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

The 2004 Annual Report from the National Haemovigilance Office (NHO) completes five full years of reporting of serious adverse reactions and events relating to blood transfusion in Ireland. In these five years, numerous recommendations and findings have been issued, based on analysis of the incidents reported to the NHO. This has assisted a growing awareness of the extent and type of adverse events/reactions associated with transfusion practice in Irish hospitals and the measures available to address these.

Confidence in the scheme continues and is reflected in increasing reporting rates. As in 2003, 100% of transfusing hospitals in the Republic of Ireland participated in this scheme.

Findings and recommendations for 2004 are detailed in the relevant chapters. Of great concern are the preventable incidents in the categories of Incorrect Blood Component Transfused and the potentially preventable incidences of Transfusion Associated Circulatory Overload. These incidents, combined with events reported to the Near Miss project, highlight errors and areas of high-risk in the transfusion work processes, and provide an important opportunity to improve practice and the quality of care for patients in the context of a no/low blame culture. The findings and recommendations also provide a benchmarking tool for Hospital Transfusion Committees when reviewing practice in their own hospitals. These committees should be in place in all hospitals that transfuse blood and they provide an environment within which any errors identified, together with their root causes, can be effectively evaluated. Appropriate actions to improve future performance and ultimately the safety and care of patients can also be initiated.

Hospital-based Haemovigilance Officers (HVO) are a vital part of the haemovigilance network in Ireland. The NHO is very grateful to HVOs for their continued efforts in heightening awareness and in developing mechanisms to increase transfusion vigilance and staff consciousness in hospitals to reporting such incidents. The input of Transfusion Medical Scientists and Consultant Haematologists is also a central aspect of haemovigilance.

The NHO also acknowledges the continued support of the Medical Director and staff of the Irish Medicines Board (IMB). In particular, the expertise and support of the staff of the IMB’s Pharmacovigilance Department is especially acknowledged.

The EU Blood Directive 2002/98/EC which comes into effect on 8th November, 2005 governs the activities of Blood Transfusion Services and Hospital Blood Banks and has far reaching consequences for
the regulation and management of blood transfusion services in all EU member states. Two articles in particular are relevant to haemovigilance in that they provide a firm legislative basis for haemovigilance and remove discretionary elements currently present in relation to reporting of serious adverse reactions. Article 14 contains specific provisions in relation to the traceability of blood and blood components as far as the patient and Article 15 requires that all serious adverse reactions attributable to the quality and safety of blood and blood components transfused are captured and reported to the competent authority.

A number of cases in this report concern inappropriate use of blood components. While the risks of transmission of the known viruses HIV, HCV and HBV are now extremely small, the emergence of other infectious diseases such as variant Creutzfeldt-Jakob Disease (vCJD) and West Nile Virus (WNV) as new transfusion risks, emphasises the need to use blood appropriately. In June 2005 an Irish blood donor was subsequently diagnosed with vCJD, indicating that vCJD is potentially in the blood supply. Dr. Stefan Laspina who took over as Acting Director of the NHO from the final quarter of 2004 to July 2005, joins with me in acknowledging the ongoing support and efforts of the IBTS Chief Executive Mr. Andy Kelly, National Medical Director, Dr. Willy Murphy and the staff of the IBTS. Their efforts in the continued recruitment of blood donors, who consistently and voluntarily give blood donations and in the processing and distribution of blood and blood components to the highest safety standards are the basic foundations of the national haemovigilance scheme. Sincere thanks also to all those outside of the NHO who contributed to the writing of this report. Finally, the ongoing enthusiasm of the staff of the NHO in their daily efforts to promote best transfusion practice and also their patience and support in compiling, drafting and writing this report is personally acknowledged.

Dr. Emer Lawlor
Director,
National Haemovigilance Office

Dr. Stefan Laspina,
Acting Director,
National Haemovigilance Office
The national haemovigilance scheme is a confidential anonymised system, co-ordinated by the National Haemovigilance Office (NHO) and dedicated to the achievement of a national standard in practice and quality of care for all patients, before, during and following completion of transfusion, has similarities to pharmacovigilance, the system for monitoring drug safety. It is the professional responsibility of all healthcare professionals to support the concept of haemovigilance, which is achieved through adherence to issued best practice guidelines and reporting of transfusion incidents/events.

From 8th November, 2005, reporting of serious reactions which may be attributed to the quality and safety of blood components will be mandatory as will serious adverse events relating to the testing, storage and distribution of blood and blood components. European Communities (Quality and Safety of Blood and Blood Components) Regulations 2005 SI 360/2005.

**Definition of Terms used in Haemovigilance**

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

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

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 of blood components/products and provide feedback information to those making the report as appropriate.
• Advise on the follow-up action necessary, particularly with regard to suspected hazards.
• Report adverse reactions to the Irish Medicines Board (IMB) according to an agreed procedure.
• Provide ongoing support to hospital-based 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.

A major part of the remit of the office is education and support in relation to best transfusion practice at hospital level.

The NHO is located at the National Blood Centre, (NBC) James’s St., Dublin 8 and functions under the directorship of a Consultant Haematologist with two and a half fulltime equivalent HVO, a Programme Administrator and Assistant Administrator. A fulltime HVO coordinates the ‘Near Miss Project’.

Hospital Transfusion Committees

The NHO actively encourages the development of adequately resourced, multi-disciplinary Hospital Transfusion Committees, and this is also a recommendation of the National Blood Strategy Implementation Group, highlighted in their report to the Minister for Health and Children in 2004. (O’Reilly 2004) The Hospital Transfusion Committee acts as a forum where local transfusion issues can be discussed in a no-blame, non-punitive environment. This multi-disciplinary approach to transfusion supports the development of best practice. Smaller centres may share a committee with their supplying hospital.

Irish Medicines Board

Representatives of the IMB and the NHO had regular meetings during 2004 to review reported incidents, particularly where there was a question about the role of concomitant medication. In addition, the IMB’s Pharmacovigilance Unit provides a valuable resource to the NHO, advising in relation to the overall development of the programme.

National Blood Users Group

The National Blood Users Group, established by the Minister for Health and Children for the purpose of preparing and disseminating guidelines for the use of blood components/products in Ireland has a membership drawn from a wide range of hospital based transfusion disciplines, including haematologists, medical laboratory technologists, perfusionists, anaesthetists, surgeons and nurses, representing a wide knowledge of transfusion practice.

Guidelines published to date are:
• A Guideline for the Use of Blood and Blood Components in the Management of Massive
Haemorrhage (2002)
• Guidelines for the Administration of Blood and Blood Components (2004)

A number of further guidelines will be published shortly.

Near Miss Research Project
A three-year pilot project to capture “near miss” events, funded by the IBTS, is currently operating, with ten hospitals participating. Details of the results are featured in the Near Miss Events chapter of this report.

Education, Promotion and Developments
The NHO continues to support the development of hospital in-service training programmes by working closely with hospital based HVO. The office also encourages the development of audit functions at hospital level in an effort to promote best transfusion practice. Support is also provided in transfusion education for nursing and laboratory medical 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. Smaller centres benefit from the NHO developed ‘in-service’ education programmes as HVO appointments are primarily in centres with a sizeable blood usage. Nationwide networking among HVO is also promoted by regular correspondence through telephone/e-mail communication and personal visits.

The NHO hosted the annual conference in Naas entitled “Haemovigilance-from Concept to Reality” in October 2004. Dr. Emer Lawlor, Director of the NHO, presented a summary of the incidents reported to the NHO in 2003. The keynote speaker was Dr. Paul Ness, Director of Transfusion Medicine Division, Johns Hopkins Hospital, Maryland, USA, who presented on their haemovigilance programme, with reference to delayed haemolytic transfusion reactions (DHTR) incorrectly labelled samples and septic platelet transfusion reactions. Other presentations included:

• The Operation of the BARS System and the SATO wristbands at Addenbrookes. by Claire Sidaway, Specialist Practitioner of Transfusion, Addenbrookes NHS Trust Hospital
• Safe Track by Deirdre Gough, HVO, St. James’s Hospital
• Appropriate Blood Usage (In Neonates) by Dr. Joan O’Riordan Consultant Haematologist, IBTS
• Review of Laboratory Implicated Errors 2003 by Ken Gregg, Monaghan General Hospital
• A Web-based Approach to Improving Blood Transfusion Safety by Paul O’Brien, St. Vincent’s Hospital
• Clinical Experience with Octaplas in Ireland by Dr. Volha Chekrizova, Medical Researcher, IBTS.

The NHO again hosted a poster competition which was judged by Dr. Paul Ness and Ms Claire Sidaway. The winning poster displayed details of Pre and Post Red Cell Transfusion Haemoglobin Audit in General and Vascular Surgery Patients and was compiled by the haemovigilance group in St. James’s Hospital, Dublin.

NHO Audits
Two audits were carried out during the year to evaluate the effectiveness of the Irish Haemovigilance scheme. The first measured the level of satisfaction amongst hospital based HVOs with the support offered by the NHO. The findings were presented at the HVO workshop in October 2004, together with the NHO response and proposed action plan. Staffing levels in the NHO have been improved and
the action plan will be further addressed in the coming year.

The second audit aimed to obtain a clear picture of requirements at hospital level for effective haemovigilance. The findings of this audit were presented at a workshop for HVOs in November 2004 and circulated in early 2005. Some will be incorporated into comprehensive guidelines for standard delivery of haemovigilance.

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 2004, three editions of this newsletter were published.

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

Reports

‘Did Not Progress’

A total of 244 transfusion reactions/events were reported. Of these, 30 did not fulfil the criteria for a haemovigilance event, as on further investigation it was revealed that either the patient’s underlying condition was attributed to symptom development, or that a serious reaction to transfusion had not occurred. In total 214 incidents were reviewed for this report.

‘Nil to Report’

For the second successive year, 100% (81) of hospitals participated in the scheme by returning a ‘Nil to Report Form’ in 2004. 48 of those hospitals (59%) reported a transfusion reaction or event compared to 47 hospitals (58%) in 2003.

Table 1 NHO-Confirmed Reports by Category

<table>
<thead>
<tr>
<th>Total Incidents</th>
<th>IBCT</th>
<th>A/A</th>
<th>TACO</th>
<th>AHOSTR</th>
<th>PAD</th>
<th>TRALI</th>
<th>TTI</th>
<th>DHR</th>
</tr>
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<tbody>
<tr>
<td>214</td>
<td>126</td>
<td>35</td>
<td>15</td>
<td>24</td>
<td>7</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>100%</td>
<td>60%</td>
<td>16%</td>
<td>7%</td>
<td>11%</td>
<td>3%</td>
<td>0</td>
<td>1%</td>
<td>2%</td>
</tr>
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</table>
An Overview:

The First FIVE YEARS of the National Haemovigilance Scheme

Findings: 2000-2004

The NHO scheme has been fully operational since January 2000, and has published annual reports for 2000, 2001, 2002 and 2003. This year represents the fifth year of reporting and presents an opportunity to review the findings for the previous five years.

Approximately 875,841 blood components were issued during the five-year period and a total of 778 adverse transfusion reactions/events were reported to the NHO. During 2000, the first full year of reporting, there were 85 incidents which fulfilled the criteria for a reportable event (NHO Annual Report, 2000). By 2004, the number of events has increased to 214 incidents fulfilling the criteria for a haemovigilance event.

Incorrect Blood Component Transfused (IBCT)

This category captured 428 of the 778 incidents and in keeping with other haemovigilance schemes that collect similar data, it is the largest category reported. It also includes errors and omissions relating to blood products such as anti-D and factor concentrates as these also allow evaluation of the quality of systems in place for transfusion practice. However suspected adverse drug reactions associated with use of these licensed medicinal products continue to be reported to the Irish Medicines Board (IMB) as the competent authority for licensing of medicinal products.

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

- Level 1 incidents are defined as those with the potential for permanent injury or are life threatening, and include wrong blood for wrong patient and the transfusion of blood components/products, which were not required.
- Level 2 incidents were classified as unlikely to cause permanent harm. Between 2001- 2004, 139 (32%) of all IBCT were captured in this group.
- Level 3 incidents have no realistic potential for harm: During the four year period 65 incidents (15%) were reported.
Wrong ABO Transfusion
During the five-year period 2000-2004, 20 reports were received of incorrect ABO group red cells transfused. In 13 of these cases, the red cells were ABO incompatible. The total number of red cells and whole blood issued for this period was 639,198. Therefore, the risk of receiving a wrong ABO red cell transfusion is about 1:31,959 units issued and of receiving an ABO incompatible red cell transfusion is of the order of 1:49,169 units issued. Seven of the thirteen patients who received an ABO incompatible red cell transfusion had symptoms of an acute transfusion reaction. However, all recovered and no fatalities were reported from the reaction.

Table 2 Breakdown of NHO incidents (2000-2004) (n=778)

<table>
<thead>
<tr>
<th>YEAR</th>
<th>IBCT</th>
<th>AA</th>
<th>TACO</th>
<th>DHTR</th>
<th>AHOSTR</th>
<th>TRALI</th>
<th>TTI</th>
<th>PAD</th>
<th>Unusual</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>31</td>
<td>22</td>
<td>8</td>
<td>2</td>
<td>14</td>
<td>-</td>
<td>7</td>
<td>-</td>
<td>1</td>
<td>85</td>
</tr>
<tr>
<td>2001</td>
<td>69</td>
<td>35</td>
<td>16</td>
<td>1</td>
<td>12</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>144</td>
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<tr>
<td>2002</td>
<td>87</td>
<td>31</td>
<td>10</td>
<td>9</td>
<td>8</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>-</td>
<td>155</td>
</tr>
<tr>
<td>2003</td>
<td>115</td>
<td>23</td>
<td>14</td>
<td>9</td>
<td>8</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td>-</td>
<td>180</td>
</tr>
<tr>
<td>2004</td>
<td>126</td>
<td>35</td>
<td>15</td>
<td>4</td>
<td>24</td>
<td>-</td>
<td>3</td>
<td>7</td>
<td>-</td>
<td>214</td>
</tr>
<tr>
<td>TOTAL</td>
<td>428</td>
<td>146</td>
<td>63</td>
<td>25</td>
<td>66</td>
<td>6</td>
<td>19</td>
<td>21</td>
<td>4</td>
<td>778</td>
</tr>
</tbody>
</table>

55% 19% 8% 3% 8% 1% 2% 3% 1% 100%

Table 3 Wrong ABO red cell transfusions 2000-2004

<table>
<thead>
<tr>
<th>Year</th>
<th>Total IBCT</th>
<th>IBCT Involving incorrect ABO red cells</th>
<th>IBCT Involving ABO incompatible red cells</th>
<th>Units of red cells &amp; whole blood issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>31</td>
<td>3</td>
<td>2</td>
<td>124,797</td>
</tr>
<tr>
<td>2001</td>
<td>69</td>
<td>6</td>
<td>4</td>
<td>120,482</td>
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<tr>
<td>2002</td>
<td>87</td>
<td>4</td>
<td>1</td>
<td>127,001</td>
</tr>
<tr>
<td>2003</td>
<td>115</td>
<td>5</td>
<td>5</td>
<td>130,088</td>
</tr>
<tr>
<td>2004</td>
<td>126</td>
<td>2</td>
<td>1</td>
<td>136,230</td>
</tr>
<tr>
<td>Total</td>
<td>428</td>
<td>20</td>
<td>13</td>
<td>639,198</td>
</tr>
</tbody>
</table>

Number per units issued
1:31959 1:49169
Prescription and Request
In 152 cases (36%) the error was the first stage of the transfusion process i.e. at prescription and request indicating the importance of continuing education for medical and nursing staff involved in prescribing and ordering blood components.

Pre transfusion sampling
Pre transfusion sampling has been identified as the site of first error in 32 (7 %) cases. Three of these events were associated with the transfusion of ABO incompatible red cells. This highlights the importance of secure procedures for positive patient identification and emphasises the necessity for each patient to wear a secure ID band at the time of sampling. In one case the transfusion was delayed because of sample labelling problems. It is likely this delay contributed to mortality. The introduction of automated solutions, sample bar coding (Turner et al, 2003), extended/24 hours phlebotomy services, as well as the provision of an ongoing transfusion education programme are key recommendations.

Laboratory Procedures
In 125 cases (29%) the first error occurred in the laboratory. In many cases the error occurred on call and often involved staff from other laboratory disciplines covering the transfusion laboratories indicating the importance of regular training of on call staff. The use of automated grouping and automated transmission of results would help reduce human error through transcription and reading errors.

Site of Collection
In 25 cases (6%) the first error was at the site of collection. These resulted from absence or inadequacy of checking procedures at the time of collecting the component. Adequate checking systems must be in place at the time of collection of blood components/products from either the hospital transfusion laboratory or the satellite fridge.

Bedside administration
In 59 (14%) cases, the site of first error involved the final bedside checking procedure with a failure to accurately identify the patient or the component/product pre transfusion. This resulted in an incorrect component/product being administered. The reasons for such errors are varied but as the final bedside check provides the opportunity to detect and prevent earlier errors its importance is highlighted. The checking procedure must be performed at the bedside and the patient should be asked to verify their identification details. In addition, the patient must be positively identified and an identity (ID) band must be worn at the time of the pre-transfusion sampling and must be in place at the time of transfusion.

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

Wrong haematology values resulting in unnecessary transfusions.
In 26 (6%) cases, transfusion was based on inaccurate or absent haematology results or inadequacy of the checking procedure. In 19 (4%) of
these cases, the transfusion of red cells was involved. Errors in communication can be minimised by using automated transfer of laboratory information to hospital patient identification systems. All clinical areas should have easy access to these systems and staff should be trained in their use so that transfusion decisions are based on the most up-to-date and correct results.

Inappropriate transfusions
Inappropriate transfusions were reported in 48 (11%) cases. Nineteen (4%) of these cases resulted in an unnecessary transfusion of either SD plasma or FFP. In addition, ten reactions captured within the A/A category were as a result of the inappropriate use of plasma. Adherence to national guidelines is important to avoid inappropriate use of blood components and unnecessary donor exposure.

All clinical staff involved in transfusion must be familiar with guidelines for administration of components which will help avoid unnecessary transfusions. SD plasma or FFP is only required for reversal of over anticoagulation in the presence of major bleeding or emergency surgery.

BLOOD PRODUCT ADMINISTRATION (Anti D and Factor concentrates)
Seventy-five of these IBCT reports related to errors in the administration of blood products, 59 (79%) of which involved the administration of Anti-D. Each hospital should have clear policies and procedures for the prescription and administration of Anti-D and the management of Rh D negative women during pregnancy. Procedures for the identification of the patient prior to Anti-D or factor concentrate administration should be as stringent as those performed for transfusion.

REACTIONS
Severe Acute Anaphylactoid or Anaphylactic Transfusion Reactions (A/A)
Severe acute anaphylactoid or anaphylactic transfusion reactions were the largest category of serious adverse reactions with 146 incidents (19%) reported. In 2004 there was an increase of 52% in these incidents compared to the 2003 figures. Between 2000 and 2003 twenty-two cases involved the use of fresh frozen plasma (FFP), six of which were for warfarin reversal as a result of over anticoagulation, which were not in compliance with current guidelines. The numbers of reactions associated with plasma have fallen consistently since the first year of reporting and the introduction of SD plasma, which is associated with a low risk of allergic type reactions. In 2004 there were two anaphylactoid/anaphylactic transfusion reactions associated with the use of SD plasma. However, this has been offset by an increase in the number of these reactions associated with platelets. Of the 87 reactions (60%) associated with platelets, the vast majority, 67 (77%) were associated with the transfusion of pooled platelet concentrates. In most cases the patients responded rapidly to treatment. Some of these transfusions were however considered to be inappropriate.

Acute Haemolytic or Other Severe Acute Transfusion Reaction. (AHOSTR)
There were 66 incidents (8%) reported in this category. In 2004 there was a three fold increase in these incidents compared to the 2003 figures. Red cell transfusion was involved in 56 (85%). Where there was documentation of the investigations carried out evidence of bacterial contamination was excluded. Only 2 cases were associated with the detection of red cell antibodies. However, seven of the 13 incidents involving ABO incompatible red cell transfusions, reported in the IBCT category were accompanied by symptoms of an acute transfusion
reaction. In total therefore, of 63 red cell transfusion reactions reported to the NHO during this period, seven (11%) were due to ABO incompatibility. This confirms the need to fully investigate all reactions associated with the transfusion of red cells.

Transfusion Associated Circulatory Overload (TACO)

Transfusion associated circulatory overload (TACO) was reported in 63 (8%) transfusions, of which 10 (15%) were associated with the use of plasma. In at least six of these 10 (60%), the transfusion was considered inappropriate and in two cases may have contributed to mortality. In light of these findings, the NHO issued an information leaflet on the use of FFP. This leaflet outlined the firm indications for the transfusion of FFP and highlighted the risks associated with its use. This was updated to reflect changes following the introduction of solvent detergent (SD) treated pooled plasma in March 2002.

Forty-eight (76%) TACO incidents related to the transfusion of red cells. Thirty-eight cases (60%) involved patients aged 70 years or over. In one case where the patient was already critically ill the transfusion may have contributed to mortality. All patients should be assessed pre-transfusion to assess their likelihood to develop TACO. Particular attention should be paid to the identification and management of “high-risk” patients such as the elderly, infants and children, patients with a low body weight and physiologically compromised patients with a history of cardiac, respiratory or renal insufficiency or chronic anaemia. Monitoring of the patient’s fluid balance, transfusing as slowly as possible and observing closely for signs and symptoms of volume overload during and soon after transfusion is recommended to minimise the risks. The use of prophylactic diuretics is also recommended.

Suspected Transfusion Transmitted Infection (TTI)

There were 19 (2%) reports of suspected transfusion transmitted infections (TTI). Investigation of these reports confirmed one case of bacterial contamination, which involved a pooled unit of

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

<table>
<thead>
<tr>
<th>Component transfused</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red cells</td>
<td>3</td>
<td>9</td>
<td>10</td>
<td>12</td>
<td>14</td>
<td>48</td>
</tr>
<tr>
<td>Pooled Platelets</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Apheresis Platelets</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>FFP or SD Plasma</td>
<td>3</td>
<td>6</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>Multi components</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>16</td>
<td>10</td>
<td>14</td>
<td>15</td>
<td>63</td>
</tr>
</tbody>
</table>
platelets from which coagulase negative staphylococcus was cultured from both the patient and the unit. The patient recovered without complications.

Eighteen reports of possible viral transmission were investigated: six Hepatitis C virus (HCV), seven Hepatitis B virus (HBV), four Human immunodeficiency virus (HIV) and one case of co-infection with both HBV and HCV. Transfusion has been excluded as the source of infection in 16 of the 18 patients by re-testing of donors or the archived samples from the time of donation. In one case, one donor could not be traced and so HBV transmission by transfusion could not be excluded. In the second, also a case of HBV, investigations are ongoing, however in both cases the patients had other risk factors.

This low incidence of confirmed TTI is in keeping with the estimated risk of transfusion transmitted viral infection which since the introduction by IBTS of Nucleic Acid Amplification Testing (NAT) has been estimated at 1 in 4 million units transfused for HIV, 1 in 4 million units transfused for HCV and 1 in 200,000 units transfused for HBV (O’Riordan J., Personal Communication).

Delayed Haemolytic Transfusion Reaction (DHTR)
There were 25 (3%) reports received which were categorised as DHTRs during 2000-2004. There were no fatalities. These reactions, which are largely unavoidable, are likely to increase as our patient population, particularly the elderly, receive more transfusions. In 15 (60%) of the 25 cases the patients were aged over 70 years.

Transfusion Related Lung Injury (TRALI)
Six cases (1%) suggestive of transfusion related acute lung injury (TRALI) were reported. Three cases involved red cells, one was associated with apheresis platelets, one with fresh frozen plasma and one case involved multiple blood products. TRALI was confirmed in one case and considered highly probable in three cases, one of which was associated with fatality. It was considered possible in one case and unlikely in a final case. There were no incidents which met the criteria for TRALI reported in 2004.

Post-Transfusion Purpura (PTP) and Transfusion-Associated Graft-versus Host Disease (TA-GvHD)
There were no incidents reported in these categories during the first five years.

Pre-deposit Autologous Donor Incident (PAD)
In 2001 the NHO began to collect reports relating to pre-deposit autologous donor incidents. Twenty-one (3%) incidents were reported and one of the adverse events involved hospitalization of the patient but none involved rescheduling of surgery. Seven, or one third of the incidents involved children. In a number of cases the donated blood was not required suggesting the importance of careful donor selection for PAD.

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

In November 2005, the EU Blood Directive 2002/98/EC will come into effect. This directive governs the activities of Blood Transfusion Services and Hospital Blood Banks. Article 14 of the Directive contains specific provisions in relation to traceability of blood and blood components in regard to the patient. Article 15 requires all serious adverse reactions attributable to the quality and safety of blood and blood components transfused are
captured and reported to the competent authority. This removes the previous discretionary element in relation to reporting of serious adverse reactions and gives haemovigilance a firm legislative basis.

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted incident</td>
<td>37%</td>
<td>50%</td>
<td>49%</td>
<td>60%</td>
<td>59%</td>
</tr>
<tr>
<td>Nil to Report</td>
<td>31%</td>
<td>27½</td>
<td>44%</td>
<td>40%</td>
<td>41%</td>
</tr>
<tr>
<td>Participation</td>
<td>68%</td>
<td>77½</td>
<td>93%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

A number of strategies are currently being examined to improve the reporting rates, such as changes to the “Nil to Report” form, to allow feedback to hospitals of their reporting rates in comparison to hospitals with similar transfusion requirements. It is hoped to address this issue in the future.
Incorrect Blood Component Transfused

**Definition:**
Incorrect blood component transfused (IBCT) is the transfusion of a blood component/product which did not meet appropriate requirements and/or was intended for another patient (SHOT 1996).

This category account for 60% of incidents reported (126 of 214)

There were no fatalities or major morbidity associated with the transfusions and all patients recovered without complications. It is likely that in one case where transfusion was delayed because of sample labelling problems that this contributed to mortality (Case 18).

The Site of First Error indicates the stage in the transfusion chain where the IBCT first occurred.

*Figure 4 Site of first error - IBCT Cases including Anti-D (n=125*)

*One Anti-D case (case 79) has not been allocated a site of first error*
Introduction

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

- **Level 1**
  Events with the real potential for permanent injury or to be life threatening.

- **Level 2**
  Events that are very unlikely to cause permanent harm or have the potential for minimal or transient harm.

- **Level 3**
  Events with no realistic potential for harm.

**Level 1**

The transfusion of a unit of blood or blood component or product to the wrong recipient has been taken as a major or level 1 incident, irrespective of whether the blood was by chance ABO compatible or whether or not there were complications. This is due to the potentially disastrous effects of the transfusion of the wrong blood to the wrong patient and the level of system failure involved. Similarly, mistakes where either Rh D positive blood components were given to a Rh D negative female of child bearing age, or Anti-D prophylaxis was omitted in error or given inappropriately have also been classified as level 1 incidents. Inappropriate transfusions or events where patients who did not require a transfusion of a blood component/product but who received one inadvertently on the basis of incorrect haematology results were also classified as level 1 incidents.

In 2004 there were 52 cases (42%) reported which were classified as Level 1 incidents.

**Level 2**

Incidents such as failure to give cytomegalovirus (CMV) negative or irradiated cellular blood components have been classified as level 2 incidents. Although the effects of such a mistake are potentially very serious, they are in fact extremely rare because leukodepletion of all blood components has very largely abrogated the risks. Incidents where guidelines were not adhered to or discrepancies in patient identification or errors in handling blood components not meeting the criteria for a level 1 incident have also been classified as level 2.

In 2004 there were 53 cases (42%) reported which were classified as Level 2 incidents.

**Level 3**

Level 3 incidents on the other hand, do not pose any risk to patients. However, they do indicate defects in the quality of the service delivered. Where multiple errors have been reported in the same patient, we have reclassified Level 3 incidents as Level 2 because of the possible cumulative effects on the quality of service delivery. Those that are collected under the programme can be instructive and useful for education purposes as they are indicative of a breakdown in procedures. The National Blood Users Group (2002) recommends that any such breakdown should be investigated and corrected even if the recipient of the transfusion is unharmed.

In 2004 there were 20 cases (16%) reported which were classified as Level 3 incidents.

*One Anti-D case (case 79) has not been levelled.

Summary of the key IBCT Findings and Recommendations

Tables of all cases, selected detailed case histories and the detailed findings and recommendations are included in the relevant subsections. Anti-D IBCT incidents are presented in a separate section at the end of this chapter.
Errors involving wrong ABO/Rh group, wrong blood or wrong blood to patient

Findings

• There were 16 Level 1 incidents where the patient received blood components of the wrong ABO/Rh group or where the wrong blood or blood component was given. A number of these involved components given to the wrong patient.

• An ABO incompatible red cell transfusion was given to the wrong patient who did not require a blood transfusion (Case 116). This occurred in an A&E department where remote checking of the unit and failure to check the identity of the patient who was not wearing an ID band were responsible for the error. The patient who was Group O, suffered a reaction after 100mls of Group A red cells had been transfused, by which time the error was discovered. The patient recovered fully.

• A further patient (Case 76), who also did not require transfusion, received blood which was fortunately ABO compatible. This error occurred because the wrong patient’s compatibility report was used to collect blood from the laboratory. The wrong blood was therefore collected for the wrong patient. The unit was checked remotely from the patient’s bedside. The nurse then brought the unit to the wrong patient’s bedside and administered it without checking the patient’s wristband.

• Two patients (Cases 27, 82) received red cells of the incorrect Rh group due to a laboratory error in recording the results of testing.

• One patient (Case 1) was transfused with red cells crossmatched with a sample from a different patient of the same name because incomplete details were taken when a telephone order was made. A further patient (Case 87) was transfused with red cells crossmatched using a frozen serum sample from the wrong patient due to a sample transposition. Fortunately in the two cases, both patients were the same ABO Rh group.

• One case (Case 57) involved the use of ABO compatible ‘walk in’ donors to provide fresh whole blood in a massive transfusion setting.

• Three patients (Cases 20, 23, 46) received O plasma instead of their correct group which was A. One case (Case 20) involved the collection, thawing and administration of unlabelled plasma in error by nursing staff. In two cases (Cases 23, 46) the units were incorrectly issued by the laboratory.

• Two patients (Cases 53 and 78) received O platelets instead of their correct ABO group which was B and A respectively. One of these (Case 78) was an infant.

Recommendations

• Staff administering transfusions must adhere strictly to the policies and procedures for transfusing blood.

• The checking procedure must be performed at the bedside. Remote checking is unacceptable and dangerous practice.

• The patient should be asked to verify their identification details and be involved in the identification and checking process where possible.

• The patient identification details must always be checked against the wristband during the bedside check. The medical record alone must not be used to check patient identity.

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

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

• When possible written or electronic blood/blood component transfusion requests are preferred. In the event of telephone orders hospitals should have a SOP or policy regarding the information required (NBUG, 2004).

• There is no place in the current management of massive haemorrhage for the use of ‘walk in’ donors (NBUG, 2002).

• 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. This is particularly important in obstetric haemorrhage. This protocol should be activated periodically to ensure that flaws are identified and staff are familiar with it (NBUG, 2002).

Inappropriate Transfusions

Findings

There were 17 cases reported in this category. These were of two types, transfusions based on incorrect laboratory values and transfusions based on error in clinical judgement.

Incorrect Hb result
There were two cases reported (Case 31, 93) where transfusion was based on the wrong Hb result. One (Case 93) arose because of a communication error between the clinical area and the laboratory and in the second (Case 31), the sample was unsuitable due to haemolysis and should not have been processed.

Errors in clinical judgement
There were 15 cases reported where the transfusion was based on error in clinical judgement. Seven involved red cells and eight involved plasma.

Red Cells
• Seven cases (Cases 4, 15, 33, 64, 70, 99, and 122) were reported where transfusion was considered inappropriate because the Hb was not checked between transfusions and the patient received more units than necessary. All seven patients were elderly and six were female.
  • In two cases (Case 122 and 33), the Hb results were known. In Case 122, the Hb result of 12.0g/dl was known, but the transfusion was prescribed regardless.
  • In the other case (Case 33), the Hb results were also available but not checked and an elderly female was over transfused. The Hb post transfusion was 16.8 g/dl.
  • In one case (Case 99), two units were prescribed and subsequently transfused where the patient was stable and the clinical picture did not warrant transfusion.

Plasma
Seven Level 1 cases involved the inappropriate use of plasma.

• In one case (Case 22), plasma was given to correct a low serum protein.

• In five cases (Cases 38, 62, 67, 71 and 120), plasma was given to reverse anticoagulants in patients who were not bleeding. In Case 38, the patient was scheduled for elective surgery.
• In case 119, plasma was administered to manage intra-operative bleeding, which had stopped. Coagulation studies were not performed.

Recommendations
• Red cell transfusion must be administered on a unit by unit basis in the non-emergency setting.

• Plasma is not indicated for the correction of a low serum albumin.

• 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.

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

Findings
• Fifteen cases involved failure to administer CMV negative and/or irradiated components to patients requiring them.

• Fourteen cases involved failure to prescribe the correct component and as in all but one case (Case 88), clinical details were not entered on the request form, the laboratory was not alerted to the error.

• Three cases (Cases 51, 89 and 91) involved transfusion in an emergency but in one case (Case 51) although the patient had stabilised and the need for specialised requirements was recognised, two of the remaining units were not withdrawn but were transfused on subsequent days.

• In two cases (Cases 107, 108) the patient was receiving shared care between centres but the patient had not been transfused in that centre before. In three cases (Cases 89, 91 and 17), the patient was admitted to a different facility and the necessity for specialised components was not recognised.

• In three cases (Cases 50, 88 and 123), the error involved the laboratory. In one case (Case 88), the requirements on the request form were overlooked. In two cases (Cases 50 and 123), the laboratory system alert was not noticed on one occasion (Case 123) and had not been activated in the other (Case 50), although previous transfusions had been CMV negative and irradiated.

• One case (Case 98) involved failure to prescribe CMV components to a pregnant woman.

• The final bedside check did not detect any of the errors.

Failure to give Antigen Negative Blood

Findings
In two cases (Case 63 and 110), antigen negative blood was not supplied when requested. In one of these cases (Case 63), the patient had a pre-existing Rh antibody documented, but this information was not clearly available from either the poorly organised manual records or the incomplete computer records in the laboratory. In the second case (Case 110), incorrectly antigen typed blood was issued in error in an emergency.

Recommendations
• Consideration should be given to issuing antibody cards to all patients with clinically significant antibodies (NBUG, 2002).

• The possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated.

• Once a clinically significant red cell antibody has been detected in the past, the patient should always receive antigen negative blood, even though the antibody is no longer detectable, except in an emergency situation where antigen negative blood is not available.
**Recommendations**

- The importance of providing clinical details to laboratories is re-emphasised. In all but one case, clinical details which would have alerted the laboratory were not supplied.

- Blood transfusion request forms should be fully read at processing with particular attention to any special requirements.

- Blood transfusion laboratory computer system alerts which draw attention to the need for specialised components should be used wherever possible.

- Hospitals must put in place systems to ensure that patients who require specialised products receive the correct component wherever possible.

- These systems should include labelling of the patient’s medical record. As some of the incidents involved shared care or admission to different hospitals, issuing of a patient card should be considered.

- There are situations where CMV negative components cannot be supplied, as in the case of specialised components such as HLA matched or HPA 1a negative apheresis platelets where only small suitable numbers of donors are available, or in cases of blood shortage. In these cases, the use of non CMV negative product is appropriate and as the product is leucodepleted, the risk of CMV infection is very small and is outweighed by the risks of failure to transfuse.

**Patient/sample identification problems**

**Findings**

- In a number of cases, samples were not properly labelled with the correct patient details. In one case (Case 18), an elderly patient with severe anaemia had an unidentified antibody which led to delay in obtaining the correct blood. The patient died before transfusion and this delay probably contributed to mortality.

- There were two cases where an incomplete telephone order to the laboratory led to problems in patient identity where there were two patients with the same names in the hospital. In one case already described, (Case 1), the blood was crossmatched against a sample from the wrong patient.

- In Case 28, although the correct blood was issued on the crossmatch sample from this patient, the patient’s identity was incorrectly assigned in the laboratory because the incorrect patient with the same name was selected from the computer database.

- In one case (Case 35), the patient who had been transfused earlier expressed concern when he noticed he had an incorrect ID band. However the correct blood was transfused as the correct ID band had been on at sampling and the ID band was not checked prior to transfusion.

**Recommendations**

- A secure patient identification procedure should be in place in all hospitals and the ID wristband should be worn from the taking of the crossmatch sample right through the transfusion. This ID wristband should contain three unique identifiers, which include the patient’s full name, date of birth and unique identification number (NBUG, 2004).

- It is the professional responsibility of the person who removes the ID wristband to replace it.

- Sample tubes should be handwritten correctly and legibly immediately after sampling at the patients side. Until automated systems are available, identification procedures must be strictly adhered to at the bedside to reduce sample errors. Where possible the patient should be involved.

- Hospital laboratories should have SOP or policies
for the acceptance or rejection criteria for incorrectly labelled samples. Such policies should cover amendments, which are acceptable, and those, which are unacceptable and require a fresh sample to be taken.

• In an emergency where there is insufficient time to obtain results from a fresh sample, the policy should include the use of emergency Group O Rh negative blood until the patient has been regrouped.

• It is important that existing policies are fully understood and regularly updated. It is critical to ensure that on going education highlights to all medical, nursing and laboratory staff, especially those not regularly working in transfusion or returning from leave, the importance of strict compliance.

**Errors surrounding the Collection, Storage and Handling of Blood Components**

**Findings**

• There were four cases (Cases 109, 114, 121 and 127) where units were not correctly stored before transfusion, three involving red cells and one involving SD plasma.

• These cases were Level 2 and Level 3 incidents and are described in the appropriate tables.

• Case 121 involved a paedipack aliquot and is described in the paediatric chapter.

**Recommendations**

• Documentation including the prescription should be completed prior to collection of components in the non-emergency setting.

• Should an unforeseen delay in the commencement of the transfusion occur, it is necessary to return the unit to controlled storage within 30 minutes and inform the laboratory to ensure the unit is being returned to the appropriate fridge.

**IBCT due to problems with infusion**

**Findings**

There were eight cases involving problems with infusions.

• One case (Case 126), involved the transfusion of antibiotics into the same line as a red cell transfusion via a three way tap. The patient who was septic developed a fever and hypertension post transfusion. It is likely that this was related to his underlying condition rather than the transfusion.

• In one case (Case 111), the second of two units of blood prescribed over three hours was administered in 50 minutes. The patient, a young post partum female, showed an increase in pulse rate and blood pressure and chest tightness suggestive of fluid overload but recovered quickly without therapy.

• Four cases involved the use of a fluid giving set without an integral filter instead of a blood giving set (Cases 42, 58, 66 and 113). In two cases (Case 42, 113), the incident involved a new member of staff. In one of these, the staff member thought all fluids in theatre were administered through a blood giving set as in the hospitals she had previously worked in and presumed she was using a filtered set. In the second case, the person was unfamiliar with the different packaging of the sets.

• One case (Case 66) arose because the fluid giving sets and the blood administration sets were stored together and the wrong set was selected.
Recommendations
• No fluids other than normal saline should be added to blood due to risk of haemolysis or clotting.

• It is recommended that blood administration sets be stored separately to fluid administration sets.

• In the non-bleeding patient, infusion rates depend on the clinical context, age and cardiac status of the patient. Except for patients in the massive transfusion setting, transfusion rates for blood should not exceed 2-4 mls/kg/hr (NBUG, 2004).

• The use of calibrated infusion pumps to ensure correct infusion rates should be evaluated.

Unit labelling Errors

Findings
• There were three incidents (Cases 6, 24 and 105), where red cell units issued for transfusion were mislabelled. In one of these cases (Case 24), blood for two patients was labelled at the same time and the unit labels were transposed between patients. Both were fortunately Group O Rh negative and the patients suffered no harm.

Recommendations
• There should be a dedicated area in the laboratory for labelling products. At the time a unit is issued, there shall be a final check of transfusion records and each unit of blood or component (Brecher et al, 2003).

• Processing should be performed on samples from the beginning of the process to the end individually and by one person, wherever possible.

• Where possible, two people should read and interpret results in the laboratory.

• Wherever possible, only the units from one crossmatch should be labelled and issued at any given time to avoid errors.

Blood Centre Supply problems

Findings
• Three incidents involved the supply centre, (Cases 25, 77, 110), where there was difficulty in supplying the correct component or where the incorrect component was issued in error.

• In one case (Case 77) there were no in-date Rh negative platelets available to treat emergency obstetric haemorrhage. A clinical decision was made to use Rh D negative platelets which had expired a few hours earlier in preference to Rh D positive platelets with Anti D.

• In Case 25, the product of choice for plasma exchange was group B Octaplas. Due, however, to a shortage of group B Octaplas, Uniplas was used.

• In another case (Case 110), an incompletely antigen typed unit of red cells was selected and labelled manually as antigen negative and issued in error in an emergency, when in fact it was antigen positive.

Miscellaneous

Findings
• There were a number of incidents where errors occurred during issuing and administration of blood where the possibility of patient harm was low but which reflected failure to adhere to best practice.

• These included incidents where units had expired pre-transfusion (Cases 39, 77), where more than 72 hours had elapsed between the crossmatch sample being taken and the transfusion being administered (Case 5, 9, 54, 69, 80 and 117) or the units were given too slowly (Case 13, 59, 100 and 101).
Recommendations

- While blood stock management to avoid wastage due to outdating of units is an important aspect of laboratory practice, laboratories should try to ensure that blood close to expiry is not released for patients who are unlikely to be able to complete the transfusion within the expiry period.

- Where blood is used near to expiry date the AABB 2002 recommends that transfusion should be completed prior to component expiration. In individual cases, 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.

- From starting the infusion to completion, infusion of the pack should take a maximum of four hours (NBUG, 2004).

- 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.

Incorrect Factor Concentrate administered

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.

Findings

Six adverse events were reported involving factor concentrates.

- In one case (Case 73), where recombinant factor VIII concentrate was given to the wrong patient who was not a haemophilia patient, the prescription and drug were checked away from the bedside. When the patient’s first name was called, another patient with the same first name replied and the patient’s ID wristband was not checked.

- One patient (Case 112) who did not normally require factor concentrate for control of his Von Willibrand’s disease received plasma derived factor concentrate in error through communication failure.

- Inadequate dosage was reported in two cases (Cases 19, 81).

- The wrong make of factor VIII concentrate was administered in one case (Case 21), and in another (Case 115), the patient who required treatment received the correct dose of prothrombin complex which however had been issued for a different patient.

Recommendations

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

- The importance of the bedside check is reiterated.

- Clear communication between treating centres is paramount in preventing error, as Case 112 demonstrates.

- Except in the emergency situation, transfusion of factor concentrate products should only be administered on the basis of a written prescription.
**TABLE 6: Errors involving Wrong ABO/Rh Group, Wrong Blood or Blood to Wrong Patient (Red Cells) (N=11)**

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 116*</td>
<td>Group O Rh D positive</td>
<td>Group A Rh D positive</td>
<td>10 mls of red cells</td>
<td>Hypertension, tachycardia, dyspnoea, wheeze, restlessness and anxiety.</td>
<td>ABO incompatible blood administered to the wrong patient due to remote checking at the nurses station and failure to check patient’s ID at the bedside. Patient was not wearing a wristband.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 76*</td>
<td>Group A Rh D positive</td>
<td>Group O Rh D negative</td>
<td>70 mls of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Compatibility form from the wrong patient sent to the laboratory and a unit of red cells was collected. The unit was remotely checked in the treatment room. The patient’s ID was not checked at the bedside prior to transfusion.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 87*</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>Three units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Serum sample incorrectly labelled. Wrong patients’ serum crossmatched. Three units of the wrong blood transfused which happened to be Group O Rh D negative.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 1*</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D negative</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Telephone request to laboratory for blood for patient. The only detail requested by the laboratory was the patient’s name. There were two patients with similar names in the hospital and blood was crossmatched and issued on the wrong patient’s sample. This was not detected at the bedside check as the unit was not checked against the wristband.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 27*</td>
<td>Group A Rh D negative</td>
<td>Group A Rh D positive</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Rh D group recorded incorrectly by on call medical scientist during change over of shift.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 57</td>
<td>Group A Rh D positive</td>
<td>Two units A Rh D positive One unit O Rh D positive</td>
<td>Three units of red cells</td>
<td>Donors subsequently tested negative for viral markers. No complications as a result of this transfusion.</td>
<td>Three units of whole blood taken from “walk in donors” and transfused during a massive haemorrhage.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 82*</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D negative</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient incorrectly grouped as Rh D negative, discovered on rechecking as Rh D positive.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 49</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Rh D positive unit given to Rh D negative patient because an incorrect comment was attached to the unit which read “Unit group different from patient but OK to transfuse” instead of “Use only in Emergency”.</td>
</tr>
</tbody>
</table>

* Included as full case history
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 94 *P</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of paedipack red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Three aliquots of red cells were incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 96 *P</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of paedipack red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Three aliquots of red cells were incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 97 *P</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of paedipack red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Three aliquots of red cells were incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.</td>
</tr>
</tbody>
</table>

*P Included as full case history in Paediatric Chapter
Errors involving wrong ABO/Rh group or blood to wrong patient

A number of these cases are discussed in detail.

ERRORS INVOLVING BLOOD TO WRONG PATIENT: Case Histories (Red Cells)

Level 1 IBCT Case 116
This elderly patient was being assessed in the A&E department and was not prescribed for blood. Two staff members checked a unit of Group A positive red cells, which was intended for another patient, remotely at the nurse's station against the compatibility label. One staff member then went to this patient who was not wearing a wristband. The staff member did not ask the patient to identify herself or check that she had a wristband. The transfusion was commenced and following administration of 10 mls of blood the patient developed symptoms of hypertension, tachycardia, dyspnoea, wheeze, restlessness and anxiety. The staff member was still at the bedside and realised that the wrong patient had been selected. The unit was discontinued and chlorpheniramine, hydrocortisone IV, salbutamol nebuliser and oxygen at 4 L/min were administered. Intravenous NaCL was also commenced. The patient settled shortly after the medication had been administered with resolution of symptoms within 24 hours. The laboratory investigations showed that the patient was Group O positive. The post transfusion DAT was positive but Hb, LFT’s, renal function tests and coagulation screen were normal and the patient recovered fully.

Level 1 IBCT Case 76
This incident involved the transfusion of 70 mls of Group O Rh D negative red cells to a group A Rh D positive patient who was not scheduled for transfusion. The error occurred because a compatibility form for another patient was sent to the laboratory requesting one unit of red cells. The laboratory provided a crossmatched unit for this request and it was collected and brought to the clinical area. Two people checked the unit in the treatment room against the patient’s medical record. The nurse then went to the wrong patient’s bedside. The patient was not asked to identify themselves and the details on the patient’s wristband were not checked against the unit before the transfusion was commenced. The nurse discovered the error after 70 mls had been transfused when it was noted that the compatibility form, which was now in the medical record, contained a different name to that on the patient’s medical record. The unit was immediately discontinued and the patient suffered no complications as a result of this transfusion.

Level 1 IBCT Case 87
This female patient required a transfusion of three units of red cells for a perioperative bleed. A phone request for blood was made on-call to the laboratory. This patient had already been group and screened and the medical scientist regularly working in blood transfusion thawed the specimen for crossmatch. In error, another patients frozen serum sample was used for this crossmatch. This occurred because the sample tube was incompletely labelled and while it contained a similar unique number to that of the patient, there were no other patient details. Also the sample tubes were normally stored in numerical order but on this occasion were out of sequence. The patient grouped as O Rh D negative. Three units of group specific crossmatched red cells were issued for the patient. All three units were transfused uneventfully. The error was discovered during a routine check of all on-call work. The ward staff were immediately alerted and a sample was taken which confirmed the patient group as O Rh D negative. Laboratory investigations showed no evidence of haemolysis as the sample processed was the same group as the patient. As a result of this incident all serum samples are now bar-coded and must be scanned electronically prior to crossmatch.

Level 1 IBCT Case 1
This elderly ITU patient, Patient X, with multi organ
failure required a transfusion. A telephone call was made to the laboratory asking if a group and hold had been performed on this patient and this was confirmed. Later, a further telephone call was made requesting red cells for this patient. The telephone log was not filled in, and no other details other than the patients name were requested by the laboratory. There were two patients with the same name in the hospital and the blood was crossmatched and issued for the wrong patient, Patient Y. When the blood was collected from the fridge, only name details were checked. During the bedside check, the compatibility label was checked against Patient Y’s details on the compatibility form. Patient’s X ID wristband was checked against his medical records. However the unit of blood, labelled with Patient Y details, was not checked against Patient X’s wristband. On retrospective crossmatch it was found by fortunate coincidence that the unit was the same group as the recipient.

Errors involving blood of wrong Rh group: Case histories (Red Cells)

Level 1 IBCT Case 27
This elderly male patient, admitted for investigation of symptomatic anaemia, required a transfusion of two units of red cells. The patient had no historical record of transfusion in this hospital. The group and crossmatch were done during the on call period. Two medical scientists were covering the session from 17:00 hrs to midnight and one of these had started the procedure. The other medical scientist, who would not normally work in blood transfusion, completed the procedure. The blood group was done using gel cards and the result was recorded as group A Rh D positive. The actual result was Group A Rh D negative. Two A Rh D positive units were issued and transfused uneventfully when the error was discovered the following day, during a routine audit of on call work. This incident highlighted that as far as possible the person starting the group and crossmatch should also complete the procedure.

Level 1 IBCT Case 82
This group O Rh D positive female required a transfusion of two units of red cells for anaemia Hb 6.3g/dl. A medical scientist not normally working in transfusion did the crossmatch during the on call period over a weekend. No historical group was available for the patient. The patient’s group was identified and recorded as O Rh D negative. Two units of compatible red cells were issued and transfused. Three days later when a further transfusion was required the patient grouped as group O Rh D positive which was confirmed on testing a second sample. Retrospective testing of the original pre transfusion sample also confirmed the patient as O Rh D positive. Investigation of the incident has shown that an error occurred when recording the results of the grouping procedure. A second medical scientist reviewing on call work the next day failed to identify the error. As a result of this incident it is now recommended that a second group must be processed to confirm all on call work if a historical group is not available.

Errors involving wrong ABO/Rh group: Case histories (Plasma)

Level 1 IBCT Case 20
This male patient on warfarin therapy, required an emergency transfusion of solvent detergent (SD) plasma following a fall. The pre-transfusion sample was processed on call and the patient grouped as A Rh D positive. In error four units of Group O SD plasma instead of Group A SD plasma were collected from the storage fridge by nursing staff and signed out of the central plasma log, thawed by the nursing staff and brought unlabelled to the ITU for this patient. There was no compatibility form and the nursing staff thought this was the product of choice. The error went unnoticed during the bedside checking procedure. The patient suffered no complications as a result of this transfusion. The error was identified during routine retrospective audit by the HVO. This incident has highlighted the necessity for a medical scientist to be involved in the issue of blood components.
Level 1 IBCT Case 23
This elderly male patient with multiple medical problems on warfarin had suffered an internal haemorrhage. Three units of SD Plasma were prescribed for emergency anticoagulant reversal. The patient was Group A Rh D negative. A medical scientist who normally works in this area issued three units of Group O SD Plasma in error. Two members of staff checked the units at the bedside but the error remained undetected. The error was discovered on a routine check of the issued plasma several days later. A software change on the laboratory computer has been requested to include a warning if SD Plasma which is not the same ABO blood group of the patient is requested for issue.
### Table 7: Errors involving wrong ABO/Rh group Plasma (N=3)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 20*</td>
<td>Group A Rh D positive</td>
<td>Group O SD Plasma</td>
<td>4 units of SD Plasma</td>
<td>No complications as a result of this transfusion.</td>
<td>Group O SD Plasma was issued by nursing staff in error instead of group A Octaplas.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 46</td>
<td>Group A Rh D positive</td>
<td>Group O SD Plasma</td>
<td>Two units of SD Plasma</td>
<td>No complications as a result of this transfusion.</td>
<td>Group O SD Plasma issued by the laboratory to a group A patient.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 23*</td>
<td>Group A Rh D negative</td>
<td>Group O SD Plasma</td>
<td>Three units of SD Plasma</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect group SD Plasma issued in laboratory in error for a group A patient.</td>
</tr>
</tbody>
</table>

* Included as full case history

### Table 8: Errors involving wrong ABO/Rh group platelets (N=2)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 53</td>
<td>Group B Rh D negative with immune anti D</td>
<td>Group O Rh D positive</td>
<td>One unit of pooled platelets</td>
<td>No complications as a result of this transfusion.</td>
<td>Group O Rh D positive platelets issued to a Group B Rh D negative patient due to incorrect group selection in laboratory.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 78</td>
<td>Group A Rh D positive</td>
<td>Group O Rh D positive</td>
<td>15mls of apheresis platelets x 2</td>
<td>No complications as a result of this transfusion.</td>
<td>Group O platelets issued from the laboratory for a Group A infant.</td>
</tr>
</tbody>
</table>

*P Included as full case history in Paediatric Chapter
## INAPPROPRIATE TRANSFUSIONS (N=17)

### Table 9: Transfusion based on incorrect result (Red Cells) (N=2)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 31</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient admitted with breathlessness. Phone result misheard as Hb 8.2g/dl, actual result 10.8g/dl. Post transfusion Hb 13.9g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 93</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion</td>
<td>Pre transfusion FBC specimen haemolysed. Haemolysis of the U/E specimen identified which should have prompted inspection of the FBC specimen.</td>
</tr>
</tbody>
</table>

### Table 10: Transfusion based on error in clinical judgement (Red cells) (N=7)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 4*</td>
<td>At least one unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>The patient received four units of red cells over a two-day period but the Hb was not checked between transfusions. Post transfusion Hb was 13.4g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 15</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Hb prior to transfusion was 7.9 g/dl. Following transfusion of second unit of red cells Hb was 9.7g/dl. Third unit of red cells was inappropriately transfused. The post transfusion Hb was 13.5g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 33*</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Two units of red cells prescribed although the Hb was 12.8g/dl. Post transfusion Hb was 16.8g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 64*</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Inappropriate transfusion of red cells. Post transfusion Hb 14.4g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 70*</td>
<td>Three units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Three units of red cells transfused to a patient on weekly erythropoietin therapy without checking the Hb between units. Post transfusion Hb 13.3g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 99</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Inappropriate transfusion. Patient had frank haematuria but was haemodynamically stable. Hb 12.4g/dl pre transfusion.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 122*</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Communication error regarding updated Hb result. Two units of red cells transfused with a Hb of 12.0g/dl.</td>
</tr>
</tbody>
</table>

* Included as full case history
Inappropriate Transfusion: Red Cells

Transfusion based on incorrect result: Case histories

Level 1 IBCT Case 31
This elderly male patient with malignancy was admitted for investigations for shortness of breath. The patient had been discharged from hospital two weeks earlier when the Hb was 10.8g/dl. On this occasion following admission to the ward, a phoned Hb result from the A&E department was misheard as 8.2g/dl. Two unit of red cells were prescribed and the first was administered uneventfully. A repeat Hb prior to the second unit was 10.8g/dl and therefore this unit was not transfused. Subsequent investigations showed that the shortness of breath was actually caused by a chest infection.

Level 1 IBCT Case 93
This elderly female patient with a history of cardiovascular disease received a perioperative transfusion of two units of red cells for a reported Hb 6.5g/dl. The medical scientist processed the urea, electrolytes and the FBC samples on call. The U/E result showed serum potassium of 10mmols/L as the specimen was haemolysed. While this should have raised the suspicion of a problem with the FBC specimen, this was not repeated. Two units of red cells were crossmatched and transfused uneventfully with no Hb measurement on a unit by unit basis. The post transfusion Hb was 13.9g/dl which was discovered during a routine audit by the haemovigilance officer.

Level 1 IBCT Case 4
This elderly female patient with a history of gastric bleeding was transfused for anaemia, Hb. 6.7 g/dl. The patient received a total of four units of red cells on consecutive days - two units on the first day and two on the following day. During this two day period there had been no further evidence of active bleeding. The Hb was not checked between transfusions. On the next day, the patient’s Hb was 13.4 g/dl, therefore, at least one unit of red cells was inappropriately transfused. The patient suffered no complications as a result of this transfusion. The incident was picked up by the HVO on retrospective audit.

Level 1 IBCT Case 33
This elderly female patient with chronic medical problems including malignancy and generalised weakness was prescribed a transfusion of four units of red cells. The pre transfusion Hb was 9.5 g/dl. Two units were transfused and the repeat Hb was 12.8 g/dl. Despite this, two further units were transfused. On the day following transfusion the Hb was 16.8 g/dl. The laboratory staff detected the error when the Hb results were being issued.

Level 1 IBCT Case 64
This elderly female patient with underlying ischaemic heart disease and severe rheumatoid arthritis was transfused with three units of red cells. The units were prescribed for a Hb of 9.5g/dl. The patient’s haemoglobin post transfusion of two units was 11.9g/dl and following the third unit was 14.4g/dl. Subsequent investigation into the cause of the dyspnoea revealed pulmonary fibrosis with a suspected respiratory tract infection and the transfusion of these units was considered inappropriate. While the guideline in the hospital states the need to assess transfusion on a unit by unit basis, this was not done.

Level 1 IBCT Case 70
This female patient with chronic renal failure, hypertension and underlying malignancy was receiving weekly erythropoietin therapy for chronic anaemia. On this admission the Hb was 5.8g/dl and three units of red cells were prescribed. The transfusion took place over a weekend period uneventfully but the Hb was not checked on a unit by unit basis. On routine audit the HVO discovered the
patient’s post transfusion Hb was in fact 13.3g/dl. The patient suffered no complications as a result of this transfusion. It is likely that there was a problem with the pre transfusion Hb sample although it appeared to be from the correct patient.

**Level 1 IBCT Case 122**

This patient with an underlying cardiac disease and other medical problems was awaiting surgery. The surgical procedure had been cancelled on a previous occasion due to anaemia Hb 10.2 g/dl. The GP contacted the consultant and requested that the patient be admitted for transfusion prior to surgery in order to avoid a further cancellation. The consultant thought this was the current Hb result but in fact it was from a month before. On admission the consultant left instructions that the patient was for transfusion of three units of red cells. The patient had a FBC drawn on admission and the result was Hb 12.0 g/dl. The medical officer did not convey this result to the consultant and the transfusion proceeded as directed. The patient received two units of red cells but the third was cancelled when the pre-transfusion result was reviewed. This error was discovered during routine audit by the HVO.
Inappropriate transfusion: Plasma

Transfusion based on error in clinical judgement: Case histories

**Level 1 IBCT Case 38**

This elderly patient was admitted in the afternoon for an elective procedure the following morning. The patient had taken 3mg warfarin in the morning prior to admission. There was no documentation regarding stopping warfarin prior to the procedure in the patient’s medical record. The target range for INR prior to the procedure was 1.2 to 1.7. Vitamin K 2mg IV was administered in order to reverse the anticoagulation. The INR following this was 2.2. One unit of SD treated plasma was transfused and three hours later a further 2mg of Vitamin K was administered. The INR prior to the procedure was 1.6.
**Level 1 IBCT Case 62**
This elderly female patient on warfarin therapy, INR 4.4, was admitted and was due to have an invasive procedure. Vitamin K 10mgs was given IV on admission. A repeat INR ten hours later was 1.37. Two units of SD plasma were then prescribed stat with a further two units prescribed over 13 minutes each for the reversal of oral anticoagulation. In addition to the unnecessary transfusion, the entire four unit transfusion was completed within 30 minutes which was against hospital policy which states that each individual unit should be transfused over 30 minutes. The patient suffered no complications as a result of this transfusion. The incident was discovered during a routine audit.

**Level 1 IBCT Case 67**
This patient with a history of cardiovascular disease and pulmonary embolus following previous surgery, was admitted for investigation of a knee injury. The patient was taking oral anticoagulants and the INR was 2.8 with no associated bleeding. Six units of SD plasma were administered and the transfusion was completed prior to surgical review when it was decided that surgical intervention was not required. A trial of Vitamin K was not considered. The patient suffered no complications as a result of this unnecessary transfusion.

**Level 1 IBCT Case 71**
This elderly patient on warfarin therapy who was one week post surgery when the INR was found to be 7.4. There was no associated bleeding. A clinical decision was taken to administer two units of SD plasma to reverse this instead of administering Vitamin K despite being aware of current national guidelines regarding the use of SD plasma. The following day the INR was recorded at 5.7. The patient suffered no complications as a result of this unnecessary transfusion.

**Level 1 IBCT Case 119**
Two units of SD plasma were prescribed post operatively for a patient following an elective surgical procedure. No coagulation studies requested on this patient. During a routine audit, the haemovigilance officer could not find a documented reason for this transfusion as no other products were prescribed. When the prescription was questioned, the prescribing clinician felt that the patient bled excessively during surgery although this appears to have settled when the patient returned to the ward. The patient suffered no sequelae as a result of this unnecessary transfusion.

**Level 1 IBCT Case 120**
This patient admitted for medical investigations with a history of cardiac, respiratory and vascular disease, required treatment for raised INR of 17. The patient was on warfarin therapy but there were no signs of active bleeding. One mg of vitamin K was administered and two units of SD plasma were ordered. The medical scientist queried the request but the two units were transfused overnight. The INR the following day was 5.8. This transfusion did not comply with national and local recommendations for management of excessive anticoagulation. The HTC has recommended that a consultant approve all requests for plasma in future.
Failure to give antigen negative red cells: 
Case History

**Level 1 IBCT Case 63**
This elderly patient with underlying malignancy and cardiac disease required a transfusion for anaemia 5.5 g/dl. The patient had an anti C antibody present on a previous occasion but the current antibody screen was negative. Manual and computer records were checked prior to transfusion but failed to detect this history. On the manual records, two cards were stuck together, on the computer records two episodes were present but only one contained a full history, so this information was missed. Three units of red cells were transfused uneventfully. The error was discovered during a training session. Post transfusion the units were screened and one of the units was found to be C antigen positive. Post transfusion testing showed the patient to be antibody screen negative, DAT negative.

---

**Table 12: Failure to give antigen negative red cells (N = 2)**

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Antibody specificity</th>
<th>Volume of red cells transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 63*</td>
<td>Anti-C</td>
<td>Three units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Antigen positive blood transfused to an antigen negative patient. Details missed during manual and computer record checking.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 110</td>
<td>Possible anti Jka-detected previously</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient with previous history of anti Jka antibodies. Unit of red cells issued as an emergency from the supply centre was incorrectly selected and labelled as antigen negative when in fact it was antigen positive.</td>
</tr>
</tbody>
</table>

* Included as full case history
## Table 13: Error in CMV negative and irradiated component administration (N=15)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 2</td>
<td>Two units of red cells. Two units of platelet concentrate</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated blood not requested.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 17</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to request CMV antibody negative and irradiated red cells for post solid organ transplant patient in a different facility.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 50</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated red cells not ordered and error not detected on processing in laboratory as this requirement had not been flagged on a previous transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 51</td>
<td>Five units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated red cells not prescribed in emergency setting.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 55</td>
<td>Four units of red cells Two units of platelet concentrate</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient on list for solid organ transplant. CMV negative and irradiated products not ordered.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 85</td>
<td>Four units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated red cells required but not prescribed.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 86</td>
<td>Three units of red cells, one unit of apheresed platelets, one unit of platelet concentrate</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated components required but not prescribed. No clinical details included on the request form, which could have alerted laboratory staff.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 88</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated units were prescribed but not issued from the laboratory and the units were subsequently transfused without special requirements being noticed.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 89</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>During an emergency admission CMV negative and irradiated units were not requested and with no transfusion history, the units were issued and transfused without special requirements being met in this different facility.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 91</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to prescribe CMV negative or irradiated red cells for an emergency transfusion for anaemia following a solid organ transplant in a different facility.</td>
</tr>
</tbody>
</table>

*P Included as full case history in paediatric chapter
Error in CMV negative and irradiated component administration: Case History

**Level 2  IBCT Case 98**
This young female patient required a transfusion of two units of red cells Hb 6.4g/dl for an ante partum haemorrhage at 21 weeks gestation. The prescription did not specify that CMV negative blood would be required and the request form did not indicate that this was an antenatal patient thus the laboratory were not prompted to issue according to hospital policy. Two units of red cells were issued and transfused uneventfully and the error was not discovered until a further request was made to the laboratory specifying that this was an antenatal patient. Of the two units that had been transfused one was CMV positive. The patient has suffered no sequelae to date as a result of this transfusion.

---

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 98*</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to prescribe CMV negative red cells for antenatal patient.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 102</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient with haematological malignancy, on chemotherapy, was not prescribed CMV negative or irradiated red cells.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 107 *P</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to prescribe CMV negative or irradiated red cells for a patient with a malignant haematological disorder. Patient was receiving shared care between two different centres.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 108</td>
<td>60 mls of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to request and prescribe irradiated blood products for a patient with a malignant haematological disorder. Patient was receiving shared care between two different centres.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 123</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to prescribe CMV negative or irradiated red cells for a potential solid organ transplant patient. Requirement for special needs flagged in computer from previous transfusions but not noted.</td>
</tr>
</tbody>
</table>

* Included as full case history
*P Included as full case history in paediatric chapter
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 18*</td>
<td>Units not transfused</td>
<td>Failure to transfuse. Possible contribution to mortality.</td>
<td>Patient’s name, date of birth, and hospital number incorrect on sample referred to reference centre. Patient had an unidentified antibody. Delay in providing compatible red cells.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 35*</td>
<td>Three units of red cells over two days</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient expressed concern that he had received the wrong blood as he was wearing a wristband belonging to another patient. However he had received the right blood as the ID band was correct during sampling. Incorrect ID band not checked at time of transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 28*</td>
<td>One paedi-pack</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect date of birth was transcribed from notes onto request form and sample tube.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 43</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Crossmatch sample without MRN number sent in from GP. Transfused in hospital but the patient’s MRN number did not appear on either the sample tube, the crossmatch form, the compatibility label, the issue voucher or the wristband.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 14</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Surname incorrectly spelled on both request form and sample tube, leading to the issue and transfusion of two units with surname incorrectly spelled on both units and the collection slip.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 29</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>One digit error in date of birth on pre transfusion sample request form and on unit transfused.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 45</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect date of birth inadvertently entered on the patient’s ID wristband and sample tube.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 47</td>
<td>Three units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect date of birth given by patient when extremely unwell. Correct date of birth in previous records. Computer system in laboratory and hospital information system not linked.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 74</td>
<td>Eight units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Units transfused with incorrect DOB not confirmed during bedside checking procedure.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 75</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Mother of patient stated patient’s date of birth incorrectly, i.e month, day, year instead of day, month, year.</td>
</tr>
</tbody>
</table>

* Included as full case history
Patient/sample identification problems: Case Histories

Level 1 IBCT Case 18
This elderly male patient with a symptomatic anaemia, Hb 3.1g/dl, was admitted from a care facility for evaluation and treatment. The patient had a history of a CVA. The pre-transfusion sample was taken during routine working hours. A positive antibody screen was discovered and a further sample was taken and sent to a reference laboratory for confirmation and compatibility testing. The sample was incorrectly labelled with respect to name and date of birth and a repeat sample was requested. A transfusion history was not recorded on the request form and the care facility was contacted but there was a delay in getting the information. A Chido antibody was identified in the reference centre and compatible red cells were issued. The patient became extremely unwell, suffered a cardiac arrest and died before receiving the blood. The post mortem result revealed a severe chest infection with bilateral pleural effusions, however, the delay in providing compatible red cells may have contributed to the patient’s death.

Level 1 IBCT Case 35
This male patient with a history of malignancy required a transfusion of three units of red cells for postoperative anaemia. He had a previous transfusion history on file in this hospital. Two days following the transfusion a relative approached the clinical staff concerned that the wrong blood may have been administered as the patient was wearing an identity wristband that belonged to a different patient. Subsequent investigation has revealed that the patient actually received the correct units intended for transfusion. During pre transfusion sampling the patient was wearing the correct identity wristband but this was removed in theatre and replaced by a hand written identity band. Following transfer to the ward it was noted that the identity band was hand written and this was replaced with a printed identity wristband from the patient’s medical record, taken from the wrong record. The final bedside checking procedure pretransfusion involved verbal confirmation of identity with the patient but did not include the step to confirm the identity wristband. The patient suffered no complications as a result of this incident.

Level 2 IBCT Case 28
This patient was prescribed a transfusion of three units of red cells for anaemia and a sample was sent to the laboratory for group and crossmatch. The laboratory computer system does not require the patient details for processing. The user was given a choice of two patients on the system with the same name and the same date of birth; one was not an in-patient. The user selected the wrong patient and the request was processed using the incorrect address and hospital number. Thus the compatibility form and compatibility labels were generated with incorrect details. Each unit was collected as required separately and on each occasion the error was not detected during collection of the units from the laboratory. Two members of staff carried out the pretransfusion check at the bedside but failed to detect the error as each unit was checked against the blood compatibility form only and the patient’s identity band had been removed to gain IV access and not replaced. When the last unit was collected a member of the staff noticed the incorrect details on the unit.
### Table 15: IBCT due to problems with infusion (N=10)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 111*</td>
<td>One unit of red cells</td>
<td>Chest tightness 40 minutes following transfusion.</td>
<td>One unit of red cells prescribed over 3 hours infused in error within 50 minutes.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 126*</td>
<td>One unit of red cells with iv antibiotics</td>
<td>Pyrexia &gt;1.5°C Hypertension. Chlorpheniramine and hydrocortisone administered. Recovered within 24 hours. Reaction probably related to patient’s underlying condition.</td>
<td>Antibiotics administered through a three-way tap into the same line as the blood transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 30</td>
<td>One unit of CMV antibody negative and irradiated red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit of red cells transfused using an IV administration set that had been used for a previous platelet transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 40</td>
<td>One unit of apheresed platelets</td>
<td>No complications as a result of this transfusion.</td>
<td>Platelets infused via an unsuitable pump.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 42*</td>
<td>Four units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Four units of red cells administered through a non filtered giving set because the staff member presumed that all fluids in the operating theatre were transfused through blood administration sets.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 58</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Two units of red cells inadvertently administered through a non filtered giving set.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 66</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit of red cells administered through a non filtered administration set. Blood administration sets and regular administration sets are stored together.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 113</td>
<td>Half a unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect administration set used inadvertently by new staff member.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 124</td>
<td>90 mls of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect administration set inadvertently used.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 125</td>
<td>100 mls of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Transfusion not checked against written prescription, blood warmer not used as indicated.</td>
</tr>
</tbody>
</table>

* Included as full case history
IBCT due to problems with infusion: Case histories

Level 1 IBCT Case 111
This young female patient required a transfusion of red cells for postnatal anaemia - Hb 6.1g/dl. Two units were prescribed, each over a three hour period. The first unit was given uneventfully however the second unit had been infused in error within 50 minutes. Forty minutes following transfusion the patient complained of chest tightness and the heart rate and blood pressure were elevated from the baseline and the patient required medical review. The examination was unremarkable and no specific medication was prescribed. The patient recovered from this incident within four hours. The incident was discovered when the HVO was asked in the ward about the need for infusion pumps to avoid transfusion being administered too quickly and the incident of the inadvertent transfusion was described. As a result of this incident a report is currently being prepared into the use of infusion pumps for transfusion.

Level 1 IBCT Case 126
This elderly male patient with underlying sepsis was receiving a transfusion of red cells for anaemia. The patient was prescribed IV antibiotics, which were checked by two members of staff. The antibiotics were administered through a three-way tap into the same line as the blood transfusion. Later another member of staff noticed the empty antibiotic bag in situ. The antibiotics were completed and the remainder of the transfusion was completed. Immediately following completion the patient developed a rise in temperature of 1.2°C and a rise in blood pressure. Two and half-hours post transfusion the temperature had further increased by 2.7°C above base line. Chlorpheniramine and hydrocortisone IV were administered. Post transfusion the DAT and antibody screen was negative. The patient recovered fully within 24 hours.

Level 2 IBCT Case 42
This patient with a malignancy required a transfusion of four units of red cells for an intra-operative blood loss. All four units were administered through a giving set without an integral filter. A new member of the staff thought that all fluids in the operating theatre were transfused through a blood giving set, as was the practice in other hospitals and she had worked in and presumed she was using a filtered set. Another staff member detected the error. The patient suffered no complications as a result of this transfusion.
Unit Labelling Errors: Case histories

Level 1 IBCT Case 24
This female patient with a history of cardiac disease was prescribed a unit of red cells for anemia. In the laboratory, the crossmatch was conducted simultaneously with a crossmatch for another patient who was prescribed two units of red cells. Both patients typed as Group O Rh D negative and had negative antibody screens. The unit numbers for each patient were transposed and subsequently incorrectly entered on the computer system. One of the units was issued from the laboratory and the transfusion commenced. One hour after the product had been collected, laboratory staff detected the error during routine audit. The transfusion was discontinued. On retrospective crossmatch the unit was confirmed compatible with the recipient.

Level 2 IBCT Case 105
This female patient with an underlying malignancy was admitted via A&E and required a transfusion of red cells for symptomatic anaemia Hb 5.8g/dl. The patient regularly attended the day ward for transfusion. On this occasion, three units of red cells were prescribed during the on call period. During issue of the units, however, a problem was encountered with the computer printer and only two issue labels were printed. These two labels were reversed and then fixed to crossmatch compatible but incorrect units. Undetected during the final bedside checking procedure.

Level 2 IBCT Case 6

Level 3 IBCT Case 41

Table 16: Unit labelling errors (N=4)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 24*</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit numbers for two different crossmatched patients transposed on compatibility slip.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 105*</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit labels for crossmatched units attached to the incorrect units. Undetected during the final bedside checking procedure.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 6</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>The medical scientist crossmatched three units for this patient. The labels for two of the intended units were transposed.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 41</td>
<td>24 units of SD Plasma</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect batch number and group on SD Plasma on label in error in emergency due to incorrect selection of batch number from computer.</td>
</tr>
</tbody>
</table>

* Included as full case history
### Table 17: Blood supply centre problems (N=3)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>ABO and Rh Group of Patient</th>
<th>Volume of IBCT</th>
<th>ABO and Rh Group of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 77</td>
<td>Group A Rh D negative</td>
<td>Two units of platelet concentrate</td>
<td>Rh D negative</td>
<td>No complications as a result of this transfusion.</td>
<td>No in-date Rh negative product available. Expired units issued and transfused in emergency obstetric haemology.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 110 IBCT</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>Group O Rh D positive</td>
<td>Significant rise in BP during transfusion, which resolved on cessation of transfusion and without medication. Unlikely to be related to the transfusion.</td>
<td>Unit of red cells issued as an emergency from the supply centre was incorrectly selected and labelled as antigen negative when in fact it was antigen positive.</td>
</tr>
<tr>
<td>2</td>
<td>Case 25 *P</td>
<td>Group B Rh D negative</td>
<td>Plasma exchanged on four occasions with 12 units of Uniplas</td>
<td>Uniplas - SD Plasma</td>
<td>Positive DAT. No other complications as a result of this transfusion. Subsequently transfused with group B FFP.</td>
<td>Inability of supply centre to supply group B SD plasma for large volume exchange.</td>
</tr>
</tbody>
</table>

*P Included as full case history in paediatric chapter

### Table 18: Errors surrounding collection, storage or improper handling of components (N=4)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 114</td>
<td>Two units of SD plasma</td>
<td>No complications as a result of this transfusion</td>
<td>SD Plasma transfused 12 hours after it was thawed.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 121 *P</td>
<td>One aliquot of red cells</td>
<td>No complications as a result of this transfusion</td>
<td>Last aliquot of paedipack red cells removed from fridge in error and wasted. Stock neonatal red cells used.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 109</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion</td>
<td>Blood out of controlled storage for 1 hour and 25 minutes, then returned to fridge. Later transfused.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 127</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion</td>
<td>Unit recalled by blood issue centre as the temperature of the blood storage area on the vehicle during delivery was not within specification on one probe, although van temperature chart was within specification.</td>
</tr>
</tbody>
</table>

*P Included as full case history in paediatric chapter
Miscellaneous (n=14)

Included in this category are reports of:

- Expired pre-transfusion sample/units (6)
- Expired units transfused (1)
- Transfusion time exceeded (5)
- Unit inappropriately checked (1)
- Failure to prescribe transfusion (1)

Table 19: Expired pre-transfusion sample/units (N=6)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 5</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Crossmatch sample should have been repeated as more than 72 hours had elapsed since the original crossmatch had been taken. The patient had been transfused within that time.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 9</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Patient needed three units of red cells. Third unit given outside 72 hours from the collection of the crossmatch sample. A new sample would have been required.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 117</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>A unit of red cells was collected from the issue fridge more than 48 hours after the first unit was transfused outside hospital policy.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 69</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit issued using a crossmatch specimen which was 58 hours old when the patient had been transfused within this period outside hospital policy.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 54</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Transfusion &gt;72 hours from time of sample. Failure by laboratory to remove blood from the fridge.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 80</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>An on call medical scientist crossmatched 2 units of red cells outside the 48 hour period required by hospital policy.</td>
</tr>
</tbody>
</table>

Table 20: Expired units transfused (N=1)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>IBCT Case 39</td>
<td>Two units of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Two units transfused which had expired. Due to a bank holiday the day before ward staff checking the unit had mixed up the date and thought it was correct. It is not clear why short-dated blood was issued from the laboratory.</td>
</tr>
</tbody>
</table>
Table 21: Transfusion time exceeded (N=5)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>IBCT Case 13</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Transfusion time exceeded four hours and resulted in some of the product being transfused after midnight on the date of expiry.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 59</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>One unit of red cells transfused over 5 hours and 10 mins following removal from fridge.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 83</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>One unit of red cells transfused over 6 hours.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 100</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit transfused over 6 hours.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 101</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Unit transfused over 5 hours and 10 minutes.</td>
</tr>
</tbody>
</table>

Table 22: Unit inappropriately checked prior to transfusion (N=1)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 90</td>
<td>Half a unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>In a busy, short staffed ward, collection slip used to cross check unit instead of compatibility report form.</td>
</tr>
</tbody>
</table>

Table 23: Failure to prescribe transfusion (N=1)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Volume of IBCT</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>IBCT Case 118</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Red cells documented in patients notes but not transcribed into the transfusion prescription chart.</td>
</tr>
</tbody>
</table>
Wrong component transfused - Factor concentrate: Case history

Level 1 IBCT Case 73
This patient with an underlying malignancy received recombinant factor VIII in error. The product had been prescribed for a patient with factor VIII deficiency. The patient was sharing a room with three other patients and the product was checked against the prescription by two people in the clinic room, away from the patient’s bedside. When the patient’s first name was called in the ward, the incorrect patient answered and the ID band or the mandatory three identifiers were not confirmed. The product was given to this patient. The error was discovered following administration when the patient was again called by the first name and replied that was not his name. The correct patient was then identified and factor VII was then given to the correct patient.
Findings
There were 25 incidents involving Anti-D. Thirteen (54%) were classified as serious or level 1 incidents. Nine (38%) were classified as level 2 and 2 (8%) were classified as level 3. One case was not levelled as it occurred outside the control of the hospital.

Errors in administration (N=7)
- Six level 1 incidents involved the administration of Anti-D in error (Cases 37, 48, 60, 92, 95 and 106). Three involved administration of Anti-D to Rh positive women.
- Two of these cases involved administration to the wrong patient (Cases 37 and 106), one of whom was Rh D positive, because of failure to follow correct identification procedures.
- In two further cases, patients were given Anti-D because of a transcription error in the patient's chart in one case (Case 60), and a faxed report of an incomplete laboratory investigation entered onto the computer in the second case (Case 95).

Omission/Delay (N=12)
Anti-D was omitted in six cases (Cases 3, 10, 26, 56, 103 and 104).

The reasons for failure to give Anti-D include:
- In one case, due to a laboratory transcription error, a test result was recorded incorrectly (Case 103).
- In another case (Case 3), there was an incorrect phoned result from the laboratory and the correct report was only received five days post discharge.
- In a further case (Case 56), the patient had suffered a fall and a due to failure to review the Kleihauer result prior to discharge, administration of Anti-D was omitted. Subsequently the patient
was readmitted to the hospital five weeks later for bleeding and received Anti-D on that admission.

- In another case (Case 104), Anti-D was not given for a large vaginal bleed at 35 weeks by the GP or at a routine hospital visit one week later. The patient was found to be alloimmunised at delivery.

In six cases Anti-D administration was delayed from between four to 11 days (Cases 7, 8, 12, 36, 84, and 79).

The causes of the delay include:

- Failure to take a cord blood sample and the subsequent transfer of the mother to another hospital (Case 8).
- Failure to prescribe Anti-D at time of receipt of the cord blood result and subsequently the result was incorrectly transcribed into the chart (Case 84).
- In one case (Case 7), the result was only available after discharge. The patient was booked to return for a procedure which would have been within 72 hours of delivery. A decision was made to administer the Anti-D at this visit and while it was issued it was not administered at that time.
- In three cases (Cases 12, 26, and 79), the patient could not be contacted/failed to return to receive Anti-D. However, in one of these cases (Case 26) the delay was originally caused by the fact that the initial blood group sample was incorrectly labelled and had therefore not been processed.

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).
- There should be easy access to current laboratory results, either in written or electronic format. Both the prescriber and the person administering Anti-D should always check the most recent report of the patient’s RhD and antibody screen to assess the need for the product prior to administration. Transcribed RhD results must not be accepted; the original reports must always be consulted. Wherever possible, these written results rather than telephone results should be used to prescribe and administer Anti-D.
- Anti-D results should not be entered into the computer/released before the result has been confirmed.
- Effective communication between clinical and laboratory staff relating to antibody screening and the issuing of Anti-D, both in the ante and postnatal period is vital in preventing errors. This is particularly important where patients are receiving shared care between their GP and Obstetrician.
- Where mothers or babies are being nursed outside the normal clinical areas or in a different hospital, it should be the responsibility of the referring unit to follow up these patients and ensure that clinical staffs are aware of specific requirements.
- Medical and Nursing staff working in all clinical areas where RhD 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.
- 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 (BCSH, 1999).
Problems with weak RhD groups or misinterpretation of RhD status (n = 4)

There were four cases in this category (Cases 11, 34, 61 and 65)

• It is debatable whether some of these should be regarded as true errors as appropriate reagents/techniques were used and the difficulties in identification of weak D types reflect the limitations of the technology.

• In one case (Case 11), Anti-D was administered on the basis of historical records and the significance of the weak D type (RhD^u) was not recognised by the laboratory or the administering staff.

• In two reports (Case 61 and 65), Anti-D was issued and administered while awaiting a confirmatory result from a reference centre which showed the patient to be RhD positive (weak D identified). The administration of Anti-D in these cases was in fact appropriate as the practice is in line with BCSH guidelines (2004).

• In one case (Case 34), a patient who had been previously been classified as Rh D negative and had received Anti-D, was now reclassified as RhD positive (weak D) using different technology. This new result was misfiled resulting in unnecessary administration of Anti-D.

Recommendations for weak RhD typing

• The use of D^u terminology is no longer recommended. The phrase D^u was originally used for D antigens detected by only some Anti-D reagents. High grade D^u cells are those that are directly agglutinated by some Anti-D reagents and low grade D^u refers to D antigens only detected using the indirect antiglobulin technique (IAT). The BCSH Guidelines (2004) for compatibility testing recommend that the IAT should not be used for D typing of patients to reduce the potential for mistyping partial D variants as Rh D positive.

• RhD variants may be divided into those that reflect a quantitative change or a qualitative change in the RhD antigen.

• Partial RhD variants are qualitatively different. The RhD antigen is a mosaic of epitopes and partial RhD variants lack a proportion of these epitopes. People whose red cells lack part of the RhD mosaic can then form antibodies to the missing epitope which behave like Anti–D when tested against normal RhD types. The most common partial D type associated with risk of alloimmunization to RhD is DVI.

• Weak D variants are considered to have all the D epitopes present but expressed weakly i.e. fewer D antigen sites per cell.

• Partial weak D cells have some epitopes missing, the remainder being expressed weakly.

• Most examples of weak D can be easily detected by selecting high affinity monoclonal reagents for routine RhD typing. The reagents/techniques used should not detect partial DVI types.

• Patients should not be regarded as RhD positive where a weak positive result has been obtained using only a single Anti-D reagent (or a pool of more than one reagent). It is safer to regard the patient as RhD negative until confirmatory grouping has been performed by a reference laboratory.

• Where verification checks against historical results reveal a discrepancy of an RhD group (previous RhD negative – now RhD positive) it should not be assumed that this was due to failure of previous technology to identify a weak RhD phenotype. Confirmatory typing should be
performed on a new sample to exclude a sample identification error.

- Investigation of discrepancies may require involve referral to a reference serology laboratory. As Anti-D should be given as soon as possible after the sensitizing event and always within 72 hours, administration should not be delayed pending availability of results.

- The BCSH guidelines on compatibility testing (BCSH 2004) which includes RhD typing advise that where uncertainty arises regarding a patient’s RhD status that the patient is treated as RhD negative pending further investigation, as in Case 61 and 65.

- Because it may be difficult or impossible to distinguish between passive Anti-D resulting from a previous Anti-D injection during pregnancy and weak Anti-D resulting from early immunisation, Anti-D immunoglobulin should be given to any eligible woman with weak Anti-D antibody at delivery unless it has been clearly confirmed that she is already immunised (BBTS/RCOG 1999).

- Patients identified as having a partial D antigen should be regarded as RhD negative and the significance should be explained to the patient and her clinician.

- Patients who are confirmed as weak RhD positive should be regarded as RhD positive for transfusion and Anti-D prophylaxis purposes. If the patient was treated as RhD negative in the past then the findings should be explained to both the patient and the clinician and the patient’s file clearly marked to indicate the change in status so that confusion does not arise when sensitizing events occur.
Table 25: Administration of Anti-D in error (N=7)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>RhD Group of Patient</th>
<th>Volume of Incorrect Blood Component or Product Transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WRONG IDENTITY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 106</td>
<td>RhD positive</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date. Unnecessary exposure to blood product</td>
<td>Anti-D given in error to a RhD positive mother because of remote checking and failure to confirm positive patient identification prior to administration.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 37*</td>
<td>RhD negative</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date. Unnecessary exposure to blood product</td>
<td>Two group RhD negative patients with the same name and same address delivered babies within 48 hours. One baby was RhD positive and the other RhD negative. Anti-D was given to the wrong mother.</td>
</tr>
<tr>
<td><strong>TRANSCRIPTION/RECORDING ERROR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 60*</td>
<td>RhD positive</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date. Unnecessary exposure to blood product</td>
<td>Patient’s blood group incorrectly transcribed as O RhD negative on to the inside front cover of the patient’s record based on a report from a different hospital.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 95*</td>
<td>RhD positive</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date. Unnecessary exposure to blood product</td>
<td>Blood group report faxed to ward, from computer results which had been entered before testing was complete on sample.</td>
</tr>
<tr>
<td><strong>ALLOIMMUNISED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 92*</td>
<td>RhD negative</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date. Unnecessary exposure to blood product</td>
<td>Anti-D detected in mother’s blood from previous sensitising incident, unknown cause. Laboratory instruction not to administer Anti-D. During medical follow up Anti-D ordered and administered in error.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 48</td>
<td>RhD negative</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date. Unnecessary exposure to blood product</td>
<td>One unit of Anti-D given to an already sensitised mother following delivery.</td>
</tr>
<tr>
<td><strong>INCORRECT DOSAGE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>IBCT Anti-D Case 32</td>
<td>RhD negative</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>PV bleeding during the first trimester, hospital policy specifies half the normal dose to be given in this case i.e. 626 iu. Full dose was given.</td>
</tr>
</tbody>
</table>

* Included as full case history
### Table 26: Omission in administration of Anti-D (N= 6)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>RhD Group of Patient</th>
<th>Volume of Incorrect Blood Component or Product Transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 3</td>
<td>RhD Negative</td>
<td>Anti-D omitted</td>
<td>No complications reported to date.</td>
<td>An incorrect phone result was given by the laboratory to the ward, stating that baby was RhD negative. Baby was in fact RhD positive. Mother did not receive Anti-D. The official result was only received after discharge of the mother and was not acted on.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 56</td>
<td>RhD Negative</td>
<td>Anti-D omitted</td>
<td>No complications reported to date.</td>
<td>Administration delayed pending Kleihauer result. Kleihauer test showed occasional cells but not reviewed and Anti-D not administered.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 103</td>
<td>RhD Negative</td>
<td>Anti-D omitted</td>
<td>No complications reported to date.</td>
<td>Patient miscarried; the blood group testing was performed correctly but recorded incorrectly. Patient should have received Anti-D at that time. Error detected on subsequent pregnancy.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 104</td>
<td>RhD Negative</td>
<td>Anti-D omitted</td>
<td>Anti-D antibody developed</td>
<td>Ante natal patient with a PV bleed at 35 weeks attended GP. Anti-D was not given. Routine ante natal visit one week later Anti-D not administered. At delivery it was noted that Anti-D antibodies had developed.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 10</td>
<td>RhD Negative</td>
<td>Anti-D omitted</td>
<td>No complications reported to date.</td>
<td>Failure to administer Anti-D following bleed in 13th week of pregnancy. Previous group/records not checked</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 26</td>
<td>RhD Negative</td>
<td>Anti-D omitted</td>
<td>No complications reported to date.</td>
<td>Patient presented post trauma at 36 weeks gestation. Specimen incorrectly labelled, repeat sample requested. Patient contacted and did not return for 10 days. Patient refused Anti-D.</td>
</tr>
</tbody>
</table>
Table 27: Delay in administration of Anti-D (N=6)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>RhD Group of Patient</th>
<th>Volume of Incorrect Blood Component or Product Transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 7</td>
<td>RhD Negative</td>
<td>One dose of Anti-D administered four days after threatened miscarriage.</td>
<td>No complications reported to date.</td>
<td>Patient had a threatened miscarriage, 17 weeks gestation. Sample processed the following day by which time the patient had been discharged. Patient scheduled to return for a procedure within the 72 hours Anti-D was issued for administration at this visit but it was not administered at this time.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 8*</td>
<td>RhD Negative</td>
<td>One dose of Anti-D administered eight days post delivery</td>
<td>No complications reported to date.</td>
<td>Cord blood not taken from baby prior to mothers transfer to another hospital following caesarean section. The need for Anti-D for the mother not identified.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 84</td>
<td>RhD Negative</td>
<td>Anti-D given &gt;100 hours following delivery</td>
<td>No complications reported to date.</td>
<td>Cord blood incorrectly transcribed into medical notes as RhD negative. Patient had been discharged when the error was noted</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 12</td>
<td>RhD Negative</td>
<td>One dose of Anti-D 5 days after bleed</td>
<td>No complications reported to date.</td>
<td>Delay in administering Anti-D post sample taking as the patient had been discharged and had given an incorrect telephone number.</td>
</tr>
<tr>
<td>n/a</td>
<td>IBCT Anti-D Case 79</td>
<td>RhD Negative</td>
<td>Anti-D given at 96 hours</td>
<td>No complications reported to date.</td>
<td>Patient discharged herself early. Did not return for Anti-D until &gt;72 hours in spite of four telephone calls</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 36</td>
<td>RhD Negative</td>
<td>Anti-D given 11 days post first bleed</td>
<td>Unknown</td>
<td>Attended emergency room on two occasions with heavy bleeding prior to 12th week of pregnancy. Previous group records not checked.</td>
</tr>
</tbody>
</table>

* Included as full case history
Table 28: Failure to identify weak RhD groups or misinterpretation of RhD status (N=4)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>RhD Group of Patient</th>
<th>Volume of Incorrect Blood Component or Product Transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 11</td>
<td>RhD positive (weak D positive)</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>Anti-D was administered on the basis issued of an historical records (A Rh negative, Du positive) Most recent sample was not tested until the next working day and was reported as Rh D positive. Both the laboratory and the administering staff were unaware of the significance of Du positivity.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 34</td>
<td>RhD positive (weak D positive)</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>Patient previously grouped as A RhD negative and received Anti-D in previous pregnancies. Although initial sample in current pregnancy tested in reference laboratory suggested she may have a partial D antigen, further testing on a new sample confirmed she was RhD positive (weak D). The new result was misfiled resulting in unnecessary Anti-D administration.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 61</td>
<td>RhD positive (weak D positive)</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>Patient grouped RhD negative, however, confirmation RhD status from reference centre showed the patient was RhD weak D positive.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 65</td>
<td>RhD positive (weak D positive)</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>Patient grouped RhD negative by on call medical scientist not normally working in transfusion. Scientist unaware of confirmatory testing required for weak D group patients.</td>
</tr>
</tbody>
</table>

Table 29: Anti-D batch number/labelling incorrect (N=2)

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>RhD Group of Patient</th>
<th>Volume of Incorrect Blood Component or Product Transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>IBCT Anti-D Case 44</td>
<td>RhD negative</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>Incorrect batch number on the issue label and box label of Anti-D as the batch number selected was that of the next batch which was in stock but not in use.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Anti-D Case 72</td>
<td>RhD negative</td>
<td>One dose of Anti-D</td>
<td>No complications reported to date.</td>
<td>Vial of Anti-D labelled for one patient given to a different patient who also needed Anti-D.</td>
</tr>
</tbody>
</table>
A number of case histories are described in more detail

Wrong Patient

Level 1 IBCT Anti-D Case 37
Two RhD negative mothers with the same first name surname and same address gave birth within 48 hours. One baby grouped as RhD positive and the other as RhD negative. Anti-D was prescribed and requested correctly for the RhD negative mother who had delivered the RhD positive infant. Two health care professionals checked the documentation, which included the mother and infant’s RhD status, prescription and product, at the nurse’s station. The Anti-D was administered at the bedside using the mothers name as confirmation only and was administered to the incorrect patient. Following administration a midwife highlighted the presence of two patients with the same name and address to the person who had administered the Anti-D and the error was realised. The correct patient received Anti-D subsequently.

Recording Errors

Level 1 IBCT Anti-D Case 60
This young group RhD positive patient delivered a RhD positive baby. An old report which originated from another hospital was filed in the patient’s chart, where the result was recorded as RhD negative. This result was transcribed on the inside front cover of the patients current chart and Anti-D was prescribed, issued and administered to the patient based on this result. There were in fact more recent results available from the admitting hospital which showed the patient to be RhD positive. The error remained undetected prior to issue from the laboratory which did not check their own Anti-D typing results. The error was discovered while checking the medical notes for other information.

Level 1 IBCT Anti-D Case 95
This antenatal patient presented to hospital at 11 weeks gestation with a PV bleed and bloods were sent for routine antenatal screening to a laboratory off-site. The patient was aware that her blood group was RhD positive and she was discharged later that evening. The patient’s blood group result was faxed to the ward later that weekend and the report showed the group was O RhD negative. The patient was contacted and requested to attend for administration of Anti-D. When she presented she again repeated that in fact she was RhD positive and refused Anti-D. At this point the midwife contacted the laboratory and explained the lady’s concern. The medical scientist checked the computer records and said that the correct result had been faxed to the clinical area and Anti-D was administered by the midwife. The laboratory telephoned the ward some time later and stated that the result, which had been faxed to the ward, was in fact incomplete and incorrect and the patient’s blood group was O RhD positive. On post event analysis it appears that a result had been entered on the laboratory computer system prior to the complete result being available and confirmed.

Alloimmunised

Level 1 IBCT Anti-D Case 92
This RhD negative primigravida delivered a RhD positive baby. Anti-D was detected in the mother’s blood. The reason for this sensitisation was unclear. The laboratory requested a further sample of blood from the mother for Anti-D quantitation. Following review the laboratory result forms and the nursing notes clearly stated that the mother was not for Anti-D immunoglobulin administration. The patient was discharged home. The mother attended a follow up medical appointment and in error was referred back to the maternity hospital for Anti-D administration. The product was prescribed and administered as ordered.
Omission/delay in administration of Anti-D: Case history

Level 1 IBCT Anti-D Case 8
This lady was transferred to another hospital following a caesarean section delivery. The baby did not have cord blood taken immediately post delivery although the baby was subsequently grouped as RhD positive. On transfer of the mother back to the maternity hospital medical staff realised that the mother was group RhD negative and the baby was group RhD positive. Anti-D had not been administered to the mother. Anti-D was administered eight days post delivery.
Severe Acute Anaphylactoid or Anaphylactic Transfusion Reaction

**Definition**

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

This category captures acute allergic and anaphylactic reactions. All allergic type reactions except for mild rashes and localised urticaria are collected by the NHO as are such reactions occurring despite premedication cover.

As allergists are moving away from the term ‘anaphylactoid’, the European Haemovigilance Network are proposing that the term ‘anaphylactic reaction’ which covers both anaphylactoid reactions and anaphylactic shock should replace it. The NHO proposes to change the title of this category in 2006 to Acute Allergic and Anaphylactic Reactions.

The cause of these allergic type reactions is not fully elucidated (Gilstead, 2003). Severe IgA deficiency is present in about 1:700 blood donors and a small number of individuals who are IgA deficient develop anti IgA antibodies which can be associated with severe and occasionally fatal reactions. In the Japanese population, where haptoglobin deficiency is much more common than IgA deficiency, anti-haptoglobin antibodies have been associated with allergic/anaphylactoid reactions. (Koda et al 2000)

In the majority of patients, however, no underlying cause is found in the patient to explain the reactions. Reactions may not be triggered by the blood products per se but rather by other concurrent aspects of patient treatment or parallel drug administration. It is now appreciated that angiotensin–converting enzyme (ACE) inhibitors block kininase II allowing accumulation of plasma kinins and increasing the risk of an anaphylactoid reaction (Unsworth 2005).

Plasma constituents in the product may be responsible. Since the replacement of FFP by SD plasma which is associated with a low risk of allergic type reactions, increasing numbers of these reactions have been reported to the NHO associated with platelets. The majority are associated with pooled platelets but cases have also been reported with apheresis platelets. Release of cytokines/chemokines in stored platelets such as C3a and C5a, have been suggested as a cause (Boehlen 2001) (Gilstad 2003). In a small series of patients, removal of plasma from platelet concentrates and replacement by platelet storage medium reduced the
incidence of allergic type reactions, although it did not have a significant effect on the incidence of febrile non haemolytic type reactions. (Heddle 2002).

Serum tryptase is a marker of anaphylaxis which peaks in one to two hours and may return to normal in three to four hours, but it can remain elevated for up to 48 hours. It has been suggested serum tryptase deserves further study as a potential marker for severe allergic transfusion reactions, with or without anaphylaxis. (Domen, and Hoeltge, 2003)

Findings

This category accounted for 16% (35 of 214) of the incidents reported during the reporting year. This represents an increase of 50% of submitted reports based on the 2003 figures due to increased reactions associated with platelets.

- The incidence of A/A was 1:651 units of platelets issued, 1:22705 units of red cells/whole blood issued and 1:12424 units of SD plasma issued.
- As in previous years, the majority of A/A reactions involved platelets. Twenty one involved pooled platelets and six involved apheresis platelets.
- Six (17%) of the reports were associated with red cell transfusions.
- Two reports (6%) involved SD plasma (Cases 16 and 31). In one case (Case 16), it appears that the transfusion was inappropriate as SD plasma instead of vitamin K was used for warfarin reversal.
- Paediatric patients (under 18 years old) were involved in seven reports (20%). The same paediatric patient, however, was involved in three of the reports (Cases 21, 22, and 23).
- As three patients were involved in more than one report, a total of 31 patients were involved. Of the 31 patients, 26 had an underlying malignant condition.
- In eight reports, the patient had had a previous transfusion reaction. In five cases, the patient had received premedication prior to transfusion but went on to develop a reaction nonetheless. The severity of the reaction however may have lessened. In one further report (Case 35), the patient had a previous reaction to medication and was receiving regular chlorpheniramine but did not receive premedication before the transfusion.
- In 27 reports, recommendations were made to manage future transfusions. In 12 reports premedication cover prior to future transfusions was recommended. In nine reports apheresis platelets were recommended associated with premedication. Washed components were recommended in six cases.
- The majority of cases responded well to treatment with chlorpheniramine or a combination of chlorpheniramine and hydrocortisone, within two hours. However in ten reports further treatment was required. One case (Case 34) associated with red cells required glyceryl trinitrate (GTN) spray, oxygen and IV fluids and transfer to a tertiary centre for further management, although future transfusions have been uneventful.
- In the majority of reports there were cutaneous manifestations, but in seven, these were not present. In one of these cases (Case 8), overload was also present and it is unclear if the reaction was actually A/A. In one report (Case 30) the main symptoms were nausea and vomiting.
Recommendations

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

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

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

• Protocols and training for the management of severe A/A reactions should be in place in each hospital and all staff involved in transfusion should be familiar with them. The 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 an anaphylactoid reaction during a blood component transfusion should have a label placed on their chart alerting clinical staff to their history of transfusion reactions and to ensure that appropriate premedication is given prior to future transfusions.

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

• IgA deficiency (<0.05mg/dl) with anti IgA antibodies can cause severe anaphylactoid reactions and anaphylaxis.

• Patients with severe or repeated reactions should have IgA levels performed.

• Since the transfused product may contain appreciable quantities of IgA, where possible, samples taken pre-transfusion should be used to check for 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 A/A reactions are only appropriate for patients with a history of anaphylactic or severe anaphylactoid transfusion reactions uncontrolled by premedication. A poorly justified requirement for washed components may cause undue delays when transfusions are needed in the future. In addition, washing of platelets can affect platelet yields with loss of platelet numbers and viability from the washing process and poor in vivo incremental rises.

• Before prescribing washed platelets for patients with a history of transfusion reactions to pooled products, a trial of apheresis platelets should be undertaken as patients who react to pooled platelets may often tolerate apheresis platelets.

• Classical allergic or anaphylactoid reactions do not routinely require culture of the unit or pack or serological investigations. However, where atypical symptoms such as fever are present in a suspected A/A reaction or where skin manifestations are absent, it is important to culture the implicated unit/s and the patient, to rule out underlying sepsis and/or bacterial infection in the unit and in the case of red cells to undertake serological tests to exclude incompatibility.
### Table 30: AA Cases Associated with Platelets (n=27)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age yrs</th>
<th>Gender</th>
<th>Component</th>
<th>Reason for Transfusion</th>
<th>Symptoms</th>
<th>Investigations</th>
<th>Stage Transfusion Reaction Developed</th>
<th>Treatment</th>
<th>Sequelae/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 1</td>
<td>52</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 15x10⁹/L Malignancy.</td>
<td>Urticaria, GI symptoms including cramps.</td>
<td>Unit cultured no growth. IgA levels not checked.</td>
<td>Following completion of transfusion.</td>
<td>Hydrocortisone and chlorpheniramine IV.</td>
<td>Recovery within one hour. Subsequent transfusions have been uneventful.</td>
</tr>
<tr>
<td>AA Case 2</td>
<td>46</td>
<td>M</td>
<td>Two units HLA matched platelet concentrate</td>
<td>Platelet count 14x10⁹% Haematological Malignancy.</td>
<td>Bilateral periorbital oedema.</td>
<td>Unit cultured, no growth. IgA levels not checked.</td>
<td>Following completion of transfusion.</td>
<td>Hydrocortisone and chlorpheniramine IV.</td>
<td>Recovery within minutes. No recommendations documented.</td>
</tr>
<tr>
<td>AA Case 3</td>
<td>43</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 34x10⁹% Haematological malignancy, active bleeding.</td>
<td>Dyspnoea, falling O₂ saturations, chills.</td>
<td>IgA levels normal. Culture of unit and patient no growth.</td>
<td>Following completion of transfusion.</td>
<td>Chlorpheniramine IV.</td>
<td>Recovery within 30 minutes. Apheresis platelets have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA Case 4</td>
<td>22</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 17x10⁹% Malignancy.</td>
<td>Dyspnoea, sub-ternal discomfort, tachycardia (170bpm), falling O₂ saturations, chills.</td>
<td>Patient cultured, no growth, unit not cultured. IgA levels not checked</td>
<td>Following completion of transfusion.</td>
<td>Hydrocortisone and chlorpheniramine IV and salbutamol nebulizer.</td>
<td>Recovery within 20 minutes. Apheresis platelets have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA Case 5 *</td>
<td>51</td>
<td>M</td>
<td>One unit of pooled platelet concentrate</td>
<td>Platelet count 76x10⁹% Malignancy, active bleeding.</td>
<td>Urticaria, dyspnoea, GI symptoms, tachycardia, falling O₂ saturations.</td>
<td>Culture of both unit and patient, no growth. IgA levels not checked.</td>
<td>Following completion of transfusion.</td>
<td>Hydrocortisone and chlorpheniramine IV.</td>
<td>Recovery within 45 minutes. Patient subsequently had a mild urticarial reaction following apheresis platelets and is now being transfused with washed platelets.</td>
</tr>
<tr>
<td>AA Case 7</td>
<td>68</td>
<td>M</td>
<td>One unit of pooled platelet concentrate</td>
<td>Platelet count 28 x10⁹% Malignancy.</td>
<td>Flushing, urticaria.</td>
<td>None</td>
<td>Following completion of transfusion.</td>
<td>Hydrocortisone and chlorpheniramine IV.</td>
<td>Recovery within one hour. Premedication of chlorpheniramine and paracetamol have been recommended for future transfusions.</td>
</tr>
</tbody>
</table>

* Included as a full case history
*P Included as a full case history in paediatric chapter
<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age yrs</th>
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<th>Treatment</th>
<th>Sequelea/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 8</td>
<td>82</td>
<td>M</td>
<td>One unit of pooled platelet concentrate</td>
<td>Platelet count 6 x10^9/L, Haematological malignancy.</td>
<td>Hypertension, tachycardia, chills, rigors, fall in O_2 saturation and rise in PCO_2, ECG changes.</td>
<td>Culture of pack and patient, no growth.</td>
<td>Following transfusion of 50 mls.</td>
<td>Hydrocortisone, chlorpheniramine, adrenaline IV, salbutamol nebulizer. Transfusion discontinued</td>
<td>Died unrelated to transfusion.</td>
</tr>
<tr>
<td>AA Case 9</td>
<td>20</td>
<td>F</td>
<td>One unit of apheresis platelet concentrate</td>
<td>Platelet count &lt;10x10^9/L, Malignancy.</td>
<td>Dyspnoea, substernal discomfort, falling O_2 saturations, restlessness and anxiety.</td>
<td>IgA level normal. Culture of the patient and unit, no growth.</td>
<td>45 minutes into the transfusion when 190 mls had been transfused.</td>
<td>Hydrocortisone and chlorpheniramine IV. Transfusion discontinued.</td>
<td>Recovery within twenty minutes. Apheresis platelets and premedication have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA Case 10</td>
<td>12</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 54 x 10^9/L, Haematological malignancy, sepsis.</td>
<td>Urticaria despite premedication with hydrocortisone and chlorpheniramine IV.</td>
<td>None</td>
<td>Following completion of transfusion</td>
<td>None</td>
<td>Recovery within thirty minutes. Washed components have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA Case 11</td>
<td>11</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 18 x10^9/L, Haematological malignancy.</td>
<td>Urticaria, itch and discomfort despite premedication with hydrocortisone and chlorpheniramine IV.</td>
<td>None</td>
<td>45 minutes after commencing transfusion.</td>
<td>Hydrocortisone IV.</td>
<td>Recovery within thirty minutes. Washed components have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA Case 12</td>
<td>45</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 18 x10^9/L, Haematological malignancy.</td>
<td>Urticaria, chills, rigors, vomiting, cough and tightness in throat.</td>
<td>ABO incompatibility excluded. IgA levels normal.</td>
<td>One hour following completion of transfusion.</td>
<td>Hydrocortisone and chlorpheniramine IV.</td>
<td>Recovery within four hours. Recommendations not documented.</td>
</tr>
<tr>
<td>AA Case 13 *</td>
<td>58</td>
<td>M</td>
<td>One unit of apheresis platelet concentrate</td>
<td>Platelet count &lt;10x10^9/L, Haematological malignancy.</td>
<td>Urticaria, dyspnoea, stridor, wheeze, and falling O_2 saturations.</td>
<td>None</td>
<td>Twenty minutes into the transfusion when 160 mls had been transfused.</td>
<td>Hydrocortisone and chlorpheniramine IV oxygen and salbutamol nebulizer.</td>
<td>Recovery within 10 minutes. Subsequent transfusions with premedication of chlorpheniramine have been uneventful.</td>
</tr>
</tbody>
</table>

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### Table 30: AA Cases Associated with Platelets (n=27) (cont)

<table>
<thead>
<tr>
<th>Case No.</th>
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<th>Stage Transfusion Reaction Developed</th>
<th>Treatment</th>
<th>Sequelea/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 14</td>
<td>26 F</td>
<td>One unit of apheresis platelet concentrate</td>
<td>Platelet count 67x10⁹/L. Haematological malignancy, active bleeding.</td>
<td>Hypertension, dyspnoea, substernal discomfort despite premedication of chlorpheniramine.</td>
<td>IgA level normal, HLA antibody screen negative.</td>
<td>Two hours Following completion of transfusion.</td>
<td>Chlorpheniramine.</td>
<td>Recovery within five minutes. Premedication with chlorpheniramine and apheresis planned. If unsuccessful saline washed platelets to be used.</td>
<td></td>
</tr>
<tr>
<td>AA Case 19</td>
<td>20 M</td>
<td>One unit of pooled platelet concentrate</td>
<td>Platelet count 15x10⁹/L. Haematological malignancy.</td>
<td>Extensive rash on all limbs. Dyspnoea stridor, wheeze, tachycardia, hypertension, anxiety and periorbital oedema.</td>
<td>IgA levels post transfusion normal.</td>
<td>Post transfusion</td>
<td>Hydrocortisone and chlorpheniramine IV</td>
<td>Recovery within four hours. Subsequent transfusions using apheresis platelets have been uneventful.</td>
<td></td>
</tr>
<tr>
<td>AA Case 20, 24</td>
<td>62 F</td>
<td>Two units of apheresis platelet concentrate (1st transfusion)</td>
<td>Platelet count &lt;10x10⁹/L. Haematological malignancy.</td>
<td>Feeling of sunburn on both legs and nausea. Diarrhoea following day.</td>
<td>HLA antibody screen negative.</td>
<td>Post transfusion following day at home.</td>
<td>None, patient was at home.</td>
<td>Recovery time unclear.</td>
<td></td>
</tr>
<tr>
<td>Same patient</td>
<td></td>
<td>Two units apheresis platelet concentrate (2nd transfusion)</td>
<td>Platelet count &lt;10x10⁹/L. Haematological malignancy.</td>
<td>Rash on anterior aspect of foot and swollen foot.</td>
<td>IgA levels normal.</td>
<td>Post transfusion at home.</td>
<td>Subsequent transfusions with apheresis platelets and premedication of chlorpheniramine have been uneventful.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AA Case 21, 22 &amp; 23</td>
<td>6 M</td>
<td>One unit of pooled platelet concentrate (1st transfusion)</td>
<td>Platelet count 10x10⁹/L. Malignancy.</td>
<td>Urticaria</td>
<td>None</td>
<td>Post transfusion</td>
<td>None</td>
<td>Recovery within one hour.</td>
<td></td>
</tr>
</tbody>
</table>

* Included as a full case history

*P Included as a full case history in paediatric chapter
#### Table 30: AA Cases Associated with Platelets (n=27) (cont)

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</tr>
</thead>
<tbody>
<tr>
<td>AA Case 25</td>
<td>46 M</td>
<td>Two units pooled platelet concentrate</td>
<td>Platelet count 27x10^9/L. Haematological malignancy.</td>
<td>Periorbital oedema, redness and extreme itching of both palms.</td>
<td>None</td>
<td>45 mins after commencing first unit and 10 mins into the second unit.</td>
<td>Hydrocortisone and chlorphenamine IV.</td>
<td>Recovery within eight hours. Previous reaction to platelets. Washed platelets and premedication with hydrocortisone and chlorphenamine for future transfusions have been recommended.</td>
<td></td>
</tr>
<tr>
<td>AA Case 25</td>
<td>68 F</td>
<td>One unit pooled platelet concentrate (1st transfusion)</td>
<td>Platelet count 16x10^9/L. Haematological malignancy.</td>
<td>Urticaria, rise in temperature of 1°C.</td>
<td>None</td>
<td>16 mls had been transfused</td>
<td>Hydrocortisone and chlorphenamine IV. Transfusion discontinued.</td>
<td>Recovered within seven hours. Premed with hydrocortisone and chlorphenamine recommended.</td>
<td></td>
</tr>
<tr>
<td>AA Case 25</td>
<td>One unit pooled platelet concentrate (2nd transfusion)</td>
<td>Platelet count 6x10^9/L. Haematological malignancy</td>
<td>Urticaria, dyspnoea, wheeze, chest tightness and cough despite pre-med with hydrocortisone and chlorphenamine IV.</td>
<td>None</td>
<td>140 mls had been transfused</td>
<td>Hydrocortisone O₂ administered.</td>
<td>Recovery within two hours. Premedication with chlorphenamine and apheresis platelets have been recommended for future transfusions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AA Case 28</td>
<td>49 F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 11x10^9/L. Haematological malignancy.</td>
<td>Culture of patient and pack, no growth.</td>
<td>Following completion of transfusion</td>
<td>Hydrocortisone and chlorphenamine IV.</td>
<td>Recovered within two hours. Premedication of antihistamine prior to platelet transfusion has been recommended for future transfusions.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Table 30: AA Cases Associated with Platelets (n=27) (cont)

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<th>Stage Transfusion Reaction Developed</th>
<th>Treatment</th>
<th>Sequelae/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA case 29</td>
<td>54</td>
<td>F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 16x10^9/L. Haematological malignancy, post BMT.</td>
<td>Dyspnoea, wheeze, throat swelling, fall in O₂ saturations.</td>
<td>None</td>
<td>Within 15 minutes of commencing transfusion when 150 mls had been transfused.</td>
<td>Hydrocortisone, chlorpheniramine IV and O₂ administered.</td>
<td>Recovered within 30 minutes. Premedication and platelet apheresis have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA case 30</td>
<td>73</td>
<td>M</td>
<td>One unit of A pooled platelet concentrate Patient O</td>
<td>Platelet count 2x10^9/L. Haematological malignancy.</td>
<td>Nausea and vomiting</td>
<td>Culture of the patient, no growth. Pack culture, Coagulase negative staphylococcus, probable contamination.</td>
<td>After four minutes of transfusion</td>
<td>None</td>
<td>Recovered within minutes. Subsequent platelet transfusions with chlorpheniramine premedication have been uneventful.</td>
</tr>
<tr>
<td>AA case 33</td>
<td>55</td>
<td>M</td>
<td>One unit of pooled platelet concentrate</td>
<td>Platelet count 57x10^9/L. Liver biopsy.</td>
<td>Urticaria, dyspnoea, GI symptoms and periorbital oedema.</td>
<td>Culture of the patient and unit no growth.</td>
<td>Following completion of transfusion</td>
<td>None</td>
<td>Recovered within one hour. Premedication of chlorpheniramine has been recommended.</td>
</tr>
<tr>
<td>AA case 35</td>
<td>30</td>
<td>M</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 10x10^9/L. Haematological malignancy, post BMT.</td>
<td>Chest tightness, nausea, vomiting, feeling of apprehension and doom, facial swelling.</td>
<td>IgA levels normal.</td>
<td>After 20 minutes of transfusion. 150 mls transfused.</td>
<td>Hydrocortisone and chlorpheniramine IV.</td>
<td>Recovered within 20 minutes. Premedication of hydrocortisone, chlorpheniramine and washed platelets have been recommended for future transfusions.</td>
</tr>
<tr>
<td>Case No.</td>
<td>Age yrs</td>
<td>Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Treatment</td>
<td>Stage/Reaction Developed</td>
<td>Sequelae/Recommendations for future transfusions</td>
</tr>
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</tr>
<tr>
<td>AA Case 6</td>
<td>19</td>
<td>M</td>
<td>One unit red cells</td>
<td>Anaemia</td>
<td>Dyspnoea, itching, nausea, generalised joint pain.</td>
<td>ABO incompatibility excluded.</td>
<td>Chlorpheniramine</td>
<td>Transfusion discontinued. 58 mls transfused.</td>
<td>Recovery within 30 minutes of receiving treatment. Further transfusions have been uneventful.</td>
</tr>
<tr>
<td>AA Case 15</td>
<td>5</td>
<td>M</td>
<td>One unit red cells</td>
<td>Anaemia</td>
<td>Anaemia</td>
<td>None</td>
<td>None</td>
<td>Within two hours of commencing transfusion. 240 mls had been transfused.</td>
<td>Recovery within two and a half hours of transfusion. Premedication of chlorpheniramine has been recommended for future transfusion.</td>
</tr>
<tr>
<td>AA Case 17</td>
<td>83</td>
<td>M</td>
<td>One unit red cells</td>
<td>Anaemia</td>
<td>Anaemia</td>
<td>Oedema of upper lip</td>
<td>ABO incompatibility excluded. IgA level normal.</td>
<td>Transfusion discontinued. No treatment given.</td>
<td>Recovery within 4.5 hours of transfusion. Premedication of chlorpheniramine has been recommended for future transfusion.</td>
</tr>
<tr>
<td>AA Case 18</td>
<td>11</td>
<td>M</td>
<td>One unit red cells</td>
<td>Anaemia</td>
<td>Anaemia</td>
<td>Urticaria, periorbital oedema.</td>
<td>ABO incompatibility excluded. Culture of patient and unit, no growth.</td>
<td>Transfusion discontinued.</td>
<td>Recovery within 4.5 hours of transfusion. Premedication of chlorpheniramine has been recommended for future transfusion.</td>
</tr>
<tr>
<td>AA Case 32</td>
<td>50</td>
<td>F</td>
<td>One unit red cells</td>
<td>Anaemia</td>
<td>Anaemia</td>
<td>Urticaria, fever rise of 1.9° C, chills, rigors, tachycardia.</td>
<td>ABO incompatibility excluded. Culture of the unit, no growth.</td>
<td>Transfusion discontinued.</td>
<td>Recovery within 4.5 hours of transfusion. Premedication of chlorpheniramine has been recommended for future transfusion.</td>
</tr>
<tr>
<td>AA Case 34</td>
<td>62</td>
<td>F</td>
<td>One unit red cells</td>
<td>Anaemia</td>
<td>Anaemia</td>
<td>Urticaria and puffy eyes.</td>
<td>ABO incompatibility excluded. Culture of the unit, no growth.</td>
<td>Transfusion discontinued.</td>
<td>Recovery within 4.5 hours of transfusion. Premedication of chlorpheniramine has been recommended for future transfusion.</td>
</tr>
</tbody>
</table>

Table 31: AA Cases Associated With Red Cells (n=6)

* Included as a full case history
*P Included as a full case history in paediatric chapter
<table>
<thead>
<tr>
<th>Case No.</th>
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<th>Investigations</th>
<th>Stage Transfusion Reaction Developed</th>
<th>Treatment</th>
<th>Sequelae/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 16 *</td>
<td>83</td>
<td>M</td>
<td>Two units SD plasma</td>
<td>INR 3.8 Haematoma secondary to trauma, cardiac disease.</td>
<td>Dyspnoea, rash on arms and stomach, pyrexia, rise of 2°C in temperature. IgA levels not checked.</td>
<td>Culture of both packs, no growth. Patient not cultured.</td>
<td>Within 30 minutes following completion of transfusion.</td>
<td>Hydrocortisone, chlorpheniramine IV and oxygen therapy.</td>
<td>Recovered within two hours. Subsequent transfusions of SD plasma with hydrocortisone and chlorpheniramine premedication have been uneventful.</td>
</tr>
<tr>
<td>AA Case 31</td>
<td>22</td>
<td>F</td>
<td>Three units SD plasma</td>
<td>INR 1.6 Major trauma.</td>
<td>Urticaria, marked hypotension, bronchospasm.</td>
<td>None</td>
<td>Following completion of three units of SD plasma.</td>
<td>Hydrocortisone, chlorpheniramine IV, noradrenaline and gelofusin.</td>
<td>Patient died five days later unrelated to transfusion.</td>
</tr>
</tbody>
</table>

* Included as a full case history

**P** Included as a full case history in paediatric chapter

Table 32: AA Cases Associated With Plasma (n=2)
Severe Acute Anaphylactoid or Anaphylactic Transfusion Reaction. Case Histories:
The following stories are described in detail as they show the problems encountered. (Cases 15, 21, 22 and 23 are discussed in the Paediatric Chapter)

AA Case 5
This male patient with a newly diagnosed malignant haematological disorder was actively bleeding. He was prescribed a transfusion of one unit of CMV antibody negative and irradiated pooled platelets for a platelet count of 76x10^9/L. The patient’s primary care team had indicated that the platelet count should be maintained above 70x10^9/L. On completion of the unit the patient developed symptoms of urticaria, dyspnoea, tachycardia and falling oxygen saturations. Chlorpheniramine and hydrocortisone were administered intravenously and the patient recovered within 45 minutes. Bacteriological investigations of both the patient and the unit isolated no microorganism, IgA levels were not done. One subsequent transfusion with apheresis platelets resulted in a mild urticarial reaction and as a result, future needs have been managed with saline washed platelets uneventfully.

AA Case 13
This male patient with a malignant haematological disorder required a transfusion of one unit of platelets for a low platelet count. The patient had received previous transfusions of pooled and apheresis platelets uneventfully. On this occasion, following 160 mls of apheresis platelets, the patient developed urticaria, dyspnoea, stridor, wheeze and falling oxygen saturations. The transfusion was initially continued at a slower rate and then discontinued completely and chlorpheniramine, hydrocortisone and salbutamol nebulizers were administered. The patient recovered within ten minutes without complications. Subsequently the patient had several transfusions of apheresis platelets with pre medication of chlorpheniramine without complications.

AA Case 14
This young female patient with a newly diagnosed malignant haematological disorder was administered a transfusion of one unit of platelets for a platelet count of 67x10^9/L as she was actively bleeding. The patient had received a previous transfusion of pooled platelets and developed a mild urticarial reaction and as a result, had been subsequently transfused with pooled platelets with pre medication of chlorpheniramine. On this occasion following pre medication and 180 mls of platelet apheresis, the patient developed hypertension, dyspnoea and substernal discomfort. The transfusion was discontinued and chlorpheniramine and oxygen administered. The patient recovered within five minutes without complications. The HLA antibody screen was negative and IgA level pre transfusion was within normal limits. Future transfusions will include a further attempt at pre medication and apheresis platelets and should the patient react again, saline washed platelets will be recommended.

AA Case 16
This elderly patient with underlying cardiac disease was on multiple medication including warfarin and antibiotic therapy. The patient was transfused with two units of SD plasma over a three-hour period for a haematoma secondary to trauma, INR 3.8. Warfarin therapy had been discontinued the day prior to transfusion but vitamin K was not given. Thirty minutes following the transfusion the patient developed symptoms of dyspnoea, a rash on both arms and abdomen and a rise in temperature of 2°C to 38.2°C. Oxygen was given and IV hydrocortisone and chlorpheniramine were administered. Symptoms resolved within two hours. Both packs were cultured and found to be negative. The patient was not cultured. IgA level not checked. The patient received subsequent transfusions of SD treated plasma to treat further bleeding with antihistamine and steroid cover which were uneventful. Vitamin K was not administered.
AA Case 34

This female patient required a transfusion of one unit of red cells for symptomatic anaemia of malignancy Hb 8.6g/dl. One hour and 40 minutes into the transfusion when 240 mls had been transfused the patient became flushed and developed symptoms of urticaria, tachycardia, stridor/wheeze, falling oxygen saturation and substernal discomfort. The transfusion was discontinued and IV chlorpheniramine, hydrocortisone, epinephrine and glycerine trinitrate spray (GTN) was given. Bacteriological culture of the unit showed no growth. The patient required transfer to a tertiary centre for further observation and management. Investigations of the reaction were inconclusive and the IgA level was not checked. Further transfusions were required following transfer to the tertiary facility and were uneventful.
Transfusion Associated Circulatory Overload (TACO)

Definition
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).

Introduction
Transfusion–associated circulatory overload (TACO) occurs when the transfusion rate or volume exceeds the capacity of a compromised cardiovascular system (Zhou et al, 2005). Pulmonary complications (either TACO or TRALI) are now among the most frequently noted life threatening hazards of transfusion. TACO is often under-recognised (Popovsky, 2004, Andrzejewski and Popovsky 2005) and consequently can be under-reported. The incidence for this reporting year in the NHO is 0.01% (1: 9730 units of red cells issued) and TACO accounts for 7% of the incidents reported. Popovsky (2004) suggests that the incidence of TACO occurring in a patient undergoing transfusion is more likely to be in the region of 1-8% (Popovsky, 2004).

TACO can result from over-transfusion to individuals at risk, often the elderly or the very young, in whom fluid infusion engulfs the capacity of the left ventricle, causing congestive cardiac failure and ultimately pulmonary oedema (Bux, 2005). However while these patient populations are particularly susceptible, no recipient of blood is resistant (Stack et al, 1996).

Patients with severe chronic anaemia are also at risk of TACO resulting from rapid changes in circulating volume. Such patients should be transfused slowly to avoid acute changes in blood volume which may precipitate heart failure (Stack et al, 1996). Transfusion should not be required in the vast majority of patients with chronic anaemia due to underlying haematoclinic deficiencies of iron, B12 or folate. These patients respond quickly to specific replacement therapy (Saxena et al1993). Where compliance is poor, parenteral iron should be used to treat iron deficiency. Iron sucrose preparations are associated with less side effects than iron dextran preparations (Bailie et al 2005).

Anaemia in the context of cardiac disease presents particular problems. It is found to be present in 25-50% of this patient group and its presence in heart failure is associated with a poorer prognosis (Anand et al, 2005). The causes of the anaemia appear to be multi-factorial and include decreased erythropoiesis, hemodilution and inhibition of erythropoietin synthesis by ACE inhibitors. Iron deficiency due to nutritional
anaemia, malabsorption and gastrointestinal bleeding may also be important. (Anand 2005). There is encouraging evidence that the anaemia of heart failure, not due to other causes, may be improved by treatment with erythropoietin and iron therapy. This treatment may improve symptoms and reduce the risk of hospitalisation for worsening heart failure (NHS, Clinical Guideline 5, Silverberg et al, 2001, Mancini et al 2003). Transfusion in patients with acute coronary syndromes who develop bleeding or anaemia during their hospitalisation, may be associated with higher mortality rates (Rao et al, 2004).

TACO can manifest itself during or within hours of the transfusion. Non-specific symptoms frequently reported include chest tightness, headache and dry cough. TACO in patients can often be readily identified. Occasionally, however, symptoms associated with other transfusion reactions or medical conditions can overlap making it difficult to diagnose. Zhou et al (2005) suggest that measurement of B-natriuretic peptide (BNP), which is secreted from the cardiac ventricles in response to volume expansion and overload, is useful in evaluation of patients with suspected transfusion related respiratory distress. It may be considered as a useful adjunct marker in diagnosing overload.

Findings
- The cases included in this chapter illustrate the difficulty of managing anaemia in patients with pre-existing cardiac disease.
- 14 out of 15 cases (93%) of TACO cases reported involved the transfusion of red cells.
- One case, (Case 15) was difficult to categorise as definitely TACO and was initially reported as an AA. It is not possible to be sure whether the symptoms and signs in the patient who had pre-existing cardiac disease were due to the transfusion or were coincidental. However the development of cardiac arrhythmias and subsequent myocardial infarction is suggestive of a cardiac cause for the symptoms and the incident has been captured as a TACO.

- One case, (Case 12) was associated with a transfusion of apheresis platelets. Although the volume of apheresis platelets is only 220-250 mls, the transfusion was given over 15-20 minutes.
- All but one of the patients were aged between 60-88 years and all were at risk of TACO, due to their underlying medical conditions.
- In six out of 15 cases, TACO occurred on the first unit, and in two cases the patient received 100mls or less of the transfusion before developing symptoms.
- In a number of cases, the patient was either in positive fluid balance or had evidence of peripheral oedema prior to transfusion.
- In seven cases, records show that a fluid balance chart was either not kept, or was inaccurate due to incontinence. In two cases other fluids were infusing simultaneously with the red cells. In both of these cases the fluid balance chart was noted to be inaccurate due to incontinence.
- Most patients responded quickly to diuretic therapy, but in one case (Case 11), where the patient was already critically ill with underlying malignancy, the transfusion may have contributed to mortality.
- In nine cases, the patients were on regular diuretic therapy. In one case, (Case 13) this was stopped three days earlier due to dehydration. In three of these cases, additional diuretics were given before transfusion or between units.
- In four cases, pre-transfusion diuretics were
administered but proved insufficient in preventing TACO.

- In one case (Case 6), two units prescribed over two days were inadvertently given on the same day resulting in TACO. However in two further cases (Cases 3 & 7), where the transfusion was given over two days, the patients still developed TACO.

- In one of these two cases (Case 3), further transfusions were administered uneventfully with diuretic cover.

**Recommendations**

- As no patient is immune, all patients should be reviewed pre-transfusion to assess their risk of developing TACO. Particular attention should be paid to the identification and management of ‘high-risk’ patients which include:
  
  - Patients of low body weight,
  
  - Elderly
  
  - Infants and children,
  
  - Physiologically compromised patients, especially with a history of cardiac, respiratory or renal insufficiency or chronic anaemia.

- At risk patients should be transfused slowly at a rate of 1 ml/kg/hour (Popovsky 1985) and close attention, where possible, 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 (Andrzejewski and Popovsky, 2005).

- Transfusion should be on a unit-by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component. This assessment should include:
  
  - A careful estimation of the patient’s hydration status prior to transfusion.
  
  - Thorough review of the patient’s fluid balance during transfusion of any blood component.
  
  - The possible need for ‘prophylactic’ diuretic therapy.

- 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 24 hours between each unit in combination with pre transfusion diuretics. Some subjects take as long as 24 hours to readjust blood volume particularly in those patients whose venous pressure is raised pre-transfusion (Mollison et al 1998).

- Where possible, simultaneous infusion of other fluids during transfusion should be avoided in patients at risk of TACO.

- In cases of iron-deficiency anaemia, transfusion should only be considered when the anaemia is symptomatic. (Saxena et al, 1993). Where oral iron is not tolerated or compliance is poor, parenteral iron therapy should be considered.
# Table 33: TACO Cases (n=15)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age yrs Gender</th>
<th>Weight kg</th>
<th>Volume Transfused</th>
<th>Rate of Transfusion</th>
<th>Pre-existing Problems</th>
<th>Symptoms &amp; Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TACO Case 1</td>
<td>63 M</td>
<td>68</td>
<td>One complete unit and &gt;100 mls of the second unit of red cells</td>
<td>90mls per hour</td>
<td>Myocardial infarction and left ventricular failure. Hb 7.2g/dl Positive fluid balance of 1512mls</td>
<td>Developed dyspnoea and pulmonary oedema during the second unit. Treatment: Frusemide IV administered and symptoms resolved. No complications.</td>
<td>No diuretic prior to transfusion</td>
</tr>
<tr>
<td>TACO Case 2</td>
<td>88 M</td>
<td>Unk</td>
<td>&gt; 100mls red cells over two hours</td>
<td>Two units over four hours each</td>
<td>Severe congestive cardiac failure, ischaemic heart disease, renal impairment. Hb 7.7g/dl Positive fluid balance of 122mls</td>
<td>Dyspnoea, tachycardia, expiratory wheeze, decreased air entry both bases, raised JVP. Treatment: hydrocortisone, frusemide, nebuliser symptoms resolved. No complications</td>
<td>Regular diuretic therapy and diuretic prior to transfusion. Ejection fraction 10% - patient susceptible to overload.</td>
</tr>
<tr>
<td>TACO Case 3*</td>
<td>56 F</td>
<td>55</td>
<td>Two units of red cells</td>
<td>Three units over four hours each over two days</td>
<td>Carcinoma of the lung.</td>
<td>Tachypnoea, coughing and vomiting. Treatment: oral diuretics given with good response. Dyspnoea and symptoms resolved. No complications</td>
<td>First unit given over 4 hours, second given next day over 3 hours and 40 minutes. Fluid balance was not recorded prior to or during the transfusion. Diuretic given prior to 3rd unit - transfused uneventfully</td>
</tr>
<tr>
<td>TACO Case 4</td>
<td>64 F</td>
<td>Unk</td>
<td>One unit red cell concentrate</td>
<td>One unit over four hours</td>
<td>History of myocardial infarction, hypertension, peripheral vascular disease and epilepsy. Hb 6.5g/dl</td>
<td>Dyspnoea, tachycardia, bilateral creps and wheeze, lowered O₂ saturations and chest tightness. Treatment: frusemide, glyceryltrinitrate-full recovery No complications</td>
<td>Haemacel infusing simultaneously. No regular or prophylactic diuretic. Fluid balance chart inaccurate.</td>
</tr>
<tr>
<td>TACO Case 5</td>
<td>63 M</td>
<td>Unk</td>
<td>One unit of red cells</td>
<td>Over four hours</td>
<td>Haematological malignancy Recurrent pneumonia Peripheral oedema Hb 8.8g/dl</td>
<td>Dyspnoea, clammy, pale, sweaty. Chest x-ray showed extensive alveolar shadowing Treatment: hydrocortisone, frusemide, O₂ nebulisers Died days later unrelated to transfusion</td>
<td>Reaction occurred when only 60-80mls had transfused 90 minutes after commencement of transfusion. On regular diuretics. Fluid balance inaccurate prior to the transfusion</td>
</tr>
</tbody>
</table>

* Included as a full case history
<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age yrs</th>
<th>Gender</th>
<th>Weight kg</th>
<th>Volume Transfused</th>
<th>Rate of Transfusion</th>
<th>Pre-existing Problems</th>
<th>Symptoms &amp; Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TACO Case 6*</td>
<td>74</td>
<td>F</td>
<td>37</td>
<td>One unit and 150 mls red cells</td>
<td>Two units over four hours each over two days.</td>
<td>Malignancy. Lower limb oedema. Hb 8g/dl</td>
<td>Dyspnoea falling oxygen saturation. Treatment: Oxygen, discontinued unit – full recovery. No complications.</td>
<td>Both units inadvertently given on the same day. On regular diuretics and also between units.</td>
</tr>
<tr>
<td>TACO Case 7</td>
<td>74</td>
<td>F</td>
<td>Unk</td>
<td>Two units and 300mls of third unit of Red Cells</td>
<td>Three units over two days</td>
<td>Malignancy with lung secondaries and underlying infection. Renal failure Hb 6.6g/dl</td>
<td>Pyrexia, tachycardia, hypertension, back pain, dyspnoea and wheeze. Treatment: Frusemide, paracetamol – recovery in 6 hours. No complications.</td>
<td>Palliative care patient. Frusemide given following second unit. Following first unit was in negative fluid balance of 200mls.</td>
</tr>
<tr>
<td>TACO Case 8</td>
<td>60</td>
<td>F</td>
<td>46</td>
<td>220mls of red cells</td>
<td>Over four hours</td>
<td>Post operative anaemia, hypertension Hb 6.3g/dl</td>
<td>Hypertension, tachycardia. Treatment: Discontinued transfusion, frusemide and oxygen. No complications.</td>
<td>No regular diuretics. No fluid balance recorded prior to the transfusion.</td>
</tr>
<tr>
<td>TACO Case 9</td>
<td>80</td>
<td>F</td>
<td>&lt;70</td>
<td>One unit and 200mls of red cells</td>
<td>Over four hours each</td>
<td>Cardiac condition, peripheral vascular disease and anaemia Hb 7.4g/dl Positive fluid balance of 1000mls.</td>
<td>Atrial fibrillation, hypertension tachycardia, dyspnoea falling oxygen saturations, urticaria. Treatment: frusemide 40 mgs given with an effective diuresis of 1960mls. No complications.</td>
<td>On regular diuretics. First unit transfused uneventfully. No pre-transfusion diuretic.</td>
</tr>
<tr>
<td>TACO Case 10</td>
<td>76</td>
<td>M</td>
<td>Unk</td>
<td>60mls of first unit of red cells</td>
<td>Four units over 4 hours each</td>
<td>GI bleeding, congestive cardiac failure Hb 4.3g</td>
<td>Bradycardia, dyspnoea, and falling O₂ saturations. Treatment: Frusemide, cyclomorph, isosorbide dinitrate infusion, oxygen No complications.</td>
<td>On regular diuretics On NaCl infusion simultaneously. Inaccurate fluid balance prior to transfusion. Transfusion recommenced and other units given with further frusemide and morphine.</td>
</tr>
</tbody>
</table>

* Included as a full case history
<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age yrs</th>
<th>Gender</th>
<th>Weight kg</th>
<th>Volume Transfused</th>
<th>Rate of Transfusion</th>
<th>Pre-existing Problems</th>
<th>Symptoms &amp; Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TACO Case 11</td>
<td>63 M</td>
<td>69</td>
<td>Two units of red cells</td>
<td>Over 4 hours each</td>
<td>Cardiomyopathy, carcinoma of the lung Hb 8g/dl</td>
<td>Hypertension, falling oxygen saturations. Treatment: Diuretic with good response Patient died 24 hours post transfusion possibly related to transfusion, although the patient was very ill.</td>
<td>On regular diuretic therapy and pre-transfusion diuretic.</td>
<td></td>
</tr>
<tr>
<td>TACO Case 12</td>
<td>66 M</td>
<td>72</td>
<td>One unit of apheresis platelets</td>
<td>Over 30 minutes</td>
<td>Haematological disorder, anaemia</td>
<td>Increased heart rate, dyspnoea Treatment: Hydrocortisone, chlorphenamine – recovery in one hour No complications</td>
<td>Platelets given over 15-20 minutes. No regular diuretics. No fluid balance</td>
<td></td>
</tr>
<tr>
<td>TACO Case 13</td>
<td>85 F</td>
<td>38</td>
<td>One unit of red cells and 200 mls of second unit. (received one unit of red cells the previous day)</td>
<td>Over four hours each</td>
<td>Congestive cardiac failure, other medical and gastrointestinal conditions Hb 6.5g/dl</td>
<td>Dyspnoea, fall in O₂ saturation, falling urinary output Treatment: frusemide and oxygen No complications</td>
<td>Stopped regular diuretic therapy three days prior to transfusion. Inaccurate fluid balance.</td>
<td></td>
</tr>
<tr>
<td>TACO Case 14</td>
<td>80 M</td>
<td>Unk</td>
<td>150 mls of red cells over two hours and 20 minutes</td>
<td>Over six hours</td>
<td>Chronic obstructive pulmonary disease, cardiac disease, diabetes, hypertension. Hb 8.9g/dl Positive fluid balance of 370mls prior to transfusion</td>
<td>Dyspnoea, hypertension, fall in urinary output Treatment: frusemide, response unclear Patient died 2 months later unrelated to transfusion.</td>
<td>On regular diuretics</td>
<td></td>
</tr>
<tr>
<td>TACO Case 15</td>
<td>81 F</td>
<td>Unk</td>
<td>One unit of red cells</td>
<td>Given over 40 minutes</td>
<td>Peripheral vascular disease, history of malignancy, cerebral infarct and hypertension Hb 9.9g/dl</td>
<td>Supraventricular tachycardia, hypotension facial rash, Treatment: gelofusin, chlorpheniramine, hydrocortisone, adenosine, frusemide and oxygen Patient died 10 days later unrelated to the transfusion</td>
<td>Myocardial infarction following day</td>
<td></td>
</tr>
</tbody>
</table>
TACO Case Histories

We describe 2 of the case reports in detail to illustrate some of the issues highlighted:

TACO Case 3
This low weight female patient (weight 55kg) with a history of malignant lung disease and a Hb of 7.6g/dl required a transfusion of three units of red cells. One unit was transfused without incident. The next day, immediately following the administration of the second unit over 3 hours and 40 minutes, the patient developed symptoms of dyspnoea, increased respiratory rate (40/min), excessive coughing and vomiting. Oral diuretics were prescribed and administered with a good diuretic response. The symptoms improved quickly with full resolution within four hours. Eight hours after the completion of the second unit, a third unit of red cells was prescribed and administered uneventfully. An oral diuretic was administered prior to this transfusion.

TACO Case 6
This elderly low weight female patient with malignancy required a transfusion of two units of red cells. Her Hb level was 8g/dl. The patient had no documented underlying history of cardiac or respiratory disease but was receiving regular diuretic therapy for limb oedema. The two units were prescribed over four hours each and were to be given on two separate days. Inadvertently both units were administered on the same day. The patient received her regular diuretic that morning and the first unit infused uneventfully over three hours. Oral frusemide 20 mgs was given between the first and second units. Within 30 minutes of commencing the second unit, following transfusion of approximately 150 mls, the patient developed symptoms of dyspnoea and falling oxygen saturations. The transfusion was discontinued completely. Nasal oxygen therapy was commenced and no further diuretics were administered. The patient recovered without sequelae and although the timeframe is unclear a note in the patients chart four hours after the event suggests she had recovered at that stage.
This category accounted for 2% of the incidents reported (4 of 214), down from nine cases in the preceding two years. This type of reaction is thought to occur at a frequency of 1:400-1:700 transfusions. It is therefore, likely that a number of these reactions go undiagnosed. This is possibly due to the fact that most of the patients receiving transfusions are already very ill and the symptoms are attributed to their underlying condition. Typically patients present with falling haemoglobin and other signs of haemolysis including a raised bilirubin and possibly renal impairment a few days (usually 4-10) after transfusion. On the vast majority of occasions the antibody screen prior to the transfusion is found to be negative for the antibody responsible. The antibodies usually involved belong to the Rh and Kidd families.

Findings:
- There were four cases reported this year, down from nine in the previous two years.
- Grading:
  - **Group 1:**
    Asymptomatic with ‘antibody only’ detected (with or without a positive antiglobulin test (DAT)). Two cases; Case 2 and Case 4.
  - **Group 2:**
    Evidence of haemolysis measured by falling haemoglobin and positive DAT. None
  - **Group 3:**
    Falling Hb with jaundice with or without a positive DAT. Two cases; Case 1 and Case 3.
  - **Group 4:**
    As for Group 3, but with renal impairment. None.
- As in previous years, the antibodies implicated belong to the Rh, Kidd and Duffy families.
- There were no fatalities associated with these reactions.
- In Case 1, the patient presented ten days after a transfusion with a rising bilirubin but this was thought to be due to the underlying condition or to...
the patient’s medication. It was only at a subsequent stage during DAT testing that the diagnosis was made.

- In Case 2, allo-absorption studies were not carried out prior to transfusion with the result that some of the units of blood transfused were positive for an antigen to which the patient already had an antibody.

**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 depends also on accurate history taking and the elicitation of a history of recent transfusion.

- Use of red cell panels in sensitive antibody screening techniques, adequate training and proficiency testing of all staff involved in cross-matching and participation by all concerned in external quality assurance schemes should contribute to the minimisation of this complication.

- Patients with Autoimmune Haemolytic Anaemia with strong autoantibody reactions present a particular problem. In non emergencies absorption studies should be carried out to exclude the presence of an underlying clinically significant antibody prior to transfusion of these patients. If emergency transfusion is required then Rh phenotype compatible, K negative blood should be provided and the clinician advised of the potential incompatibility. Patients with transfusion dependent autoimmune haemolytic anaemia should be monitored at regular intervals so that transfusion requirements are anticipated, providing sufficient time for extended compatibility testing procedures to be performed prior to transfusion. Absorption studies should be carried out prior to transfusion wherever possible. However, urgent treatment should not be delayed.

- Undue delay in transfusion rather than the delayed reaction itself may lead to fatalities (SHOT 2002). Urgent transfusion should not be delayed unnecessarily and in the case of a DHTR, specialist advice should be sought for future transfusion management.

- There is a need for the on-call facility to perform complex serological investigations such as absorption studies in autoimmune haemolytic anaemia out of hours.

- Local policies/procedures should be in place for the management of emergency transfusion where unidentified antibody(ies) or difficulties in provision of compatible blood occur.

- 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 & Fisher 2005)
<table>
<thead>
<tr>
<th>Case No.</th>
<th>Gender</th>
<th>Pre-existing condition</th>
<th>Interval between transfusion and onset of symptoms/signs</th>
<th>Treatment</th>
<th>Findings</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 2*</td>
<td>F</td>
<td>Autoimmune haemolytic anaemia with multiple medical problems.</td>
<td>Multiple transfusions administered over three months.</td>
<td>None</td>
<td>Auto-anti-Jk detected after emergency transfusion of three units of blood that were later found to be Jk positive.</td>
<td>Patient died seventeen days later unrelated to transfusion.</td>
</tr>
<tr>
<td>Case 4</td>
<td>F</td>
<td>COAD, CVA, hypertension, Addison’s disease with underlying malignancy and widespread metastasis</td>
<td>Anti-Ch/Rh 18 days after transfusion</td>
<td>None</td>
<td>Bilirubin, LDH, GGT all raised pre-transfusion. Renal function tests abnormal pre-transfusion.</td>
<td>Least incompatible blood was issued and transfused uneventfully.</td>
</tr>
<tr>
<td>Case 1*</td>
<td>F</td>
<td>Post major GI surgery and renal failure.</td>
<td>11 days.</td>
<td>None</td>
<td>Anaemia, raised bilirubin, DAT positive. Anti-E, -c, -Jk detected.</td>
<td>Patient died one month after transfusion – death unrelated to the reaction.</td>
</tr>
<tr>
<td>Case 3</td>
<td>F</td>
<td>Anaemia, GI bleed - Haematemesis and melaena</td>
<td>8 days</td>
<td>None</td>
<td>Raised bilirubin. Anti-Jk, Anti-c detected.</td>
<td>Transfused with compatible antigen negative blood. Recovered within two weeks. No complications.</td>
</tr>
</tbody>
</table>

* Included as a full case history
Delayed Haemolytic Transfusion Reaction (DHTR). Case Histories:

DHTR Case 1
This acutely ill patient required transfusion due to intraoperative bleeding. The patient had five transfusion episodes over a period of eleven days, totalling 15 units RCC, 16 units of plasma and three packs of platelets. The antibody screen was negative on two occasions. Despite continued transfusion therapy her Hb remained consistently low. Ten days after the first transfusion episode it was noted that the patient’s bilirubin level had raised but it was felt that this might be related to the patient’s condition and medication. At the same time the DAT (previously negative) was found to be positive and subsequent antibody screening showed the patient had developed anti-E, anti-c and anti-Jkα. The patient died a month later, although the death was deemed unrelated to the transfusion reaction.

DHTR Case 2
This elderly patient required a transfusion for long standing warm AIHA. The Hb level at transfusion was 5.4 g/dl. Previously the patient had been referred to the IBTS and was shown to have an autoantibody as well as an allo anti-Cw. On a previous admission over a weekend, the patient required an urgent transfusion for a low Hb 5.8 g/dl, and three units of genotyped matched blood were transfused without complications. A pre-transfusion sample confirmed the continuing presence of the auto-antibody, however no allo anti-Cw was detected. The patient continued to have Cw negative blood. On the next admission, again on a weekend, the patient was symptomatic with a Hb of 7.2g/dl and blood was urgently needed. The transfusion went ahead without full absorption studies. Although further samples were requested for full work up at the IBTS, these were not taken. The next admission occurred one month later, once again at a weekend. The Hb level was 5.4 g/dl and the patient received a transfusion of four units of red cells. No absorption studies were carried out prior to the transfusion. These were carried out on the next working day and they revealed an allo anti-Jkα. All four packs transfused were tested and three units were found to be Jkα positive. Since no absorption studies were performed on the previous occasion, it is unclear when the allo anti Jkα developed. The patient died unrelated to the transfusion seventeen days post transfusion.
This category accounted for 11% of incidents reported (24 of 214). The differential diagnosis for these reactions will always include red cell incompatibility and bacterial infection and an effort should be made to exclude both these possibilities. As in reports in previous years, it has been noted that it is not always possible to establish the cause of the reaction and that symptoms caused by the patient’s underlying condition may have contributed to the presentation.

Findings 2004

- There was a sharp rise in the number of reactions in this category as compared to previous years. Apart from increased awareness and therefore increased reporting, no specific reason was identified to explain this increase.

- 20 out of the 24 cases occurred after transfusion of red cell units. 16 out of the 24 patients had an underlying history of malignancy. Of the 18 patients where information was available about patient recovery, 11 recovered within four hours and the remainder, except for one patient whose recovery was delayed, recovered within 24 hours. Of the cases where treatment is recorded, 17 patients received treatment that included paracetamol, chlorpheniramine and hydrocortisone. Five patients received no treatment and recovered spontaneously.

- The haemoglobin prior to transfusion ranged from 5 g/dl to 8.8 g/dl. Most of these patients were elderly and had multiple underlying problems. Only one patient was transfused at a Hb of 10g/dl. The patient had a history of multiple medical problems and was on antibiotics and had received two units of red cells on the previous day without problems.

- In the majority of the 14 cases where a temperature rise of >1.5°C was documented, either the patient or the unit or both were cultured. However, only two out of the four cases involving a platelet transfusion were cultured.
Positive cultures were found in four cases – in three of them, the patient sample cultured positive and in the fourth, culture of the unit was positive. On further evaluation, however, these results were not considered to be associated with the transfusion but were due to the patient’s underlying condition or contamination.

- Red cell incompatibility was excluded in 13 cases. In one case (Case 1) associated with fever and rigors, anti-Fy^a^ antibody was detected 5 days after the transfusion and in another, (Case 26) where the patient showed evidence of haemolysis, an anti-Lu^a^ antibody was identified. However, an anti Lu^a^ antibody is not usually of significance and was not considered to be the cause of the patient’s reaction, which remains unexplained. In the rest of the cases, no serology investigations were reported.

- In one case (Case 11), a reaction to platelets, the patient had developed HLA antibodies which were probably responsible for the reaction.

**Recommendations:**

- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly, and the patient observed closely for the first 15 minutes/50 mls as severe reactions are most likely to occur within this time. (BCSH 1999).

- Each hospital must have a policy in place for the management of an acute transfusion reaction. This should include the medical and nursing management of the patient’s symptoms and the investigations necessary to complete the transfusion reaction analysis. Following a severe transfusion reaction, the transfusion should be discontinued completely and no further units from this crossmatch should be transfused until an ABO incompatible transfusion has been excluded and the blood has been re-crossmatched.

- Investigations should include: -
  - Re-confirming the identification of the patient and the unit
  - Re-confirming the ABO and Rh D group of the patient and the unit

**Blood samples for:**

- Repeat group, antibody screen and crossmatch to exclude an ABO or red cell incompatible transfusion including a clotted sample for antibody identification using serum
  - full blood count (FBC)
  - direct antiglobulin test (DAT)
  - coagulation screen
  - biochemistry analysis to include serum bilirubin and LDH (NBUG 2000)
  - blood cultures

- 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 in platelet
transfusion as platelet concentrates are stored at
20°C and the incidence of bacterial contamination
is highest in platelet concentrates. To reduce this
risk, the IBTS has undertaken bacteriological
screening of all platelet concentrates before issue
since the last quarter of 2004.

• A protocol for culturing of the blood component is
available by writing to the QA/QC Department of
the IBTS. This protocol outlines the procedure to
be followed when culturing a unit implicated in a
febrile transfusion reaction.

• Specimens e.g. urine, sputum, necessary to
exclude other possible sources of infection should
also be cultured.
<table>
<thead>
<tr>
<th>Case No.</th>
<th>Component Prescribed</th>
<th>Age Yrs Gender</th>
<th>Underlying condition</th>
<th>Volume transfused onset</th>
<th>Symptoms/signs</th>
<th>Investigations</th>
<th>Treatment &amp; Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHOSTR Case 1*</td>
<td>Two units of red cells</td>
<td>78 F</td>
<td>Sepsis secondary to gastric surgery</td>
<td>Following transfusion of 150 mls of red cells. Patient had received a transfusion 1 month previously.</td>
<td>Patient complained of rigors and fever. Rising bilirubin post transfusion within 6 hours. Urine positive for urobilinogen</td>
<td>The DAT was positive in IgG in pre and post transfusion samples. Antibody screen was positive. Subsequent investigations 5 days later showed anti-FyA.</td>
<td>Non steroidal anti-inflammatory. Patient recovered with no ill effects within 6 hours.</td>
</tr>
<tr>
<td>AHOSTR Case 2</td>
<td>Two units of red cells</td>
<td>74 F</td>
<td>Haematological malignancy</td>
<td>150 mls of second unit</td>
<td>Agitation, feeling of impending doom and tachycardia.</td>
<td>Pack cultured – no organisms isolated. Red cell incompatibility excluded.</td>
<td>Oxygen therapy. Spontaneous recovery after 10 to 15 minutes.</td>
</tr>
<tr>
<td>AHOSTR Case 3</td>
<td>Two units of red cells</td>
<td>83 F</td>
<td>Ischaemic Heart Disease</td>
<td>100mls red cells</td>
<td>Temperature rise &gt; 1.5°C, chills, rigors, restlessness, anxiety, tachycardia and feeling of impending doom</td>
<td>Patient not cultured. Unit cultured - no organisms isolated. Red cell incompatibility excluded.</td>
<td>Transfusion discontinued completely. Hydrocortisone given. Recovered within one hour.</td>
</tr>
<tr>
<td>AHOSTR Case 5</td>
<td>Four units of red cells</td>
<td>89 F</td>
<td>Pulmonary embolus. Chronic anaemia</td>
<td>100mls of 4th unit.</td>
<td>Temperature &gt; 1.5°C, chills and rigors</td>
<td>Patient cultured positive for staphylococcus aureus - probable contaminant. Unit not cultured.</td>
<td>Unit discontinued completely. Paracetamol given. Recovered fully within one hour and remained apyrexial.</td>
</tr>
<tr>
<td>AHOSTR Case 6</td>
<td>One unit of red cells</td>
<td>72 F</td>
<td>Malignancy postoperative anaemia, sepsis</td>
<td>One unit of red cells</td>
<td>Hypertension, tachycardia. Temperature rise &gt;1.5°C</td>
<td>Patient and unit cultured - no organism isolated</td>
<td>Paracetamol given. Observed recovery within two hours.</td>
</tr>
<tr>
<td>AHOSTR Case 8*</td>
<td>One unit of washed red cells</td>
<td>42 F</td>
<td>Paroxysmal Nocturnal Haemoglobinuria</td>
<td>150 mls of red cells.</td>
<td>Temperature rise of 2.5°C, hypertension, nausea and general aches.</td>
<td>Bacteriological screening of the unit was negative. History of previous red cell antibodies and history of previous transfusion reaction.</td>
<td>Paracetamol given. Recovered without complications.</td>
</tr>
<tr>
<td>AHOSTR Case 9</td>
<td>One unit of red cells</td>
<td>60 F</td>
<td>Haematological malignancy</td>
<td>120 mls of red cells</td>
<td>Temperature rise 0.6°C, chills and rigors. Rise in blood pressure but remained normotensive</td>
<td>Red cell incompatibility excluded. Bacteriological screening of both patient and unit was negative</td>
<td>Transfusion discontinued completely. Hydrocortisone and chlorpheniramine given. Patient recovered within one hour</td>
</tr>
</tbody>
</table>

* Included as a full case history
Table 36: AHOSTR cases (n=24) (Cont)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Component Prescribed</th>
<th>Age Yrs Gender</th>
<th>Underlying condition</th>
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</tr>
</thead>
<tbody>
<tr>
<td>AHOSTR Case 10</td>
<td>One unit of red cells</td>
<td>43 F</td>
<td>Haematological malignancy</td>
<td>150 mls of red cells</td>
<td>Hypertension, tachycardia, dyspnoea, restlessness, anxiety and a feeling of impending doom</td>
<td>Red cell incompatibility excluded. Culture of the patient and the unit negative</td>
<td>Initially the unit was stopped temporarily after 150 mls had been infused and then continued at a slower rate. Subsequently discontinued completely. Symptoms immediately resolved without treatment.</td>
</tr>
<tr>
<td>AHOSTR Case 12</td>
<td>Red cells</td>
<td>86 M</td>
<td>Haematological malignancy</td>
<td>150 mls</td>
<td>Temperature rise of 2.9°C, tachycardia, chills, nausea, vomiting</td>
<td>Red cell incompatibility excluded. Culture of unit negative, patient showed coagulase negative staphlococci-coincidental contamination</td>
<td>Hydrocortisone 200mg IV, paracetamol 1g, metoclopramide IV. Recovered within one hour with no ill effects.</td>
</tr>
<tr>
<td>AHOSTR Case 13</td>
<td>One unit of red cells</td>
<td>58 M</td>
<td>Malignancy</td>
<td>Few mls</td>
<td>Temperature rise &gt; 1.5°C. Chills and rigors. Hypertension</td>
<td>Red cell incompatibility excluded. DAT post transfusion negative</td>
<td>Transfusion discontinued. Paracetamol given. Rigors subsided within 20 minutes. Temperature normal within four hours.</td>
</tr>
<tr>
<td>AHOSTR Case 14</td>
<td>One unit of red cells</td>
<td>27 M</td>
<td>Multiple injuries following RTA</td>
<td>Within 40 minutes of commencing transfusion</td>
<td>Tachycardia, chills, rigors, apprehension.</td>
<td>Red cell incompatibility excluded and patient and unit cultured negative.</td>
<td>Transfusion discontinued, paracetamol given. Recovered within two hours.</td>
</tr>
<tr>
<td>AHOSTR Case 15</td>
<td>One unit of red cells</td>
<td>32 M</td>
<td>Malignancy</td>
<td>Within 30 minutes of commencing transfusion.</td>
<td>Hypotension, restlessness, anxiety, feeling of impending doom, tingling in both arms</td>
<td>Red cell incompatibility excluded. Post transfusion IgA level normal.</td>
<td>Transfusion discontinued. No specific treatment given. Recovered within one hour</td>
</tr>
<tr>
<td>AHOSTR Case 16*</td>
<td>One unit of red cells</td>
<td>72 M</td>
<td>Haematological disorder, cardiac disease</td>
<td>Symptoms occurred three hours after transfusion.</td>
<td>Temperature rise &gt;1.5°C. tachycardia, rigors, hypertension, dyspnoea and tachypnoea, flushed and incontinent</td>
<td>Red cell incompatibility excluded. Patient not cultured. Unit cultured negative.</td>
<td>O2, IV chlorpheniramine and hydrocortisone. Patient recovered within 48 hours Subsequent transfusions with premedication uneventful.</td>
</tr>
<tr>
<td>AHOSTR Case 26*</td>
<td>Three units of red cells</td>
<td>65 F</td>
<td>Intra operative blood loss</td>
<td>Next day.</td>
<td>Haematuria, hypotension, falling haemoglobin slight cyanosis, nausea. Raised bilirubin and LDH</td>
<td>Pre transfusion antibody screen had identified an anti-Lu&lt;sup&gt;B&lt;/sup&gt; antibody, which was also identified post operatively and confirmed at a reference centre. Not considered cause of reaction.</td>
<td>Future transfusion will be managed using Rh phenotyped Kell negative crossmatch compatible red cells.</td>
</tr>
</tbody>
</table>

* Included as a full case history
### Case Component Prescribed

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Component Prescribed</th>
<th>Age Yrs</th>
<th>Gender</th>
<th>Underlying condition</th>
<th>Volume transfused on set</th>
<th>Symptoms/signs</th>
<th>Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>One unit of red cells</td>
<td>82</td>
<td>M</td>
<td>Malignancy</td>
<td>100 mls of red cells</td>
<td>Temperature rise &gt; 1.5°C</td>
<td>Patient and unit cultured negative.</td>
</tr>
<tr>
<td>Case 2</td>
<td>One unit of CMV negative red cells</td>
<td>3</td>
<td>M</td>
<td>Haematological malignancy</td>
<td>33 mls</td>
<td>Temperature rise &gt; 1.5°C, backache, nausea</td>
<td>Patient cultured – no organisms isolated. No investigations carried out although patient had history of Anti-Jk&lt;sub&gt;a&lt;/sub&gt; antibodies.</td>
</tr>
<tr>
<td>Case 3</td>
<td>One unit of JKb negative red cells</td>
<td>50</td>
<td>F</td>
<td>Autoimmune haemolytic anemia</td>
<td>300 mls</td>
<td>Temperature rise &gt; 1.5°C, haemoglobinuria and vomiting.</td>
<td>Red cell alloantibody excluded. Unit cultured – no growth. Patient cultured – Staph. Citreus (not considered related to transfusion).</td>
</tr>
<tr>
<td>Case 4</td>
<td>One unit of red cells</td>
<td>83</td>
<td>F</td>
<td>Multiple medical problems</td>
<td>Approximately 80 mls of red cells.</td>
<td>Pyrexia, rigors, tachycardia, nausea, vomiting and respiratory problems.</td>
<td>Patient, unit and segment line cultured – no growth. Red cell incompatibility excluded.</td>
</tr>
<tr>
<td>Case 5</td>
<td>Two units of red cells</td>
<td>38</td>
<td>F</td>
<td>Treatment for post operative complication</td>
<td>During second unit of red cells.</td>
<td></td>
<td>Patient cultured – no growth. Red cell incompatibility excluded. History of temperature rise on previous transfusion - not investigated.</td>
</tr>
<tr>
<td>Case 6</td>
<td>One unit of red cells</td>
<td>85</td>
<td>M</td>
<td>Malignancy</td>
<td>Two hours and 45 mins into the transfusion.</td>
<td>Temperature rise &gt; 1.5°C, Hypotension, 6 symptoms, rigors</td>
<td>Patient not cultured.</td>
</tr>
</tbody>
</table>

**Note:** *P Included as a full case history in paediatric chapter.*

**Table 36: AHOSTR cases (n=24) (Cont)***
<table>
<thead>
<tr>
<th>Case No.</th>
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<th>Investigations</th>
<th>Treatment &amp; Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHOSTR Case 4</td>
<td>One unit of apheresis platelets</td>
<td>79 M</td>
<td>Haematological malignancy</td>
<td>150mls</td>
<td>Hypertension, light headed, nausea, vomiting and tremor</td>
<td>Patient cultured - no organisms isolated. Unit cultured positive for coagulase negative staphylococci after 31 hours. (Deemed contaminant) Positive DAT pre and post transfusion</td>
<td>IV hydrocortisone and chlorpheniramine given. Recovered within one hour and discharged later that day.</td>
</tr>
<tr>
<td>AHOSTR Case 11*</td>
<td>One unit of pooled platelets</td>
<td>51 F</td>
<td>Haematological malignancy</td>
<td>45 minutes following transfusion</td>
<td>Temperature rise &gt; 1.5°C. Chills, rigors and tachycardia</td>
<td>Patient found to be HLA alloimmunised. Blood cultures and segment line cultures - negative.</td>
<td>Hydrocortisone and chlorpheniramine. Recovered within one hour</td>
</tr>
<tr>
<td>AHOSTR Case 18*</td>
<td>One unit of apheresis platelets</td>
<td>62 F</td>
<td>Malignant haematological disorder.</td>
<td>222mls (1 unit). Reaction occurred one hour post transfusion</td>
<td>Fever, tachycardia, dyspnoea, falling oxygen saturations, chills and rigors, nausea, vomiting and bronchospasm</td>
<td>Patient cultured negative. Reaction not investigated due to communication problem. TRALI excluded. Donor investigations negative.</td>
<td>Oxygen, hydrocortisone, chlorpheniramine, and prochlorperazine administered. Patient recovered from the reaction within 24 hours. Subsequent transfusions have been uneventful.</td>
</tr>
<tr>
<td>AHOSTR Case 25</td>
<td>One unit of pooled platelets</td>
<td>75 F</td>
<td>Malignancy</td>
<td>One hour post transfusion</td>
<td>Hypertension, tachycardia, dyspnoea, fever, chills and rigors.</td>
<td>Suspected reaction not investigated</td>
<td>Chlorpheniramine</td>
</tr>
</tbody>
</table>

* Included as a full case history
Acute Haemolytic or Other Severe Transfusion Reaction (AHOSTR)

Detailed case histories (Red Cells)

AHOSTR Case 1
This elderly patient, who was in ICU and on antibiotic therapy for sepsis, was prescribed two units of red cells for anaemia secondary to gastric surgery. The patient had received a number of transfusions the most recent of which was one month previously. On this occasion, having received one hundred and fifty mls of red cells, the patient developed fever and rigors. The patient was treated with a non-steroidal antiflammatory and the transfusion was discontinued completely. She recovered with no ill effects within six hours. The DAT was positive in IgG pre and post transfusion but the eluate was negative. The initial post transfusion antibody screen was weakly positive but no specificity was detected. A urine sample showed raised urobilinogen and she was found to have a rising bilirubin. Subsequent investigations five days later at the reference centre showed the presence of anti-Fya and HLA antibodies. Culture of the unit was negative.

AHOSTR Case 8
This young female patient with Paroxysmal Nocturnal Haemoglobininuria required a transfusion of red cells for Hb of 7.5 g/dl. She had suffered a severe transfusion reaction in 2001 in another hospital and since then was to be transfused with washed red cells. In 2001 the serology on this patient had revealed anti-C, anti-S, anti-K. The patient had received several washed red cell transfusions, which were compatible, without incident. During a transfusion of washed cells in 2002 the patient developed symptoms of pyrexia, rigors and hypotension, the unit was discontinued and paracetamol was administered. A further unit was transfused with no complications following that incident. On this occasion 3hrs and 15 mins into the transfusion, 150 mls of washed antigen negative red cells had been infused. Symptoms of a temperature rise of 2.5°C, rigors, hypotension, tachycardia, nausea, and general aches developed. The unit was discontinued, the patient received paracetamol and symptoms resolved. The unit subsequently cultured negative.

AHOSTR Case 16
This elderly male patient with underlying myelodyplasia, cardiovascular disease and congestive heart failure was prescribed one unit of red cells for symptomatic anaemia -Hb 8.8g/dl. The patient had been transfused with three units of red cells over the previous month uneventfully. The patient received his regular diuretic medication that morning and the unit infused over four hours. Three hours following the transfusion, the patient became extremely flushed and developed a pyrexia (39.2°C) and symptoms of dyspnoea, tachypnoea, tachycardia, hypotension, falling O₂ saturations, rigors and agitation developed. Following medical review oxygen, hydrocortisone, and chlorpheniramine were administered. The patient’s symptoms improved but he still remained short of breath with wheezing for 24 hours which had completely resolved within 48 hours. The patient was reviewed for future transfusion management by the consultant haematologist. Subsequent transfusions have been covered by premedication with hydrocortisone, chlorpheniramine and have been uneventful. Investigations of the reaction excluded red cell incompatibility. The patient was not cultured but culture of the unit was negative.

AHOSTR Case 26
This female patient required a transfusion of one unit of red cells intra operatively for a blood loss of about 1 litre. Two days post operatively the patient had a further blood loss of 1340 mls from surgical drains. The Hb was 6.1g/dl and an additional two units of red cells were administered. The following day her urine became dark, concentrated and was positive ++ for blood. The patient was very pale with a slight cyanosis and developed symptoms of hypotension and nausea. At that time this was attributed to a suspected drug interaction. The patient’s Hb was
7.1g/dl and a further two units of red cells were prescribed. Investigations for the cause of the haematuria, revealed no abnormalities and the cause of the bleeding was not established. During transfusion of the second unit when there was again frank haematuria, the unit was discontinued and investigation of a suspected transfusion reaction was initiated.

Post transfusion investigations included re-grouping, cross match and antibody screen. The pre-transfusion antibody screen had identified an anti-Lu antibody, which was also identified post operatively and confirmed at a reference centre. Crossmatch compatible blood was provided but antigen negative blood is not required for patients with anti-Lu. The bilirubin was 32.2, the LDH was 6130 (Norm 230-460) the DAT was weakly positive. Both units from that transfusion were cultured negative. Tests for paroxysmal nocturnal haemoglobinuria (PNH) were negative. Haemosiderin was negative immediately post transfusion but positive one week later suggestive that haemolysis had occurred. The recommendation from the reference centre was that future transfusions should be managed with Rh phenotyped K negative compatible blood. During investigation of this reaction it emerged that the patient had been transfused over 20 years ago with four units of red cells. At that time she also developed “black urine” which was treated by her GP. Earlier this year she was admitted to a different hospital with symptomatic anaemia and received four units of red cells, which was followed by the occurrence of dark urine five days later. Investigations into the cause of the anaemia were inconclusive.

Detailed Case histories - Platelets

AHOSTR Case 11
This patient with a malignant haematological disorder required a transfusion of one unit of pooled platelets for a low platelet count. The patient had received thirty seven units of platelets and sixteen units of red cells over the previous two months and had a slight reaction following the last transfusion of platelets, but recovered without medication. On this occasion, forty-five minutes following transfusion, the patient developed pyrexia 39.2°C, chills, rigors and tachycardia. Hydrocortisone and chlorpheniramine were administered IV and the patient recovered with no ill effects within one hour. Patient blood cultures were negative, the segment line cultures were negative but as the pack and administration set were open to air these were not cultured. Investigations showed that the patient had developed HLA antibodies.

AHOSTR Case 18
This patient with thrombocytopenia, secondary to a malignant haematological disorder, was prescribed one unit of apheresis platelets. The transfusion was completed uneventfully. However, one hour post transfusion the patient developed fever with chills and rigors, tachycardia, dyspnoea, bronchospasm and falling oxygen saturations. Oxygen, hydrocortisone, chlorpheniramine and prochlorperazine were given and the patient recovered from the reaction within 24 hours. The patient’s chest x-ray post reaction showed a mild cardiomegaly with prominence of the upper lobe veins but no evidence of an active process. Bacteriological culture of the patient isolated no organisms, however due to a misunderstanding between clinical and laboratory staff, the implicated unit was not cultured. The transfusion laboratory was not informed of the reaction and transfusion reaction investigations were not carried out. Future transfusions for this patient using pre medication cover with chlorpheniramine have been uneventful following this regimen. This case was originally reported as a possible case of TRALI but donor investigations carried out were negative.
INTRODUCTION

Although a number of suspected cases were reported and investigated during this reporting period, there were no reported cases fulfilling the criteria for TRALI. Two reports were originally considered. One case was reported as a suspected case of TRALI but this was excluded on the basis of clinical findings, and this case was re-categorised as AHOSTR. A second case, originally reported as TRALI, was subsequently ruled out based on clinical and autopsy findings.

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

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

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

A great deal of consideration has been given to the definition of TRALI. A proposal put forward by the Canadian Consensus Conference suggests that TRALI should be divided into TRALI and possible TRALI based on the clinical symptoms/signs (adapted from Klienman et al, 2004)

Recommendations

- To prevent TRALI, it is important to underline the need for vigilance in the appropriate use of blood and blood components, as transfusion related adverse events can be associated with fatalities.

- It is important that hospital staff be made more aware of this complication of transfusion in order for it to be recognised and dealt with in an appropriate fashion. This would also facilitate prompt investigation and case review.

- The IBTS has put in place a number of measures with a view to minimising the risk from TRALI. These include avoiding the use of plasma from female donors both for suspension of pooled platelets and as FFP and from 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.

Acute Lung Injury (ALI) is characterised by
1. Acute onset
2. Hypoxemia \( \text{SpO}_2 < 90\% \) on room air or other evidence of hypoxemia
3. Bilateral infiltrates on frontal chest Xray
4. No evidence of circulatory overload
5. No pre-existing acute lung injury (ALI) before transfusion or during or within six hours of transfusion.
6. No alternate risk factors for Acute Lung Injury present

Possible TRALI

1. ALI as above
2. No pre-existing ALI before transfusion or during or within six hours of transfusion.
3. Alternative risk factors for Acute Lung Injury present (see table below)

Symptoms of dyspnoea, tachypnea, tachycardia, 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

Risk Factors for ALI

**Direct Lung Injury**
- Aspiration
- Pneumonia
- Toxic inhalation
- Lung contusion
- Near drowning

**Indirect Lung Injury**
- Severe sepsis
- Shock
- Multiple trauma
- Burn injury
- Acute pancreatitis
- Cardiopulmonary bypass
- Drug overdose

The incidence of ALI varies considerably among these conditions and may be as high as 40 percent for intensive care unit-related cases of septic shock and aspiration or as low as 2 percent for cases of cardiopulmonary bypass and intensive care unit-related drug overdose.
This category accounted for 1% of incidents reported (3 of 214) in 2003. The NHO collects and investigates reports of all suspected transfusion-transmitted viral infections relating to blood components which have been transfused after the introduction of mandatory testing for that virus. Viral infections which not covered by mandatory testing, e.g. Hepatitis A virus, CMV and Parvovirus, but are reported to the NHO and suspected to be associated with a blood transfusion during the current reporting year will be recorded as an NHO incident and investigated appropriately. The NHO also collects and investigates reports of transfusion-transmitted bacterial and parasitic infections.

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

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

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

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

and, either
A donor who had evidence of the same transmissible infection donated at least one component received by the infected recipient.

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 risks for HIV and HCV are less than 1 per 4 million components transfused (O’Riordan J., 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 estimated to be 1-500,000.

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 J., personal communication).

Hepatitis B infection is not uncommon in the community and in up to 40% of cases no risk such as sexual exposure, intravenous drug abuse or transfusion is present. Evidence of past cleared infection in blood donors, a highly selected population was found in 0.17% i.e. 17 in 10,000 donors in the first year of testing. In many of these cases, nosocomial risks in the past may be responsible. Such cleared infection does not pose a risk to recipients and in a number of countries, such individuals are acceptable as donors. In Ireland, we introduced core antibody testing in 2002 to reduce the possible risk of donors donating before HBV infection was fully cleared i.e. in the second window period when HbsAg is no longer detectable in blood but before an adequate (>100miu/l) antiHbs antibody is found. Because hepatitis B core antibodies are a mandatory test, donors with cleared infection found reactive for the marker are also deferred.

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

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

Findings
• Three incidents, which fit the criteria of suspected transfusion-transmitted infection, were reported to the NHO during this reporting year.

• There were two reports of suspected HIV infection and one of HBV.

• In all cases, transfusion was excluded as the likely cause.
### Table 37: Suspected Transfusion Transmitted Infection (n=3)

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Gender</th>
<th>Year of Transfusion</th>
<th>Adult or Child</th>
<th>Viral Marker</th>
<th>Number of donors involved</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTI Case 1</td>
<td>F</td>
<td>2004</td>
<td>Adult</td>
<td>HIV</td>
<td>53</td>
<td>Transfusion excluded</td>
</tr>
<tr>
<td>TTI Case 2</td>
<td>F</td>
<td>2004</td>
<td>Adult</td>
<td>HIV</td>
<td>3</td>
<td>Transfusion excluded</td>
</tr>
<tr>
<td>TTI Case 3</td>
<td>M</td>
<td>2004</td>
<td>Adult</td>
<td>HBV</td>
<td>16</td>
<td>Transfusion excluded</td>
</tr>
</tbody>
</table>
Adverse incidents or reactions during the donation are reported in this section. Incidents occurring during the transfusion of autologous blood are captured elsewhere in this report under the relevant category.

These adverse reactions accounted for 3% of the total incidents reported (7 of 214).

The majority of autologous donors tolerate the donation procedure without incident, but adverse reactions occur occasionally (Brecher et al, 2002). The most common reaction is vasovagal in nature (Yomtovian and Praprotnik, 2001). However, severe reactions are up to 12 times more likely in autologous donors than allogeneic donors. (Popovsky et al, 1995) High risk autologous donors include those with coronary artery disease or congestive cardiac failure or uncontrolled hypertension or on medication which affects the haemodynamic response of the cardiovascular system (Vamvakas and Pineda, 2000). Haemodynamic monitoring in high risk patients undergoing autologous blood donation has detected a significant number of adverse changes in response to blood donation not detectable by simple observation (Spiess et al, 1992).

Pre Autologous Donation (PAD) is an option for suitable patients where transfusion is anticipated during surgery (BCSH, 1993). One application for PAD has been in the field of elective orthopaedic surgery. Advances in anaesthesia and surgical technique, however, combined with reduced transfusion thresholds have diminished the need for transfusion in such patients. Politis and Richardson (2004) undertook a survey to determine the incidence of PAD throughout Europe and report almost one third of autologous units donated are not used.

The technique became popular during the 1980’s as a result of public concern regarding transfusion safety but has declined with the increasing safety of blood transfusion for the main transfusion transmitted viruses HIV, Hepatitis B & C. However other transfusion transmitted infection agents are emerging including West Nile Virus and vCJD. A case of vCJD
in a transfusion recipient was reported in the UK in late 2003 (Llewelyn et al, 2004) and the reported finding of abnormal prions at post mortem in the spleen of a second recipient who died of unrelated causes but who had received a unit of blood from a donor who developed vCJD supports the transmission of vCJD through transfusion (Peden et al, 2004). In 2005, an Irish blood donor developed symptoms considered to be due to vCJD. While a number of precautionary measures have been put in place to reduce the risk of transmitting vCJD by blood transfusion in Ireland, no universally effective measure exists to prevent its transmission and reduced exposure to transfusion and appropriate blood usage remain the most important measure.

The benefits to the patient of autologous transfusion include elimination of the risk of transmission of infectious diseases and alloimmunization and other immunological effects of allogeneic transfusion (Politis and Richardson, 2001).

Innerhofer et al (2005) in a prospective study report that despite universal white blood cell (WBC) filtration, recipients of allogeneic blood transfusion are still at greater risk of developing postoperative infections in comparison to autologous recipients.

However, Linden and Kruskall (1997) point out that although autologous blood is considered safer than allogeneic blood, it is not without risk. Bacterial contamination, febrile non-haemolytic reactions and allergic reactions have all been reported following autologous transfusion (Goldman et al, 2002). Other disadvantages associated with PAD are the necessity for a definite date for surgery, increased likelihood of receiving a transfusion, bacterial contamination, risk of error, volume overload, and additional cost. Biliotte et al (2002) demonstrated that pre-operative autologous donation increased the likelihood of transfusion at the time of surgery.

According to Carless et al, (2004) in a systematic analysis of autologous blood techniques the advantages of autologous transfusions are counteracted by lower pre-operative Hb levels and higher overall transfusion rates, and they suggest using other techniques such as antifibrinolytic drugs in conjunction with conservative transfusion thresholds to reduce the need for allogeneic blood.

Other forms of autologous transfusion in particular intraoperative cell salvage may reduce the need for allogeneic transfusion. (National Blood Conservation Strategy for NBTC and NBS Working Party Report, 2004). An audit commissioned by the National Blood Strategy Implementation Group (NBSIG) in 2001 found the use of autologous transfusion techniques in Ireland is low and has recommended that cell salvage programmes be established in major hospitals as they consider this is the most effective alternative to allogeneic blood transfusion.

**Regulatory aspects**

Hospitals collecting pre-deposit autologous blood will now be considered blood establishments in respect of the collection of autologous units and as such subject to the same scrutiny as a blood transfusion service under Article 29 of the European Directive 2002/98/EC, which came into effect in November 2005.

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

These directives can be downloaded from http://europa.eu.int.

**Findings:**

- Six of the seven incidents involved PAD for orthopaedic surgery. The remaining incident was associated with PAD for urological surgery.
Symptoms reported were generally vasovagal in nature and ranged from feeling light-headed, nauseated and faint to actually fainting. Onset of symptoms ranged from during the procedure up to twenty-four hours post donation.

- One donor developed a generalized body rash 24 hours after donating one unit and a severe urticaria on the torso, arms, legs and hands immediately following the donation of a second unit. This resolved with treatment the next day. The patient was on ACE inhibitors and it is not clear whether the reaction was related to the drug or the PAD although a sibling had had a similar reaction after blood donation.

- Six of the donors were discharged the same day. However, one donor required overnight hospitalisation. This patient was on antihypertensive medication.

- Three of the donors had each donated a unit previously, one of whom had felt nauseated and weak post donation but three of the donors involved were donating blood for the first time.

- Four of the donors were under sixteen years of age and three weighed less than 50 kgs. In one of these cases, although the donor completed a predonation questionnaire, she did not disclose that she felt faint and weak at the sight of blood or needles.

- Simultaneous volume replacement was not undertaken during the donations. However, two of the donors who experienced symptoms at the end of or following the donation were given fluids IV.

- All of the donors recovered without complications and one successfully donated a second unit uneventfully seven days later.

- The blood collected was transfused in six of the seven cases. Two donors received allogeneic blood in addition to the PAD blood. In one of the cases re-assessment post-transfusion after the first allogeneic unit might have obviated the need for further transfusions.

**Recommendations**

- Paediatric patients and adult patients weighing less than 50 kg need special consideration, and care should be taken to ensure the volume drawn does not exceed 12% of the estimated blood volume. (BCSH, 1994)

- All PAD clinics should monitor the donations using a digital scales. This would ensure that donations on children or lower weight adults could be stopped at <450mls. Patients less than 16 years may require to be bled into smaller bags as suggested by the BSCH guidelines (1994).

- Donors receiving antihypertensive medication should be carefully monitored. Volume replacement should be considered for patients on treatment with beta-blockers and/or angiotensin converting enzyme (ACE) inhibitors as their ability to respond to a reduction in blood volume may be compromised by their treatment.

- Careful selection of patients for PAD, such as young, fit adolescents may reduce the need for allogeneic transfusions in these patients and decisions to transfuse additional allogeneic blood post-operatively should be based on careful clinical assessment.
### Table 38: Pre-operative Autologous Donor Incidents (N=7)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age Yrs</th>
<th>Gender</th>
<th>Weight Kg</th>
<th>Hb g/dl</th>
<th>Planned Procedure</th>
<th>Current Medication</th>
<th>No Planned Donations</th>
<th>Reaction Donation History</th>
<th>Complications</th>
<th>Comments</th>
<th>PAD unit (s) transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAD Case 1</td>
<td>15 F</td>
<td>50</td>
<td>14.7</td>
<td>Removal of spinal rods</td>
<td>Oral iron</td>
<td>1</td>
<td>On 1st</td>
<td>Nausea and hypotension post donation.</td>
<td>Past history of nausea and feeling weak. 500mls of IV fluids administered. Recovered with no complications. Discharge Hb 10.3 g/dl.</td>
<td>None.</td>
<td></td>
</tr>
<tr>
<td>PAD Case 2</td>
<td>14 F</td>
<td>49</td>
<td>13.1</td>
<td>Ganz osteostomy</td>
<td>Oral analgesia</td>
<td>1</td>
<td>On 1st</td>
<td>Light-headed and nausea at end of donation.</td>
<td>Past history of needle phobia. 500mls of IV fluids administered. Recovered with no complications. Discharge Hb 8.9 g/dl.</td>
<td>Autologous unit transfused and 1 unit of allogeneic blood administered.</td>
<td></td>
</tr>
<tr>
<td>PAD Case 3</td>
<td>43 F</td>
<td>60</td>
<td>14.4 &amp; 12.0</td>
<td>Elective orthopaedic surgery</td>
<td>ACE inhibitor /thiazide diuretic and oral analgesics.</td>
<td>2</td>
<td>On 2nd, 1st uneventful.</td>
<td>24 hours following 1st donation urticaria over body. Following 2nd donation severe rash over torso, hands, and back.</td>
<td>Required anti-histamine tablets and cream to ease rash. Recovered with no complications. Discharge Hb 9.7 g/dl.</td>
<td>Both units transfused</td>
<td></td>
</tr>
</tbody>
</table>

* Included as a full case history
Table 39: (Continued) Pre-operative Autologous Donor Incidents (N=7)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age Yrs</th>
<th>Gender</th>
<th>Weight Kg</th>
<th>Hb g/dl</th>
<th>Planned Procedure</th>
<th>Current Medication</th>
<th>No Planned Donations</th>
<th>Reaction Donation History</th>
<th>Complications</th>
<th>Comments</th>
<th>PAD unit (s) transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAD Case 4</td>
<td>13</td>
<td>F</td>
<td>44</td>
<td>14.6</td>
<td>Orthopaedic surgery</td>
<td>Oral iron</td>
<td>3</td>
<td>On 1st. 2nd uneventful</td>
<td>Nausea and vomiting 30 mins post donation.</td>
<td>Recovered with no complications. Discharge Hb 7.9 g/dl.</td>
<td>One unit transfused.</td>
</tr>
<tr>
<td>PAD Case 5*</td>
<td>61</td>
<td>M</td>
<td>101</td>
<td>13.5</td>
<td>Orthopaedic surgery</td>
<td>Cardioselective beta-blocker, class II calcium antagonist, Bronchodilators orally and via inhalation. Oral analgesia</td>
<td>2</td>
<td>On 2nd 1st uneventful</td>
<td>Bradycardia, hypotension, loss of consciousness Fainted following donation of 500mls</td>
<td>Required overnight admission. Recovered with no complications. Discharge Hb 10.8 g/dl.</td>
<td>2 units transfused.</td>
</tr>
<tr>
<td>PAD Case 6</td>
<td>61</td>
<td>M</td>
<td>80</td>
<td>16.1</td>
<td>Urological surgery</td>
<td>None</td>
<td>2</td>
<td>On 2nd 1st uneventful</td>
<td>Light-headedness, felt faint 20 mins post donation.</td>
<td>Recovered with no complications. Discharge Hb 10.9 g/dl.</td>
<td>2 units of transfused.</td>
</tr>
<tr>
<td>PAD Case 7*</td>
<td>15</td>
<td>M</td>
<td>66</td>
<td>15.4</td>
<td>Orthopaedic surgery</td>
<td>Bronchodilator inhaler</td>
<td>3</td>
<td>On 2nd. 1st uneventful</td>
<td>Light-headedness. Fainted 25 mins post donation</td>
<td>Recovered with no complications. Post- transfusion Hb 7.4 g/dl. Discharge Hb 10.4 g/dl.</td>
<td>2 units of autologous and 2 units of allogeneic blood administered.</td>
</tr>
</tbody>
</table>

* Included as a full case history
Pre-operative Autologous Donor (PAD) Incidents (n=7) Case Histories

PAD Case 3
This female patient was pre-donating two units of blood for elective orthopaedic surgery. Assessment of donor fitness was carried out and the patient’s weight was 60 kgs and Hb 14.4 g/dl prior to the first unit and 12.0 g/dl prior to donation of the second unit. The patient had a history of hypertension, which was well controlled with the ACE inhibitor/thiazide diuretic, Capozide. The collection of the first unit was uneventful. However, the following day the patient went on holiday and developed a generalised body rash, which she attributed to a change in the sheets in the hotel. Within one hour following donation of the second unit, however, the patient developed a virulent urticaria on torso arms legs and hands that required an antihistamine cream and tablets to alleviate the itch. This settled within 24 hours. The patient’s Hb level prior to transfusion was 9.3 g/dl and the patient received the two pre-deposited units following surgery. No further allogeneic units were required. Prior to discharge home the patients Hb was 10.9 g/dl.

PAD Case 5
This male patient was scheduled to pre-donate two units of blood prior to a total hip replacement for which the MSBOS recommended two units of blood. His pre-donation Hb was 13.5 g/dl. The donor had a history of asthma and hypertension and his current medications included a cardioselective beta-blocker, a class II calcium antagonist, a bronchodilator, salbutamol inhaler and oral analgesics. Immediately following the second donation of 500mls (including anticoagulant) of whole blood, the donor felt faint had symptoms of bradycardia, hypotension and loss of consciousness. The donor was reviewed by the medical team and remained in hospital overnight and was referred to a cardiologist for review, which was normal. The patient’s haemoglobin prior to transfusion was 10.1 g/dl and the two units, which had been collected, were administered based on the intraoperative blood loss. No extra allogeneic units were required. Prior to discharge home the patients Hb was 10.9 g/dl.

PAD Case 7
This young boy was pre-donating his second unit of blood for elective orthopaedic surgery. He had donated one unit previously. Between 450-460 mls of blood were collected uneventfully and the patient rested in the donation facility for 20 minutes. Shortly afterwards he became light-headed and fainted. He returned to the donation facility and rested for a further hour and had some fluids orally. He recovered without incident from this event. A third unit was not taken. Peri-operatively when the patient had reached his maximum allowable blood loss (MABL), both autologous units were transfused. The patient’s haemoglobin post transfusion was 7.4 g/dl and his vital signs were within normal limits. However, on day three post-operatively the patient became symptomatic complaining of dizziness and feeling light-headed on getting out of bed and two further units of allogeneic red cells were administered. In this case, reassessment after the first allogeneic unit might have obviated the need for a further transfusion. The patients discharge haemoglobin was 10.4 g/dl.
Paediatric patients form an important sub group of transfusion patients. This chapter summarises the findings on the 24 paediatric cases reported, which account for 11% of the total reports received. The majority of reports were in the IBCT category, seven involved acute reactions and four were reactions associated with PAD.

For the purpose of this report, paediatric patients are defined as age 18 years or under.

**Findings IBCT**

- There were 12 reports in the IBCT category. The majority of errors were similar to those found in the adult patients.

- In one case (Case 78) a group A baby received group O platelets due to a request error to the supply centre by a medical scientist on call not normally working in the transfusion laboratory.

- One patient was involved in three reports (Cases 94, 96 & 97) where three paedipack aliquots were incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.

- In three cases (Cases 50, 107 & 108) there was a failure to prescribe CMV negative/irradiated components. Two of these (Cases 107 and 108) involved shared care between facilities and as no clinical details were provided, the laboratory was not aware of the requirements. In the third case, (Case 50) although the patient had received previous CMV negative/irradiated components, the alert on the laboratory computer had not been activated so the error was not detected.

**Findings Reactions**

There were 12 reports in the reaction category.

- The most common reaction reported was in the AA category with seven reports. Pooled platelets were involved in five cases and red cells in two.

- Three of the AA cases occurred despite the administration of premedication of
chlorpheniramine and hydrocortisone.

- Further transfusion was managed using premedication alone in three cases and washed component in three cases. One of these who required washed components was a patient who had three separate reactions to pooled platelets (Case 21, 22, 23).

- Cutaneous manifestations were present in all of the AA reports.

- There was one report in the AHOSTR category.

- Four cases involved reactions associated with pre-deposit autologous donations and are discussed in the PAD chapter.

**Recommendations.**

- On going training should be provided for medical scientists providing on call cover who do not normally work in transfusion to highlight special requirements for neonates.

- Each aliquot of a paedipack dedicated to a specific infant should be individually labelled for the intended infant to reduce the chance of issuing it to another infant.

- Medical staff must be aware of guidelines for prescribing irradiated products in paediatric patients.

- Alert stickers should be placed on charts where patients have special requirements e.g. irradiated/CMV negative components.

- Blood transfusion laboratory computer system alerts which draw attention to the need for specialised components should be used wherever possible.

- As some of the incidents involved shared care or admission to different hospitals, issuing of a patient card should be considered.

- A/A reactions are distressing for both the patient and the clinical team and washed components may be indicated for serious repeated reactions. However, poorly justified requirements for washed components may cause undue delays when transfusions are needed in the future. In addition, washing of platelets can affect platelet yields with loss of platelet numbers and viability from the washing process and poor in vivo incremental rises.

- Before prescribing washed platelets for patients with a history of transfusion reactions to pooled products, apheresis platelets (which are associated with a lower rate of reactions) with premedication cover should be tried first.

- It is important to ensure that the patient has a patent IV cannula and that all documentation is correct prior to collection of the unit. Should there be a delay in the commencement of the transfusion it is necessary to return the unit to controlled storage within thirty minutes and inform the laboratory to ensure the unit is being returned to the appropriate fridge.
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Volume of Incorrect Blood Component or Product Transfused</th>
<th>Symptoms and Outcome</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Case 78 *P</td>
<td>1 wk</td>
<td>15mls of apheresis platelets x 2</td>
<td>No complications as a result of this transfusion.</td>
<td>Group O platelets requested and issued to Group A baby.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 25</td>
<td>1 yr</td>
<td>Plasma exchanged on four occasions with 12 units of Uniplas.</td>
<td>Positive DAT. No complications as a result of this transfusion. Subsequent transfusions with Group B FFP.</td>
<td>Inability of supply centre to supply group B SD Plasma for large volume plasma exchanges.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 43</td>
<td>39 days</td>
<td>One paedipack</td>
<td>No complications as a result of this transfusion.</td>
<td>Incorrect date of birth was transcribed from notes onto request form and sample tube.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 50 *P</td>
<td>18 months</td>
<td>One unit of red cells.</td>
<td>No complications as a result of this transfusion.</td>
<td>CMV negative and irradiated red cells not ordered as required and error not detected on processing as this requirement had not been flagged on a previous transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 94, 96, 97 same patient *P</td>
<td>5 wks</td>
<td>One aliquot of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Paedipack aliquot incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>One aliquot of red cells</td>
<td></td>
<td>Paedipack aliquot incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paedipack aliquot incorrectly crossmatched and transfused from a paedipack which was crossmatched and allocated for another baby of the same name.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 107 *P</td>
<td>3 yrs</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to prescribe CMV negative or irradiated red cells for a patient with a malignant haematological disorder.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 108</td>
<td>15 yrs</td>
<td>Discovered when 60 mls of red cells transfused, discontinued.</td>
<td>No complications as a result of this transfusion.</td>
<td>Failure to request and prescribe irradiated blood products for a patient with a malignant haematological disorder.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 121 *P</td>
<td>22 days</td>
<td>One aliquot of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>In error last aliquot of paedipack removed from and left out of fridge too long and wasted.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 29</td>
<td>3 yrs</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>One digit error in date of birth on pre transfusion sample request form and on unit transfused.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 75</td>
<td>7 yrs</td>
<td>One unit of red cells</td>
<td>No complications as a result of this transfusion.</td>
<td>Mother of patient stated patient’s date of birth incorrectly, i.e. month, day, year instead of day, month, year.</td>
</tr>
</tbody>
</table>

*P Included as a full case history in this chapter
Wrong Platelet ABO group

Level 1 IBCT Case 78
This premature neonate with sepsis required a transfusion of platelets for thrombocytopenia. The patient's blood group was A Rh D positive. A Rh D positive platelets should have been requested. In error, group O Rh D positive platelets were requested by an on-call medical scientist not normally working in blood transfusion. The supply centre did not detect the error as the information about the patient's blood group was incorrect. The platelets were administered in two doses of 15 mls uneventfully and both transfusions were checked at the bedside by two clinical staff; however the group discrepancy went unnoticed. A medical scientist normally working in blood transfusion discovered the error the following day during a routine audit of on-call work. The patient suffered no complications as a result of this transfusion.

Problems with Paedipacks

Level 2 IBCT Case 94, 96, 97
This neonate required a top up transfusion for anaemia of prematurity. There were three infants with the same surname being nursed in the ITU at this time. On call a medical scientist not normally working in transfusion issued an aliquot crossmatched for this baby, from a paedipack which had been allocated and crossmatched for one of the other babies of the same name. Both babies were of the same blood group. The error occurred due to a failure to confirm correct hospital number and date of birth on the baby intended for transfusion. In the hospital, the unit, which is split into aliquots, is labelled with the baby's details but each aliquot is not individually labelled. However the crossmatch form contains the donor number, which is on each aliquot and used for confirmation during the final bedside checking procedure. The error went unnoticed and was repeated on the same baby on two further occasions. All transfusions were uneventful and a senior medical scientist discovered the error during a routine audit. Both babies required further transfusions and new aliquots were assigned.

Level 2 IBCT Case 121
This premature neonate required a transfusion of red cells for anaemia. The baby had already received three of the five neonatal aliquots available at the hospital. On this occasion the baby required one further aliquot but two units were removed from the fridge in error. One aliquot was transfused but the other one had to be discarded as it had been out of controlled storage for too long. The following day having reviewed the patient a decision was made to transfuse a further unit of red cells. A new paedipack of red cells was ordered but due to the baby’s condition a decision was made to transfuse the baby immediately using the stock red cells for neonatal use.

CMV / Negative Irradiated components not prescribed

Level 2 IBCT Case 107
This child with a malignant haematological disorder required a transfusion of two units of CMV negative and irradiated red cells for anaemia. The child was receiving shared care between two facilities. The prescription however did not state the need for special requirements and the first unit was issued from the laboratory and transfused. When the laboratory staff contacted the clinical area to see if the second unit was required they were informed of the shared care programme and it was then realised that CMV negative and irradiated components should have been prescribed. As this was the first transfusion outside the primary care facility no transfusion history was available.

Level 2 IBCT Case 50
This young child with a malignant disorder required a red cell transfusion. The patient had received previous transfusions of CMV negative and irradiated blood products. On the previous transfusion, the appropriate product was issued but the alert which
would have indicated the special requirements for future transfusions was not activated on the laboratory system. On this occasion, one unit of red cells was prescribed but the requirement for CMV negative and irradiation was not specified. The laboratory staff were not alerted by the IT system as the alert had not been activated previously. One unit of red cells was transfused. By chance the unit was CMV negative but was not irradiated. The patient suffered no complications as a result of this incident. The error was detected on a subsequent transfusion. As a result of this incident all computer records of paediatric oncology patients have been flagged as requiring CMV negative and irradiated products. All new cases with special transfusion requirements have a sticker placed on the front of the chart.

**Transfusion Reactions**

**AA Case 15**
This five-year-old male patient with a malignant haematological disorder required a red cell transfusion for anaemia. The unit of red cells was administered as prescribed over three and half-hours. Two hours after transfusion the patient developed symptoms of urticaria and periorbital oedema. Chlorpheniramine was given and the patient recovered fully within two and half-hours. The patient suffered no further complications as a result of this transfusion. No investigations were carried out. Pre-medication of chlorpheniramine for future transfusions was recommended and the patient has had received subsequent transfusions with no complications using this regime.

**AA Case 21, 22 & 23**
This young male child with a malignancy required several transfusions of platelets in the day care setting following chemotherapy. Following transfusion of a unit of pooled platelets, the patient developed an urticarial rash which did not require treatment and which subsided within 30 minutes. During a subsequent transfusion of pooled platelets one week later, the patient developed urticaria, a cough and a lump in his throat. No medication was prescribed. One unit of red cells was then transfused uneventfully and the child was discharged. On the third occasion, one week later, premedication of chlorpheniramine and hydrocortisone was given prior to a further transfusion of pooled platelets. Following transfusion, the patient developed a cough, wheeze and itch which required treatment with a salbutamol nebulizer. The symptoms resolved within one hour and future recommendations for transfusion of this child include the administration of washed platelets. Subsequent transfusions using this protocol have been successful.

**AHOSTR case 20**
This young male child with a malignant haematological disorder required one unit of CMV negative red cells for anaemia. The patient grouped as O Rh D positive, the historical antibody screen was positive for Anti Jk\(^b\) which was not detected on this occasion. Antigen negative blood was crossmatched and issued. During transfusion, when 93 mls had been transfused, the patient developed symptoms of fever (>1.5°C) with backache and nausea. The transfusion was discontinued completely and no medication was given. A full recovery was made but the recovery timeframe was not specified in the case notes. The patient was cultured and no organisms were isolated. However the suspected reaction was not investigated and the unit was not cultured.
<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age Yrs</th>
<th>Gender</th>
<th>Component</th>
<th>Reason for transfusion</th>
<th>Symptoms</th>
<th>Investigations</th>
<th>Stage Transfusion Developed</th>
<th>Treatment</th>
<th>Sequelae/ Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 10</td>
<td>12 F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 54 x10⁹/L</td>
<td>Haematological malignancy, sepsis.</td>
<td>Urticaria despite premedication with hydrocortisone and chlorpheniramine IV.</td>
<td>None</td>
<td>Following completion of transfusion</td>
<td>None</td>
<td>Recovery within thirty minutes. Washed components have been recommended for future transfusions.</td>
</tr>
<tr>
<td>AA Case 11</td>
<td>11 F</td>
<td>One unit pooled platelet concentrate</td>
<td>Platelet count 18 x10⁹/L</td>
<td>Haematological malignancy.</td>
<td>Urticaria, itch and discomfort despite premedication with hydrocortisone and chlorpheniramine IV.</td>
<td>None</td>
<td>45 minutes after commencing transfusion</td>
<td>Hydrocortisone IV.</td>
<td>Recovery within thirty minutes. Future transfusions with washed components have been recommended.</td>
</tr>
<tr>
<td>AA Case 15</td>
<td>5 F</td>
<td>One unit red cells</td>
<td>Anaemia Hb 7.6g/dl</td>
<td>Haematological malignancy, active bleeding.</td>
<td>Urticaria, periorbital oedema.</td>
<td>None</td>
<td>Following completion of transfusion</td>
<td>Chlorpheniramine</td>
<td>Recovered within two and a half hours. Subsequent transfusions with premedication of chlorpheniramine have been uneventful.</td>
</tr>
<tr>
<td>AA Case 19</td>
<td>11 F</td>
<td>One unit red cells</td>
<td>Anaemia Hb 8.1 g/dl</td>
<td>Haematological malignancy.</td>
<td>Urticaria, fever rise of 1.9°C, chills, rigors, tachycardia.</td>
<td>ABO incompatibility excluded. Culture of patient and unit, no growth.</td>
<td>Within three hours of commencing transfusion. 240mls had been transfused.</td>
<td>Hydrocortisone IV, paracetamol. Transfusion discontinued.</td>
<td>Recovery within 4-5 hours. Premedication of antihistamine has been recommended.</td>
</tr>
<tr>
<td>AA Case 21, 22 &amp; 23</td>
<td>6 M</td>
<td>One unit of pooled platelet concentrate (1st transfusion)</td>
<td>Platelet count 10x10⁹/L</td>
<td>Malignancy.</td>
<td>Urticaria</td>
<td>None</td>
<td>Post transfusion</td>
<td>None.</td>
<td>Recovery within one hour.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One unit of pooled platelet concentrate (2nd transfusion)</td>
<td>Platelet count 14x10⁹/L</td>
<td>Malignancy.</td>
<td>Urticaria, cough and lump in throat</td>
<td>Post transfusion. 55 minutes after commencing transfusion</td>
<td>None</td>
<td>Recovery within one hour. Premedication prior to future transfusions recommended.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>One unit of pooled platelet concentrate (3rd transfusion)</td>
<td>Platelet count 19x10⁹/L</td>
<td>Malignancy.</td>
<td>Urticaria, cough, lump in throat despite premedication with hydrocortisone and chlorpheniramine IV.</td>
<td>Post transfusion. 30 minutes after commencing transfusion</td>
<td>Salbutamol nebulizer.</td>
<td>Recovery within one hour. Washed cells have been recommended for future transfusions.</td>
<td></td>
</tr>
</tbody>
</table>

*P Included as a full case history in this chapter
### TABLE 42 AHOSTR Paediatric Incidents (N=1)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Component Prescribed</th>
<th>Age Yrs</th>
<th>Gender</th>
<th>Underlying condition</th>
<th>Volume transfused onset</th>
<th>Symptoms/signs</th>
<th>Investigations</th>
<th>Treatment &amp; Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHOSTR Case 20</td>
<td>One unit of red cells K+b antigen negative red cells.</td>
<td>3</td>
<td>M</td>
<td>Haematological malignancy</td>
<td>93 mls</td>
<td>Temperature rise &gt;1.5°C, backache, nausea.</td>
<td>Patient cultured, no organisms isolated. No further investigations carried out. Although patient had a history of previous antibodies.</td>
<td>Transfusion was discontinued, patient recovered fully. No treatment was given.</td>
</tr>
</tbody>
</table>

### TABLE 43: Pre-Deposit Autologous Donor Incidents (N=4)

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age Yrs</th>
<th>Gender</th>
<th>Weight kg</th>
<th>Hb g/dl</th>
<th>Planned Procedure</th>
<th>Current Medication</th>
<th>No Planned Donations</th>
<th>Reaction Donation History</th>
<th>Complications</th>
<th>Comments</th>
<th>PAD unit (s) transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAD Case 1</td>
<td>15</td>
<td>F</td>
<td>50</td>
<td>14.7</td>
<td>Removal of spinal rods</td>
<td>Oral iron</td>
<td>1</td>
<td>On 1st</td>
<td>Nausea and hypotension post donation.</td>
<td>Past history of nausea and feeling weak. 500mls of IV fluids administered. Recovered with no complications. Discharge Hb 10.3 g/dl.</td>
<td>None.</td>
</tr>
<tr>
<td>PAD Case 2</td>
<td>14</td>
<td>F</td>
<td>40</td>
<td>13.1g/</td>
<td>Ganz osteostomy</td>
<td>Oral analgesia</td>
<td>1</td>
<td>On 1st</td>
<td>Light-headed and nausea at end of donation.</td>
<td>Past history of needle phobia. 500mls of IV fluids administered. Recovered with no complications. Discharge Hb 8.9 g/dl.</td>
<td>Autologous unit transfused and 1 unit of allogeneic blood administered.</td>
</tr>
<tr>
<td>PAD Case 4</td>
<td>13</td>
<td>F</td>
<td>44</td>
<td>14.6</td>
<td>Orthopaedic surgery</td>
<td>Oral iron</td>
<td>3</td>
<td>0n 1st, 2nd uneventful</td>
<td>Nausea and vomiting 30 mins post donation.</td>
<td>Recovered with no complications. Discharge Hb 79 g/dl.</td>
<td>One unit transfused.</td>
</tr>
<tr>
<td>PAD Case 7</td>
<td>15</td>
<td>M</td>
<td>66</td>
<td>15.4</td>
<td>Orthopaedic surgery</td>
<td>Bronchodilator inhaler</td>
<td>3</td>
<td>0n 2nd, 1st uneventful</td>
<td>Light-headedness. Fainted 23 mins post donation</td>
<td>Recovered with no complications. Post-transfusion Hb 74 g/dl. Discharge Hb 10.4 g/dl.</td>
<td>2 units of autologous and 2 units of allogeneic blood administered.</td>
</tr>
</tbody>
</table>

*P Included as a full case history in this chapter

* Included as a full case history in appropriate chapter
Introduction
A three year pilot project in Near Miss event reporting commenced in November 2002. The objectives of the project were to improve the safety of transfusion by analysing the incidence of Near Miss events and their root causes so that changes could be introduced where weaknesses in the transfusion chain were identified.

The Medical Event Reporting System for Transfusion Medicine (MERS-TM), a system specifically designed to collect, classify and analyse events with potential for compromising blood transfusion safety was used to collect and analyse the data.

Ten hospital sites nationwide have been contributing to the project since it commenced and reporting rates have been steadily growing. During 2004, the first full year of reporting, a total of 467 Near Miss events were received and analysed. The total number of reports received within the IBCT category from the same ten hospital sites during 2004 was 42, confirming that Near Miss events are occurring on average, 11 times more frequently than adverse events causing harm.

The distinguishing difference between a Near Miss event and an adverse event causing harm, is that in a Near Miss event there is always a 'recovery' step that prevents harm to the patient. Recovery can either be in the form of a planned checking step in the work process or, an event can be simply caught by chance. Information about recovery within an organisation can provide us with insight about which barriers to error are effective or which are weak or missing.

The risk index of each event was calculated using the risk assessment tool provided by MERS-TM. Each event was classified into either high medium or low risk depending on the degree of risk the event posed to either the patient or the organisation.

Root causes were divided into Human, Organisational, Technical or Patient Related Failures. Most events involved more than one root cause; only significant root causes where patterns or trends in error emerged will be discussed in this report.

By analysing Near Miss event data, we can identify high risk clinical areas and steps in the work process in addition to many other factors that contribute to error. By studying the circumstances surrounding each event, we can gain vital insight into the real reasons why errors occur in the transfusion setting. Most importantly, as the lessons we can learn from Near Miss event data do not involve the patient being exposed to harm, we can improve the safety of transfusion in a way that benefits both the patient and
the organisation.

RESULTS

Fig 6: Near Miss Events versus Adverse Events reported in the 10 Project Sites
Jan - Dec 04

Near Miss events in the 10 project sites are occurring on average 11 times more frequently than adverse events causing harm.

Fig 7: Risk Index of Events

There were 353 events that were classified as low risk, 81 as medium risk and 33 as high risk.

Fig 8: Step in the Work Process where Events were Discovered N = 467

The majority of events 273 (58%) were discovered at the Sample Handling step in the laboratory highlighting this step as an effective barrier to error. There were 66 (13%) events that were not discovered until Unit Transfusion ie: at some point after the unit was issued, but before it was transfused to the patient. These relate to events discovered at either collection from site of storage or the final bedside check. A further 60 (13%) events were discovered at some point outside recognised checking steps in the work process, these events were classified as being discovered at ‘miscellaneous’ steps.
Sample Collection was the first site of error in 300 (64%) events, identifying it as the highest risk step in the work process. There were 33 (7%) events involving errors made during Prescription or Request. In addition, there were 70 (15%) events where the first site of error occurred at some point outside recognised steps in the work process, these events were classified as first occurring at 'Miscellaneous' steps.

Errors most frequently involved medical & nursing staff, 261 (56%) events involved doctors and 138 (29%) involved nurses. Laboratory staff were also involved in a significant number of events 50 (10%). A further 50 (10%) events involved ‘other’ grades of staff including portering and phlebotomy staff. Most events involved more than one grade of staff.

The high risk clinical areas identified were the general ward areas where 274 (59%) events occurred and A&E where 66 (14%) events occurred. A significant number of events, 47 (10%) occurred in the transfusion laboratory which has been traditionally viewed as an area where risk of error is low.
263 (56%) events occurred during routine working hours, the remaining 204 (44%) events occurred out of hours or at weekends.

The majority of events 383 (82%) were caught and harm to the patient prevented by planned checking steps in the work process. The remaining 84 (18%) events were caught by chance.
**Root Causes – Findings**

To date, there appears to be several significant trends emerging from the data in relation to the root causes of error. Most events involved more than one root cause and single events often contained a combination of both system and human failures.

**Human Failures**

Human slips are the most frequently occurring cause of human error. Most of the human slips involved staff forgetting to complete tasks, such as sample labelling or making transcription errors on samples and requests. These types of errors occur when staff are inattentive while carrying out a task. Reasons sited for these types of errors were tiredness and distractions caused by busy workloads and long working hours.

Other root causes relating to human failure highlighted were staff failing to verify patient or product identification at the bedside, failure to carry out cross checks correctly or at all and failure to verify test results prior to prescribing.

Failure to follow policies/procedures was also shown to be a significant root cause. Practices such as pre labelling of sample tubes, remote labelling and checking, taking samples from patients with no ID bands and failing to adhere to maximum surgical blood ordering schedules were all associated with error.

Finally lack of knowledge was also shown to contribute to error in a smaller number of events, for example medical staff prescribing plasma for warfarin reversal inappropriately or being unaware of basic procedures to follow despite having received training.

**System Failures**

Management priorities were the most frequently occurring cause of system failure. For example, decisions made about staffing levels such as not replacing staff on annual or sick leave were found to contribute to error. Short staffing in the clinical areas was frequently cited as a contributory factor when error occurred.

The absence of systems for gaining access to medical records out of hours was highlighted as a significant cause of error in some sites. This led to situations where patients who were admitted out of routine hours could not be assigned a medical record number. The hospitals involved had to use a supplementary numbering system so that each patient could have a unique transfusion number. This supplementary system was found to be flawed and very prone to user error and was frequently associated with sample collection errors.

Another significant management failure that emerged from the data relates to the limited phlebotomy services available in some hospital sites. Routine phlebotomy services were found to be minimal or absent after 1pm in many sites and were frequently not available at all in accident and emergency departments. This led to situations where medical and nursing staff were expected to take pre transfusion samples in addition to their already demanding workload.

Failures on behalf of management to ensure that systems are in place for ensuring all staff involved in transfusion are given appropriate training for the tasks they are expected to carry out was also found to be a root cause of error. Absence of mandatory training programmes for certain groups of staff such as agency, locum and medical staff was highlighted. Despite most sites having an established Haemovigilance training programme, lack of systems for ensuring all staff attended these training programmes was found to be a particular problem. Lack of appropriate training for staff doing cross call cover in the transfusion laboratory was also found to contribute to laboratory errors.

Technical failures such as computer systems in the hospital not being fully linked with computer systems in the transfusion laboratory were also highlighted. This led to situations where updated information on
hospital patient information systems (PAS) were not carried across to the laboratory system (LIS). As a result, vital information relating to patient details were missed.

Finally, failure to ensure that current policies and procedures relating to the transfusion process were available in all clinical areas and are reviewed and updated at regular intervals was also found to contribute to error in some sites.

Although these findings are only taken from one full year of reporting, significant trends in error are emerging and it is hoped that through continued reporting into the project a much better understanding of transfusion error will be gained at the end of the three year period.

The data provided in this report would not exist without the ongoing contribution of all staff involved in the transfusion chain at hospital level. In particular, the Haemovigilance Officers and laboratory staff who have coordinated this project in their individual sites in addition to their existing workload. It is hoped that reporting rates will continue to grow in the final year of the project and that the data produced will be used to target resources where they are needed most in order to reduce error and improve transfusion safety.
The NHO would like to thank a number of people for their invaluable contribution to the compilation of this report and gratefully acknowledge the assistance they provided.

Mr Geoff Lucas and Staff at the International Blood Group Reference Laboratory, National Blood Group Reference Laboratory, National Blood Service, Bristol.

Dr Joan Gilvarry, Ms Niamh Arthur, Mr John Lynch and Mr. Patrick Costello at the Irish Medicines Board, Dublin

Dr. Beatrice Nolan for her contribution towards the Transfusion Associated Circulatory Overload chapter.

Mr Geoff Connell and staff in the Virus Reference Laboratory, University College Dublin for their help in suspected transfusion transmitted donor investigations.

For those from within the IBTS, thanks are extended to:

Ms Bernie Quirke and the staff of the Virology Laboratory, Carmel Sheridan, Recipient Tracing Unit and Pauline Coakley QA Manager IBTS.

Dr Joan O’Riordan for her contribution towards the general content of this report, to Dr Joan Fitzgerald for her input into the Anti-D section and also to Mr Don Mullahy for his advice on laboratory matters.

Dr Joan Power, Dr Nuala Moore, Dr Michael Thomas, Communications Officer, Ms Mirenda O’Donovan, Training Officer, Mr Peter McDonnell, and staff of the Library Services, Ms Niamh O’Sullivan, Ms Lucy O’Doherty and Ms. Janet Kelleher.
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Bailie, G.R., Clark J.A., Lane C.E., Lane et al. (2005) Hypersensitivity reactions and deaths associated with intravenous iron preparations: Nephrol Dial Transplant. 20 (7) 1443-9


National Blood Strategy Implementation Group, Report to the Minister for Health and Children; Chairperson, Dr. Orlaith O’Reilly, 2004
National Institute for Clinical Excellence for the National Collaborating Centre for Chronic Conditions (July 2003) Management of chronic heart failure in adults in primary and secondary care Clinical Guideline 5 UK NHS


Appendix 1
Management of an Acute Transfusion reaction

**Symptoms/Signs of Acute Transfusion Reaction**
- Fever, chills, tachycardia, flushing, urticaria, bone/muscle/abdominal pain, nausea, dyspnoea, collapse, hypo/hypertension, 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.

**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.

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

**Other severe reaction-non respiratory?**

**Acute haemolysis/bacterial contamination**
- Remove unit and administration set.
- Leave cannula in place and put up 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 >100ml/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.

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

**Severe allergic/anaphylaxis reaction**
- Tachycardia, dyspnoea and cough, wheezing, malaise, angioedema (often of the lips, eyes or tongue).
- Stop transfusion.
- Call for medical assistance.
- Give oxygen.
- Give chlorpheniramine 10mg slowly IV and hydrocortisone 100-200mg IV.
- If respiratory symptoms or history of asthma give salbutamol nebuliser.
- If anaphylactic shock: hypotension, sub-sternal or abdominal pain, worsening symptoms, laryngeal oedema, respiratory obstruction, collapse.
- Give adrenaline (epinephrine) 1:1000 solution 0.5mL (600 micrograms) IM into anterior aspect of mid thigh.
- Repeat once after 5 minutes if no clinical improvement or deterioration.
- Seek expert medical advice as soon as possible.
- Investigation.
- Send sample for IgA level.

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

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

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