and post operatively which were administered in spite of haematology advice.

- In the second case associated with ITP, the medical record which indicated that the patient had ITP was not available to medical staff until four days after his admission on a Friday evening and the decision to transfuse was made on clinical symptoms and on advice from another hospital. However, the advice to give platelets was misinterpreted and the patient received six units of pooled platelets.

- In another case, the patient received four units of pooled platelets. In this case although the patient was bleeding, the patient’s platelet count was in fact normal.

- In both these cases, the clinician ordering the component did not realise that since 2000, platelets are issued by IBTS as pools of platelets from four donors, thus exposing the patients to a large number of donors each and also running the risk of volume overload.

- Three further cases involved giving platelets when the platelet count was normal (one case) or where the platelet counts were not considered low enough to warrant treatment in the given clinical situation (two cases).

- Two further cases of inappropriate transfusion of platelets which were associated with reactions have been captured in the AHOSTR reaction category see page 11.

Red cells

In one case, red cells were transfused because of a failure in communication between the medical and surgical teams looking after the patient. The surgical team requested a transfusion to bring Hb to a 9-10g/dl. The medical team prescribed a specific number of units without documenting the desired rise in Hb in the chart and did not check the Hb before transfusing the last unit. The post transfusion Hb was 13g/dl.

Recommendations

- Care must be taken in ensuring that the decision to transfuse is based on the most recent results.

- Computer access to up to date results which are presented in a user friendly format would reduce the risk of transfusion based on old results.

- Medical and nursing staff should be trained in sample taking techniques. Blood samples, wherever possible, should not be taken from the same limb where IV fluids are being infused or where this is unavoidable, the infusion should be stopped before taking the sample.

- Where the Hb level or the platelet count or coagulation profile is unexpected or does not match the clinical picture, the sample should be repeated.

- Red cell transfusions should be administered on a unit by unit basis in the non-emergency setting based on the post transfusion Hb level.

- Plasma is not indicated for elective anticoagulant reversal. Plasma should only be given where
emergency reversal of anticoagulant therapy is indicated and where prothrombin complex concentrates which are now licensed for this indication are unavailable or are considered inappropriate e.g. coexistence of DIC or liver disease. (BCSH Guideline 2004)

- These recommendations are based on the fact that FFP contains insufficient concentration of the vitamin K dependent factors to provide adequate reversal. The response to concentrates is also faster (within 15 minutes) and does not lead to volume overload and the risk of TACO or the other risks associated with plasma e.g. allergic/anaphylactic type reactions or TRALI where SD plasma is not available (Lankiewicz et al 2006).

- Reluctance to give small doses of Vitamin K to reverse warfarin because of concerns about the difficulty of re-warfarinising the patient leads to inappropriate plasma transfusions. Small doses of 1-5mg of Vitamin K IV do not render the patient refractory to re-anticoagulation. (Makris and Watson 2001).

- A mild increase in INR (INR<2.0) is rarely reversed by the use of plasma (Abdel-Waheb et al, 2006).

- Ongoing education on the indications for and the appropriate dosage of components should be provided for all grades of medical staff.

- It should be possible to access a patient’s medical records out of routine working hours.

Failure to supply special requirements in CMV negative and/or irradiated components 2005

Findings

- Twenty cases reported involved failure to administer CMV negative and/or irradiated components to patients requiring them. This figure accounts for 11.5% of errors within the total IBCT category. The vast majority, 95% (19 cases) were prescription and or request errors and 68% (13) of these were due to lack of knowledge of the indications for prescribing CMV negative/irradiated blood components.

- One error was due to failure to check the patient’s previous history in the medical record. In a further case, the information was communicated from the referring tertiary care hospital by the medical team to the laboratory in the receiving hospital. This information was logged on the laboratory system but was not transmitted to the clinical side and an alert sticker, which would have been standard practice, was not applied to the patient’s chart. When components were subsequently ordered for the patient, the Laboratory Information System (LIS) did not warn the medical scientist of the special requirements because the warning flag did not carry over from the previous record.

- One case involved failure to give CMV negative red cells to a woman in pregnancy.

- Four cases involved massive/emergency transfusions. In one of these, special requirements were prescribed but not requested on the request form. In the remaining three cases, the prescribing clinicians were also unaware of the indications for special requirements.

- Two cases involved neonatal patients; one of which was in the emergency setting. One of these
cases is discussed further in the neonatal section on page 35.

**Recommendations**

- Hospitals must ensure that patients who require specialised products receive the correct product wherever possible.

- Special chart stickers should be put on the records of patients requiring special products. In addition development of a special patient card should be considered as patients may require shared care or admission to different hospitals.

- Hospital blood banks must have fully validated computer systems which should preserve previous information entered and have audible alarms/alerts to minimise opportunities to override screen warnings.

- There is considerable variation in local guidelines on the requirements for irradiated and/or CMV negative products and not all cases reported probably required special products.

- In view of this, in the emergency setting, delay in transfusion due to failure to source CMV negative and/or irradiated components may outweigh any risks involved in not providing irradiated or CMV negative blood as all blood components are leucodepleted and the risks of CMV infection and/or GvHD are very low.

**Unit labelling Errors**

There were seven unit labelling error reports, six of which involved red cells and one involved platelets.

In one case, involving red cells, it was laboratory practice to check only the last four digits on the final check prior to issue. In this case the last four digits in the two labels were very similar and it was not noticed that they had been applied to the wrong pack. There has since been a change in practice to check all seven digits on the unit labels.

In one of these cases, the error occurred when a medical scientist who did not normally work in transfusion was covering due to staff shortages. In one case, see below, failure to remove the label from an unused unit led to a traceability problem.

**IBCT Case Report 3:**

**Problem due to unit labelling error**

An elderly male patient, with a malignant haematological disorder, required transfusion of one unit of red cells for anaemia and one unit of platelets. In error, two units of red cells were crossmatched. This was detected before issue. Only one unit of red cells was then issued as ordered but the compatibility label on the issued unit related to the other unit, which had been put back into stock. The error went unnoticed during the collection and administration of the unit. The error was discovered some days later during an attempt to issue the second unit for another patient. At this stage the laboratory computer system indicated that the unit had already been issued and transfused.

**Recommendations**

- Failure to correctly label units may lead to administration of the wrong blood to the wrong patient and may also cause problems with verification of transfusion of the unit which is required by EU Commission Directive 2005/61/EC.

- There should be a dedicated area in the laboratory for labelling products.

- Wherever possible, only the units from one crossmatch should be labelled and issued at any given time to avoid errors.
• At the time a unit is issued, there should be a final check of transfusion service records and each unit of blood or component (Brecher et al, 2002).

Errors surrounding the Collection, Storage and Handling of Blood Components

Findings

Storage and handling problems

Thirteen adverse events relating to storage and handling of components were reported.

• Eight cases involved red cells.

• In one case, as the patient was reluctant to be transfused at the time, red cells were stored in the domestic ward fridge for three hours before being returned to the laboratory fridge. The unit was subsequently reissued from the laboratory fridge although the log book showed that the unit had been out of controlled storage beyond the allowed 30 minute period.

• In another case, four units of red cells required in a massive transfusion were stored in the pharmacy fridge and two of them were transfused before the error was detected.

• In a further case, red cells left out of a satellite fridge for an hour were subsequently returned to the laboratory and transfused two days later.

• Three of the cases, all involving neonates, related to the transfusion of blood which was not commenced within 30 minutes after issue from the fridge and was not transfused within the four hours allowed by the NBUG guidelines. These cases are discussed in the neonatal section (NBUG 2004).

• Four cases related to SD plasma where thawed SD plasma was administered outside the recommended expiry time.

• A final case involved two units of platelets which were left on the laboratory bench for over eight hours due to busy workload on the ward instead of being collected and transfused immediately.

Recommendations

• Red cells must be transfused within four hours of leaving the blood fridge (NBUG 2002). If the transfusion cannot be commenced (difficulty with the venous access etc.) the unit must be returned to a blood fridge within 30 minutes and the laboratory informed.

• To prevent delays, the prescription should be completed, venous access checked and pre-transfusion observations taken prior to collection of components in the non-emergency setting.

• Blood must never be stored in ward, pharmacy or other fridges but only in temperature controlled blood fridges.

• Deviations in storage of blood components where the component is subsequently transfused must be reported to the NHO under EU Directive 2002/98/EC and Commission Directive 2005/61/EC.

Expired units

• Six cases related to use of units after expiry.

• In one case, in a massive transfusion when the computer was down for routine maintenance, a unit which had expired two days previously was issued manually. Although the expiry date was
recorded on the register, the date was not noticed at collection or when being administered.

• In a second case, again, in an emergency transfusion, six units of red cells were cross-matched and placed in the issue fridge for the patient. Two of these units were due to expire at midnight. The units were not arranged in the issue fridge in order of age and the compatibility report form did not contain a comment highlighting the expiry time. The patient received four units overnight, but the expiry dates were not checked pre-transfusion and this led to the transfusion of one of the units of expired blood some hours after expiry.

Recommendations
• The expiry date should be part of the routine pre-administration check. Units which have expired must not be transfused.

• A number of these cases arose because units which had expired had not been removed from the stock/issue fridge. Laboratory staff should routinely do a physical check of units to remove expired units. This is particularly important where a shutdown of the laboratory computer which would prevent issue of expired units is planned.

• In the interest of stock management, laboratories may issue units which are due to expire where it is expected that transfusion is needed immediately. Some of the crossmatched units may therefore be close to expiry when clinically required and clinical staff should be informed of the need to use the close to expiry units first. The compatibility report should also draw attention to this and list units in order of expiry to alert ward staff.

• Transfusion should be completed prior to component expiration wherever possible. In individual cases where a unit has commenced and will expire before a transfusion can be completed, a medical decision may be made to continue the transfusion.

• The risk of stopping a necessary transfusion particularly when supplies are short, coupled with the risk of exposing the patient to another donor, must be balanced against the remote risks of completing a transfusion shortly beyond the expiry time (AABB 2002).

Problems with infusion
• Three cases were associated with problems with infusion.

• In one case, because the ward was very busy the 15 minute transfusion check did not take place until one hour later, by which time the unit had infused completely. Fortunately the patient suffered no sequelae.

• One report related to use of wrong infusion set and a second case related to failure to use a blood warmer in a patient with cold agglutinins.

• There were also a number of reports where blood was transfused outside the four hour limit laid down by NBUG (NBUG 2004).

Identification/documentation errors
There were a number of reports related to documentation errors at initial clerking, at sampling or administration, many involving date of birth discrepancies. Most of these were level 3 errors.

One case however, which shows how an initial error can persist and give rise to further errors if protocols designed to catch/prevent errors are ignored, was classified as a level 1 error and is described below. Fortunately there were no sequelae for the patient.
IBCT Case Report 4
Wrong medical records selected
This patient, who had been transferred to another hospital for follow-up care, was prescribed four units of red cells for anaemia post surgery. The patient’s identification wristband from the first hospital was not replaced on arrival at the new hospital. At initial clerking, however, a wrong medical record was selected for this patient. The wrong record belonged to a patient with the same surname, first name and second line of address.

A pre-transfusion sample was taken from the patient and labelled using information provided by the patient. The wrong MRN, however, was used as the incorrect medical record was used to obtain this information. Therefore, the wrong MRN but the correct date of birth was printed on the compatibility label on the issued units of blood. At administration the nurses noticed that there was a discrepancy between the information on the medical record, the compatibility label on the unit of blood and the wristband. The details on the wristband were altered (i.e date of birth and MRN) to what were considered the correct patient identification details taken from the incorrect medical record. The possibility that the medical record was not the patient’s was considered, but it was felt that the correct patient and record was involved. The patient was not included in the checking process.

The error was discovered when different nurses checking the fourth unit noticed that the date of birth on the crossmatch report form and the medical record were different.

• In a further case, failure to fill in a request form correctly led to a delay in transfusion and use of emergency O Rh negative red cells.

Recommendations
• Attention to correct documentation is important to avoid the possibility of misidentification of patients or samples, leading to an incompatible transfusion. A study has shown that incorrectly labelled samples have a 40 times higher risk of being from the wrong patient (Lumadue et al 1997, Dzik, 2003)

Miscellaneous
• There were a number of miscellaneous errors most of which were categorised as level three.

• A number related to errors in writing up prescriptions for components which were correctly ordered for patients.

• Other reports related to inadequate dosage of plasma (one case) or related to the wrong batch number of plasma being recorded (one case).

• A number of reports related to units transfused more than 72 hours after the pre-transfusion crossmatch samples were taken and which had not been removed from the blood issue fridge.

Recommendations
• A repeat crossmatch sample is required if more than 72 hours have elapsed since the time of taking the pre-transfusion sample or between transfusions. If the transfusion has occurred >72 hours and within the last 14 days then the sample must be taken within 24 hours of the transfusion (BCSH 2004)

• Wherever possible laboratory staff should remove unused crossmatched units from issue fridges and
return them to stock after 24-48 hours so that crossmatch expired units are not available for transfusion. The routine pre-transfusion unit expiry checks performed by nursing staff do not cover this, and the information even if provided, may not be noticed on the compatibility form.

- Care should be taken to ensure that all blood components are prescribed.

**Blood Component Incidents involving Neonates and Infants 2005**

- Ten cases involved neonates representing 6% of IBCT cases reported in 2005. 50% of these cases were in the emergency setting. None of the babies suffered sequelae.

- Eight cases involved red cells, one involved platelets and one both plasma and red cells.

- The two reports involving transfusion of plasma and red cells of the incorrect ABO group and failure to issue washed platelets have already described in the Errors Involving Wrong ABO/Rh Group, Wrong Blood Component or Blood Given to Wrong Patient section page 25.

- The remaining eight reports all related to red cells and seven raise issues of particular concern in the neonatal transfusion setting. Paedipacks are specialised blood components for neonates which consist of red cells from the same donor subdivided into 4-5 aliquots of 50-60mls each. A paedipack is reserved for an individual baby. An aliquot of the same unit is used to transfuse the baby each time the baby needs transfusion which reduces the number of donors to which the baby is exposed.

- In three cases, where designated paedipack aliquots were available for the patient but were not used, the babies were exposed unnecessarily to a second donor and, in one of these cases, also to non-irradiated blood. In this case the clinical team opted, in spite of the request being queried by the medical scientist, to use the fresh whole blood non-irradiated emergency unit instead of one of the irradiated paedipack aliquots which were designated for the baby, who had had previous intrauterine transfusions and therefore required irradiated components.

- In another case, the blood had been moved to the standby blood bank fridge because the blood bank fridge was out of order, the paedipack aliquot (which was the last aliquot) could not be found and the computer record, which would have indicated that it was still available was not checked.

- In a further case, the fresh neonatal whole blood emergency unit was used instead of a paedipack aliquot which was the product of choice for this baby with anaemia who would require further transfusion. The clinician was not aware of the difference between the unit types nor was s/he informed that a paedipack could be made available in a short period of time. Because of this, and because of failure to reorder a replacement unit, another neonate requiring emergency transfusion later that day had to be transfused with a stored paedipack aliquot while the replacement unit was being delivered.

- Three cases already mentioned in the Collection, Storage Handling section involved transfusion of blood which had been out of controlled storage for more than the four hours allowed by the NBUG guidelines. In one case, the blood was over four hours out of the fridge before the transfusion was started. The blood which had been issued to theatre was not needed, and instead of being
returned to the laboratory, was transferred with the baby to the special baby care unit. In the other two cases, the blood was out of controlled storage for 70 minutes prior to the transfusion but the transfusion was completed only ten minutes outside allowed time.

**Recommendations**

- Ongoing training must be provided to medical and nursing staff and laboratory medical scientists involved in neonatal care on the specialised requirements of neonates and the special components needed for their care.

- Blood for neonates should not be out of controlled storage until it is required for transfusion. If there is a delay in starting the transfusion there is a danger that the unit may be infused too quickly in an attempt to ensure the product is given within the time frame. This may lead to circulatory overload.

**IBCT involving Factor Concentrates**

- The risk of errors when administering factor concentrate therapy to patients is a constant hazard, particularly if staff are unfamiliar with the different products. To minimise this, secure systems need to be put in place to ensure the administration of the correct product to the correct patient. The National Centre for Hereditary Coagulation Disorders (NCHCD) has produced a standard protocol for staff administering factor concentrates. This is available from the NCHCD, located at St James Hospital, Dublin 8.

- There were eight adverse event reports associated with factor concentrates. One event involved the wrong recombinant factor VIII product being given. Three involved errors in dosage, one due a mix-up in calculating the dosage because there had been a change in unit formulation by the manufacturer. In one case, product, which was issued for one patient was given to another patient who also required the same product due to failure to verify patient identification details when collecting the product and at the bedside. Two involved failure to prescribe the product, and one case involved a delay in administration.

**Recommendations**

- The same precautions and identification procedures need to be followed for factor concentrates as for blood components.

- The dosage should be calculated by the prescriber and wherever possible rechecked by the person administering the product.

**Errors associated with Anti-D immunoglobulin**

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

- There were 13 reports of adverse events associated with Anti-D administration.

- In 5 cases it was given in error to individuals who did not require Anti-D.

- In two of these cases, Rh D positive women received Anti-D due to failure to follow administration protocols. See IBCT case report 5 below.
IBCT Case Report 5: Unnecessary administration of Anti-D to Rh D positive mother

This patient required an elective caesarean section and a blood sample was taken for grouping and screening prior to surgery. The patient’s chart had been left out for the doctor who thought the patient was O Rh D negative but did not confirm this by checking the patient’s notes. Anti-D was given despite the patient stating that her blood group was Rh D positive. The error was discovered when the doctor who had prescribed and administered the product went to the medical notes to record the administration and discovered the patient’s group to be O Rh D positive. The patient was exposed unnecessarily to a blood product. There were no guidelines at this hospital and Anti-D was not issued by the laboratory for individual patients but stored in the ward fridge for use by clinical staff.

- In one case, Anti-D was given to a Rh D negative woman because the cord blood sample was incorrectly grouped as Rh D positive. This error occurred out of hours when a medical scientist who did not normally work in transfusion was processing a number of cord samples and transposed two samples.

- In a further case, the patient who had a bleed in early pregnancy grouped as Rh D negative and was given Anti-D. The patient subsequently presented at another hospital where she had delivered her first baby and where she had previously been found to be a weak D. The weak D result was confirmed. As a result the original hospital has changed its Rh D typing procedures.

- In a further case, an unnecessary extra dose was given after a miscarriage.

Omission
- In two cases, Anti-D which should have been given was omitted.

- In one case, the patient had received Anti-D 12 days before delivery and should have received Anti-D again at delivery in line with guidelines (BCSH, 1999).

- In a second case, the patient was not given Anti-D after a sensitizing event.

Delay
- There were five cases where administration was delayed beyond the recommended outer limit of 72 hours post exposure.

- One occurred because a cord blood sample from a baby was originally typed as Rh D negative but the baby was subsequently found to be Rh D positive. Investigations found that the cord blood had not been taken correctly and the sample collected was heavily contaminated with mother’s blood giving rise to the wrong result.

Failure to exclude possible alloimmunisation
- In one case, a Rh D negative patient who presented with a severe haemorrhage at 15 weeks was given Anti-D in line with guidelines, but a pre-administration antibody screen was not taken as a baseline. Anti-D was detected on two further occasions during the pregnancy, but was considered to be due to passive immunisation with Anti-D and no Anti-D quantitations were done. However after delivery at 39 weeks, Anti-D was quantitated and a level of 2.7 iu/ml was found. This level indicated that the patient had become alloimmunised either sometime in this pregnancy or a previous pregnancy.
Recommendations

• Procedures for the identification of the patient prior to Anti-D administration should be as stringent as those performed for transfusion, i.e. checking of the records at the bedside and correct patient identification as per national guidelines (NBUG 2004).

• 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 errors or delay in the administration of Anti-D (BCSH, 2006 a).

• Where Anti-D has not been administered within the 72 hour period every effort should still be made to administer the Anti-D within nine to ten days of the sensitising event as this may afford some protection (British Blood Transfusion Society and Royal College of Obstetricians 1999).

• The detection of Anti-D antibody in pregnancy should not automatically be ascribed to passive immunisation due to Anti-D immunoglobulin administration. The patient may be alloimmunised with the risk that undiagnosed haemolytic disease of the newborn may occur.

• A baseline sample for antibody screening should be taken prior to Anti-D administration for potential sensitising events. Anti-D quantitation should be performed where there is doubt about whether the Anti-D detected is passive following administration or immune in origin. (BCSH, 2006 b)
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McDonald, CP. (2006) Bacterial risk reduction by improved donor arm disinfection, diversion and bacterial screening. Transfusion Medicine, 16(6), 381-396.


Appendix 1
Management of an Acute Transfusion reaction

**Symptoms/Signs of Acute Transfusion Reaction**
Fever, chills, tachycardia, flushing, urticaria, bone/muscle/chest/abdominal pain, nausea, dyspnoea, collapse, hypotension, dark urine or patient generally unwell.

**Temporarily stop the transfusion and call the doctor**
Check temperature, pulse, BP, respiratory rate, oxygen saturation. Check that the identity of the recipient, details on the unit and documentation match.

**Wrong unit and/or ABO incompatible transfusion**
Remove unit and giving set. Leave cannula in place and put up new administration set. Start IV saline infusion. Inform the transfusion laboratory immediately as another patient may be at risk of receiving an incompatible unit. Return unit intact to hospital transfusion laboratory. If ABO incompatible see below for investigation and management as for acute haemolysis and seek expert haematological/medical advice.

**Mild allergic reaction**
Urticarial rash only. Give 10mg chlorpheniramine slowly IV and restart infusion at slower rate.

**Febrile non haemolytic reaction**
Temperature rise <1.5°C. Patient otherwise well and observations stable. Give paracetamol and restart transfusion at slower rate. Observe more frequently.

**Mild Fever**
Urticaria

**Persist or patient becomes unwell**

**Acute haemolysis/bacterial contamination**
Remove unit and administration set. Leave cannula in place and put up a new administration set. Start IV saline infusion. Take blood cultures and samples for repeat group/crossmatch/DCT, FBC, coagulation studies, biochemistry. Check for haemoglobinuria and monitor urine output. Maintain urine output at >100mls/hr. Start IV antibiotics immediately if suspected bacterial transmission. Return unit with all used/unused units to hospital transfusion laboratory. Inform transfusion laboratory and seek expert haematological/medical advice.

**Fever >1.5°C and/or rigors, hypotension, back pain**

**Other severe reaction-non respiratory?**

**Symptoms mainly respiratory/dyspnoea/cough**

**Transfusion Related Acute Lung injury (TRALI)**
Clinical features of acute non cardiacogenic pulmonary edema. Step transfusion. Give oxygen and ventilate if required. Contact anaesthetist for further management and investigation.

**Fluid overload/acute pulmonary overload**
Step transfusion. Give oxygen and frusemide 40-80mg IV.

**Seek Haematological advice where severe acute reactions occur**
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