NATIONAL HAEMOVIGILANCE OFFICE

ANNUAL REPORT 2002
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List of Abbreviations

AA   Severe Acute Analphylactoid/Anaphylactic Transfusion Reaction
AABB  American Association of Blood Banks
ACE  Angiotensin-converting enzyme
A&E  Accident and Emergency
AHOSATR  Acute Haemolytic or Other Severe Acute Transfusion Reaction
ARDS  Adult respiratory distress syndrome
BCHS  British Committee for Standards in Haematology
CCU  Coronary care unit
CMV  Cytomegalovirus
CPDA1  Citrate-phosphate-dextrose-adenine
DAT  Direct antiglobulin test
DHTR  Delayed Haemolytic Transfusion Reaction
DVT  Deep venous thrombosis
ECG  Electrocardiograph
EPO  Erythropoetin
EU  European Union
FBC  Full blood count
FFP  Fresh frozen plasma
GI  Gastrointestinal
GP  General practitioner
GTN  Glyceryl trinitrite
Hb  Haemoglobin
HBV  Hepatitis B virus
HCV  Hepatitis C virus
HIV  Human immunodeficiency virus
HLA  Human leucocyte antibody
IBCT  Incorrect Blood Component Transfused
IBTS  Irish Blood Transfusion Service
ID band  Identity band
IgA  Immunoglobulin A
IgG  Immunoglobulin G
IgM  Immunoglobulin M
IM  Intramuscular
IMB  Irish Medicines Board
INR  International normalised ratio
ISBT  Information Standard for Blood Transfusion
IT  Information technology
ITP  Idiopathic thrombocytopaenic purpura
ITU  Intensive therapy unit
IV  Intravenous
LDH  Lactate dehydrogenase
MRN  Medical record number
MRSA  Methicillin-resistant staphylococcus aureus
NAT  Nucleic acid amplification testing
NCHCD  National Centre for Hereditary Coagulation Disorders
NEQAS  National External Quality Assurance Scheme
NHO  National Haemovigilance Office
OPD  Out-Patient Department
PAD  Pre-deposit Autologous Donor Incident
PAS  Patient administration system
PBSC  Peripheral blood stem cell
PCC  Prothrombin Complex Concentrate
PCR  Polymerase chain reaction
PNH  Paroxysmal nocturnal haemoglobinuria
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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>pO2</td>
<td>Oxygen saturation</td>
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<tr>
<td>PTP</td>
<td>Post transfusion purpura</td>
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<tr>
<td>QA/QC</td>
<td>Quality Assurance/Quality Control</td>
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<td>Rh</td>
<td>Rhesus</td>
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<td>RTA</td>
<td>Road traffic accident</td>
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<td>SD</td>
<td>Solvent detergent</td>
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<td>SHOT</td>
<td>Serious Hazards of Transfusion</td>
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<td>SOP</td>
<td>Standard operating procedure</td>
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<td>Suspected TTI</td>
<td>Suspected Transfusion Transmitted Infection</td>
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<td>TACO</td>
<td>Transfusion associated circulatory overload</td>
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<tr>
<td>TA-GvHD</td>
<td>Transfusion associated graft-versus-host disease</td>
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<tr>
<td>THR</td>
<td>Total hip replacement</td>
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<td>TKR</td>
<td>Total knee replacement</td>
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<tr>
<td>TRALI</td>
<td>Transfusion related acute lung injury</td>
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<tr>
<td>TSO</td>
<td>Transfusion Surveillance Officer</td>
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<td>TTP</td>
<td>Thrombotic thrombocytopenic purpura</td>
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Foreword to 2002 NHO Report

With the publication of this report, the National Haemovigilance Office (NHO) has now completed three full years in operation. During that time, 384 incidents have been reported and participation in the scheme has increased with over 90% of hospitals participating.

We include a breakdown of the cumulative events reported for the first three years. As expected incorrect blood component transfused (IBCT) forms the leading adverse event reported over the three years and the numbers continue to rise which may be ascribed to increased reporting. While there was no mortality associated with the transfusion in any of these cases, there is no room for complacency. However the continued reporting of these incidents allows evaluation of the causes and implementation of solutions leading to improved patient care.

The “Near Miss” Project, which commenced in November 2002, is now up and running in the ten sites involved. On-going training and feedback to individual sites will continue and we hope to be able to present the results of the first years findings in next year’s report. The project could not have been implemented without all the support those contributing to the project have given to date.

The EU Directive 2002/98/EC\textsuperscript{1} which comes into force on 8\textsuperscript{th} February 2005 will have significant effects on the management of blood transfusion services including hospital transfusion laboratories in the future and also on the operations of the NHO and will require planning and resources to implement. Dr William Murphy, National Medical Director Irish Blood Transfusion Service (IBTS) who was involved as Ireland’s representative in drafting the Directive has written an article at the NHO’s request on the Directive and its implications which is included in this year’s report.

I would like to thank all the hospital-based Transfusion Surveillance Officers (TSO), transfusion medical scientists and consultant haematologists whose support and enthusiasm have been invaluable to the success of the programme.

The assistance and guidance of the medical director and staff of the Irish Medicines Board (IMB) have been invaluable. I particularly acknowledge in a special way the support of the staff of the IMB’s Pharmacovigilance Department.

I particularly appreciate the work of all those involved in writing and reviewing this year’s report, as listed in the acknowledgements at the end of this report. Their contributions were extremely valuable in ensuring that this report is informative, readable and a tool for implementing improvements in patient care.

Dr. Emer Lawlor
Director
National Haemovigilance Office
In January 2003 the European Union (EU) passed into law a Directive\(^1\) governing blood transfusion in Europe. A further qualifying Directive on technical requirements for blood and blood components and autologous transfusion will probably follow in 2003; specifications for a quality system and for haemovigilance will be covered later still.

The Directive\(^1\) (officially known as Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC) governs the activities of Blood Transfusion Services, Blood Transfusion Centres and Hospital Blood Banks. This legislation will have far-reaching consequences for the way blood transfusion is regulated and performed in all member states of the EU.

The thirty-three Articles in the Directive deal with general administration, quality assurance and technical standards.

**General Administration and Quality Assurance**

The Commission has a central role under the Directive – it oversees compliance by the member states with the requirements of the Directive and it assumes authority for defining the technical specifications for donor selection and deferral, component manufacture, storage, transport and distribution, autologous transfusion and adverse event reporting.

Each member state is required to have a competent authority or authorities responsible for implementing the Directive. They are also required to enact appropriate national legislation to ensure that blood establishments and hospital blood banks conform to their respective requirements under the Directive. These measures must be in place by 8 February 2005.

Many of the provisions of the Directive are aimed at blood establishments, defined as any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. These establishments should be licensed by the competent authority. This does not include hospital blood banks. Apart from the obvious inclusion of national, regional and local transfusion services and their component parts, this definition also embraces such functions as external reference laboratories and contract transport companies.

In the Directive, the Hospital Blood Bank is defined as “a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital blood banks, including hospital-based transfusion activities”. The Articles mandate several important requirements for them. These are requirements for qualification and training of personnel, for a quality system based on the principles of good practice; for maintaining documentation, operational procedures, guidelines, training and reference manuals and reporting forms; for traceability of blood and blood components; for adverse event reporting; for storage, transport and distribution of blood at hospital level; and for data protection.

Facilities collecting blood and blood components for the sole purpose and exclusive use in autologous transfusion are only required to comply with Article 29 (g) – in essence with yet-to-be-defined technical specifications for autologous transfusion.
Haemovigilance
The Directive contains specific provisions in relation to traceability of blood and blood components, and for reporting serious adverse events attributed to transfusions. Article 14 requires that member states ensure that all components can be traced as far as the patient. For this to be achievable the Government must ensure that hospitals as well as blood services have the capability to track and record the final disposition of every unit of blood or blood components. They must also ensure that the records of such dispositions are kept for 30 years. Article 15 requires that all serious adverse reactions that may be attributed to the quality and safety of blood and blood components transfused are captured and reported to the competent authority. These provisions give haemovigilance a firm legislative basis within the EU, and remove discretionary elements currently present.

Technical Standards
For many people involved in the blood transfusion chain in Europe, from the clinicians who transfuse blood components to their patients, back to the personnel in the blood donor clinic, three Articles – 27, 28 and 29 – will have the most far reaching effects.

Essentially these three Articles enjoin and empower the Commission to determine the technical specifications for donor selection and testing, component manufacture, storage and transport, pre-deposit autologous transfusion and adverse event reporting. The Commission is required to keep these specifications up to date and to have available to it the best possible scientific advice.

From now on it is the EU, and not member states or their blood transfusion services who will decide minimum standards of donation testing, donor deferral criteria, residual leucocytes content in leucoreduced components, concentrations of platelets in a therapeutic dose, for how long records must be kept, and all other specifications that define the safety and quality of blood and blood components for transfusion.

It is now up to the Department of Health and Children to define implementation of the provisions of the Directive. While hospital blood banks do not have to be licensed, they do have to comply with the relevant provisions of the Directive, and the State is required to take whatever steps are necessary to ensure that they do.

Dr. William Murphy MD FRCPEdin FRCPath
National Medical Director
Irish Blood Transfusion Services
AN OVERVIEW: THE FIRST THREE YEARS OF THE NATIONAL HAEMOVIGILANCE SCHEME

The Findings: 2000-2002
The NHO scheme has been fully operational since October 1999, and has published annual reports for 2000 and 2001. This year represents the third full year of reporting and presents an opportunity to review the findings.

Approximately 500,000 units of blood components were issued during the three-year period 2000 – 2002 and a total of 384 adverse transfusion reactions/events were reported to the NHO. During 2000², the first full year of reporting, there were 85 incidents which fulfilled the criteria for a reportable event. In 2001³ the number had risen to 144 and the figure for 2002 indicates that the number continues to increase with 155 incidents fulfilling the criteria for a haemovigilance event. This rise in the number of reports received is probably due to several factors, which include the increasing numbers of TSOs now established in post, a heightened awareness of the scheme and an increased openness among hospital staff to report.

Similar to the Serious Hazards of Transfusion (SHOT) scheme⁴, a “Nil to Report Form” is circulated to every hospital at the end of the year. When completed this form indicates that either an incident has been reported to the NHO during the year or there has been no incident fitting the reporting criteria. The number of hospitals responding has risen from 51 in 2000 to 65 in 2001 and 79 in 2002. Included in the number of non-participating hospitals are those who transfuse infrequently and therefore have no designated TSO on site.

Figure 1: Incidents Reported 2000 – 2002 (N=384)
A national audit of blood usage showed that 96,000 units of red cells were transfused in Ireland during 2001\(^5\). Six hospitals, comprising 9% of the total number of the acute care hospitals in the country, transfused 51% of the total red cell units\(^5\). While 93% of hospitals participated in the scheme by returning a "Nil to Report Form" in 2002, 49% actually reported a transfusion reaction or incident. Because the scheme is anonymised, it has not been possible to formally compare reporting rates between hospitals and their blood usage. It is our impression however, that there are considerable differences between centres in reporting incidents. This may reflect the penetration of the ethos of haemovigilance within the individual hospitals.

**Incorrect Blood Component Transfused (IBCT)**

Our findings indicate that similar to other haemovigilance schemes which collect this data, the greatest number of reports were received in the category of IBCT, with 187 cases (49%) reported during the first three years. Included in this category are errors and omissions relating to blood products such as anti–D (28 reports received) and factor concentrates (7 reports received), as these also allow evaluation of the quality of systems in place for transfusion practice. Adverse reactions associated with these licensed products continue to be reported on to the medicines regulator, the IMB.

In 2001, in response to feedback, we divided the IBCT incidents into levels of severity\(^3\).

- **Level 1 incidents** are defined as those with the potential for permanent injury or life threatening. During 2001 and 2002, 75 (48%) of all IBCT incidents reported were stratified as level 1 incidents. Included in this group are blood and blood components intended for another patient, even if they were ABO and Rhesus (Rh) D compatible, Rh D positive components being administered to a Rh D negative patient in error, anti–D immunoglobulin or factor concentrates administered or omitted in error and inappropriate transfusions.

- **Level 2 incidents** were classified as unlikely to cause permanent harm. During 2001 and 2002 57 (37%) of all IBCT incidents reported fitted this group.

- **Level 3 incidents** pose no risk to patients but rather indicate defects in the quality of service delivered. There were 23 cases (15%) reported fitting this group during 2001 and 2002.

During the three year period 2000 - 2002, there were 13 reports received of wrong ABO group transfused, seven of which were ABO incompatible red cells. The total number of red cells issued for this period was 372,880. Therefore, the risk of receiving wrong ABO red cell transfusion is about 1:29,000 units issued and of receiving an ABO incompatible red cell transfusion is likely to be of the order of 1:53,000 units issued.
The findings for the first three years of reporting illustrate that whilst receiving a blood transfusion is relatively safe compared to other forms of therapy, there is a need to develop awareness at hospital level of issues concerning transfusion safety. Bedside administration failures were the site of first error in 24 (13%) incidents reported during the three years. As nurses are the last line of defence in providing safe effective care for their patient, the final bedside check provides an opportunity to detect and prevent preceding errors. Further analysis revealed that a total of 60% of incidents could have been detected and prevented during the final bedside check. The necessity for positive patient identification and the importance of using an identity (ID) band, which must be worn while taking the pre-transfusion sample and during the transfusion, was also illustrated. Sampling was found to be the site of first error in 13 (7%) cases. The introduction of validated automated solutions i.e. sample bar-coding, automated grouping and automated transmission of results to help exclude the possibility of human error as well as the provision of a transfusion education programme are also key recommendations.

Site of Collection Errors
During the three years 2000 – 2002, there were 11 cases where the first error was at site of collection. These resulted from the failure or absence of checking procedures at the time of collecting the component and the error proceeded unnoticed through the transfusion chain. Adequate checking systems must be in place at the site of collection of blood components/products from either the hospital transfusion laboratory or the satellite storage facility.
Wrong haematology values and inappropriate/unnecessary transfusions
In 16 (9%) cases transfusion was based on inaccurate or absent haematology results. 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. There were 13 (7%) inappropriate transfusions. Adherence to guidelines is important to avoid inappropriate use of blood components.

Errors relating to blood product administration
Over the three year period from 2000 – 2002 there were 35 reports received relating to errors in the administration of blood products, 28 (80%) of which involved the administration of anti-D. Each hospital should have clear policies on the prescription and administration of anti-D and the management of Rh D negative women during pregnancy.

Severe acute anaphylactoid / anaphylactic transfusion reactions (AA)
Severe acute anaphylactoid or anaphylactic transfusion reactions were the next largest category, with 88 incidents (23%) reported. Of these 47 (53%) were associated with platelets, the vast majority, 39 of 47 (83%), being associated with pooled platelet concentrates. Twenty-two cases involved the use of plasma, six of which were for warfarin reversal / over anticoagulation. This use of plasma was not in compliance with current guidelines. There were no fatalities recorded and in general the symptoms were not considered life threatening. In most cases the patients recovered from the reactions within a short time period without sequelae. Some of these transfusions, in particular the use of plasma for warfarin reversal, were considered to be inappropriate.

Acute haemolytic or other severe acute transfusion reaction (AHOSATR)
There were 34 incidents (9%) reported in this category. The transfusion of red cells was involved in 28 (82%) of these cases. None showed evidence of haemolysis due to red cell incompatibility or evidence of bacterial contamination. However, four of the seven incidents involving ABO incompatible red cell transfusions, which were reported in the IBCT category, were accompanied by symptoms of an acute transfusion reaction. This means that of 32 red cell transfusion reactions reported during this period where acute symptoms developed requiring investigation, four (12.5%) reactions were due to an ABO incompatibility. This finding confirms the need to fully investigate all severe reactions associated with the transfusion of red cells.

Transfusion associated circulatory overload (TACO)
Transfusion associated circulatory overload (TACO) was reported in 34 (9%) cases, of which nine (26%) were associated with the use of fresh frozen plasma (FFP). At least five of these nine (56%) were considered inappropriate and in one case the transfusion may have contributed to mortality. In light of these findings the NHO issued an information leaflet on the use of FFP to each hospital. This leaflet outlined the firm indications for the transfusion of FFP and highlighted the risks associated with its use. This has since been updated to reflect changes which followed the introduction of solvent detergent (SD) treated pooled plasma in March 2002 (See Appendix 1).

There were a total of 24 (71%) TACO incidents related to the transfusion of red cells. Of these, 20 cases (83%) involved patients aged 70 years or over. In elderly patients with or without underlying cardiac, respiratory or renal disease, there is an increased risk of volume overload. This finding highlights the importance of careful attention while transfusing this group of patients. 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 are recommended to minimise the risks. The use of prophylactic diuretics is also recommended.
Suspected Transfusion Transmitted Infection (TTI)
There were 12 cases (3%) of suspected transfusion transmitted infection (TTI) reported. Investigation confirmed one case of bacterial contamination involving a pooled unit of platelets from which coagulase negative staphylococcus was cultured from both the patient and the unit. The patient recovered without sequelae. The remaining 11 cases of possible viral transmission were investigated: five hepatitis C virus (HCV), four hepatitis B virus (HBV), one human immunodeficiency virus (HIV) and one case of co-infection with both HBV and HCV. Transfusion was excluded as the source of infection in nine of the 11 cases by re-testing of donors or the archived samples from the time of donation. In one case, one donor could not be traced and so HBV could not be excluded, although the patient had other risk factors. In the outstanding case of suspected HBV investigations are ongoing but the patient has other risk factors. This low incidence of confirmed TTI is in keeping with the estimated risk of transfusion transmitted viral infection which has been estimated at 1 in 4 million units transfused for HIV, 1 in 4 million units transfused for HCV and 1 in 200,000 units transfused for HBV. These residual risk estimates are based on serological testing and nucleic acid amplification testing (NAT) for HCV and HIV.

Delayed Haemolytic Transfusion Reaction (DHTR)
There were 12 (3%) reports received which were categorised as delayed haemolytic transfusion reactions (DHTR) during 2000-2002. 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 seven (58%) of the 12 cases the patients were aged over 70 years.

Transfusion Related Acute Lung Injury (TRALI)
Five cases (1%) suggestive of transfusion related acute lung injury (TRALI) were reported, one of which has been excluded and three confirmed to date. One outstanding case is still being investigated. The probable underreporting of TRALI has prompted the issue of an information leaflet from the NHO providing assistance in its recognition and differential diagnosis (See Appendix 2).

Post-transfusion purpura and Transfusion-associated graft-versus-host disease
There were no incidents reported in these categories during the first three years.

Pre-deposit Autologous Donor Incident (PAD)
In 2002 we began collecting reports relating to pre-deposit autologous donor (PAD) incidents. There were 8 (3%) incidents reported which fitted this category during 2001 and 2002. All patients were scheduled for elective orthopaedic surgery and none of the adverse events involved hospitalisation of the patient or rescheduling of surgery. Three of the eight incidents (38%) involved patients whose current medication included betablockers and/or angiotensin-converting enzyme (ACE) inhibitors. Particular caution must be exercised during the assessment and donation of these patients.

Increasing Participation
We are examining a number of strategies to improve the reporting rates, which include:

NHO Steering Group
As highlighted in the first SHOT report, transfusion is a complicated process involving the multidisciplinary team. While acknowledging the considerable help provided by the National Blood Users Group, a formal Haemovigilance Steering Committee composed of the major stakeholders involved in transfusion is needed. This strategic group could greatly assist in reviewing incident trends, promoting reporting and ensuring support at hospital level for practice improvement.
Near Miss Project
Studies of safety incidents in commercial aviation, petrochemical processing and nuclear power industries point out that “Near Miss” events are more prevalent, but very similar to those associated with full-blown disasters\textsuperscript{11}. Such events provide a valuable source of information on deficiencies within an existing system. It is recognised that for every transfusion of the wrong blood, many other incidents are prevented by careful checking procedures, despite an error being made at some point during the process\textsuperscript{11}. It is also documented that the safety of transfusion can be improved through identification of weak points within a system, incorporating data relating to both adverse and “Near Miss” events\textsuperscript{12}. As part of the haemovigilance reporting system in Ireland a “Near Miss” research project, commenced reporting in May 2003. Ten hospitals with differing blood usage have agreed to participate in this scheme. Investigating such “Near Miss” incidents using the Medical Event Reporting System for Transfusion Medicine (MERS-TM) allows a systematic analysis of events including root-cause analysis to be carried out\textsuperscript{13}. The project should provide invaluable insight in identifying both system and human failures within organisations and allow appropriate improvements to be put in place. The project should also raise awareness and levels of error detection and reporting in a “no fault” environment so that an open reporting culture will continue to be encouraged within our hospitals.

Conclusions
There has been considerable progress made in Ireland towards acceptance and participation in the national haemovigilance scheme. However more remains to be done both to encourage reporting and ensure the recommendations which have emerged are adopted by hospitals. The success of the scheme to date can be directly attributed to the work and enthusiasm of the TSOs supported by the transfusion medical scientists and consultant haematologists.

The in-depth analysis of individual incidents, coupled with the review of incidents showing common features, generates recommendations to improve transfusion practice. By drawing attention to a systems approach to eliminating error rather than by promoting a blame culture, the haemovigilance scheme has the capacity, if implemented appropriately, to improve overall patient safety which extends well beyond the transfusion process itself.
KEY RECOMMENDATIONS: 2002

Incorrect Blood Component Transfused - Recommendations

Positive Patient Identification

- Best transfusion practice should be an integral part of induction training and education programmes for all staff involved in prescribing, ordering and administering transfusions.

- Hospitals must have secure procedures to cover blood sampling and transfusion.

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

- The importance of positive patient identification at sampling is highlighted. The patient must have a secure ID band in place at the time of pre-transfusion sampling and administration. This ID band must contain three identifiers, full name, date of birth and a unique identification number.

- When collecting blood components/products prior to transfusion, adequate checking systems must be in place at the site of collection.

- In the absence of electronic forms of patient and blood component/product identification systems, two people must confirm verification of the identity, ABO and Rh D group of the patient and unit at the bedside. Where possible, the patient must be involved.

- Because of these requirements it is desirable where possible to only transfuse when adequate staff are on duty and to avoid night-time transfusions.

Transfusion/Hospital Records

- Although full medical records may not be available, it should be possible to access the previous medical record number (MRN) and generate a new MRN on a 24-hour basis.

- Previous transfusion records should be available at all times and checked. The transfusion records of patients who may have been transfused in another hospital should be confirmed with the original hospital, wherever possible.

Improving Communication

- Ideally all requests for components should be made in writing. In practice this can be difficult in the emergency setting and/or in a hospital where the transfusion laboratory is geographically remote or off site. Hospitals need to develop protocols for such eventualities, such as a verbal request followed by a confirmatory written request, perhaps through the use of a vacuum system where they are in place, or through the hospital intranet.

- An electronic ordering system for blood components would overcome this and should be developed similar to systems already available for blood test ordering.

- Systems and procedures need to be put in place to ensure that patients with special transfusion requirements e.g CMV negative and irradiated cellular components, receive the required components. This is particularly the case where care is shared between two centres.

- The importance of providing clinical details on transfusion request forms is highlighted.
Inappropriate Transfusions and Transfusions Based on Inaccurate/Absent Haematology Results - Recommendations

- All clinical staff involved in transfusion must be familiar with guidelines for use of components.

- The most recent Haemoglobin (Hb) result must be checked prior to prescribing and administering a transfusion. When transfusing more than one unit, regular monitoring of post transfusion Hb levels is strongly recommended, ideally on a unit by unit basis.

- The importance of taking blood samples, where possible, from an alternative limb to the one where fluids are infusing is highlighted. Where the sample must be taken from the same limb, stopping the infusion before taking the sample and choosing a vein distal to the infusion is recommended.

- The need for appropriate on-going education and training of medical and nursing staff in correct blood sampling techniques is emphasised.

- As recommended in the NHO Annual Report 2000\(^2\) and 2001\(^3\), errors in communication can be minimised by using automated transfer of laboratory information to allow access to current records. All clinical areas should have easy access to these systems and staff should be trained in their use so that transfusion decisions are based on the most up-to-date and correct results.

Laboratory Operations

- There is a need to review laboratory practices to highlight the importance of checking units against written and/or verbal request prior to issue.

- There should be a dedicated area in the laboratory for labelling products. At the time a unit is issued, there shall be a final check of transfusion service records and each unit of blood or component\(^15\). Only units for one patient should be labelled up at any one time. As with all laboratory tasks, interruptions should be kept to a minimum.

- Automated systems for labelling and checking would enhance the security of the process.

- As recommended in the NHO Annual Report 2001\(^3\), computer systems should be designed with audible alarms/alerts to minimise opportunities to override screen warnings. Preferably any such overrides should require a reason or explanation as this should lead to questioning the need to override. An audit trail of any overrides should also be kept.

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

- Hospital laboratories should have a standard operational procedure (SOP) or policy for acceptance and or rejection of incorrectly labelled samples. This policy should cover amendments, which are acceptable, and those, which require a further sample to be taken.

- In the event of a difficulty with the supply of ABO compatible platelets it may be necessary to administer ABO non-identical platelet transfusions. Group O platelets should only be issued for group A, B and AB patients if they have been tested and labelled as negative for high titre anti-A and anti-B. Group AB patients should receive group A or B platelets, as group AB are generally not available. See Appendix 3 for
recommendations on selection of platelets where ABO/Rh D identical platelets are not available.

- Hospitals need to have protocols to cover massive transfusions\textsuperscript{16}. These should include timeframes for the provision of crossmatched, group specific and uncrossmatched blood taking into account the specific physical location of the laboratory/blood fridges and clinical areas. If emergency uncrossmatched blood is needed, once the patient is stabilised, he/she should be returned to group specific or crossmatched blood to conserve blood supplies.

**Incorrect Blood Component Transfused: Anti-D - Recommendations**

- Each hospital should have clear policies on prescription and administration of anti-D and the management of Rh D negative women during pregnancy.

- Some hospitals monitor requirements and issue anti-D through the laboratory as they have access to both the mother and baby’s group and antibody records and the product can be issued and labelled on a named patient basis. This seems very appropriate and would reduce the risk of errors.

- Effective communication between clinical and laboratory staff relating to antibody screening and the issuing of anti-D, both in the antenatal and postnatal period is vital in preventing errors. This is particularly important where patients are receiving shared care between their General Practitioner (GP) and Obstetrician.

- Systems must be in place to ensure that there is easy access to current laboratory results, either in written or electronic format. Both the prescriber and the person administering anti-D should always check the most recent report of the patient’s Rh D and antibody screen to assess the need for the product prior to administration. Transcribed Rh D results must not be accepted; the original reports must always be consulted.

- All babies should be given an ID band and a unique MRN immediately post delivery. All baby’s samples should be processed using the baby’s own unique identifying details.

- Where cord blood samples are received for processing in the laboratory and group as Rh D positive, clinical or laboratory staff should not assume that the mother is Rh D negative. The mother’s Rh D status must be confirmed before anti-D is issued.

- The British Committee for Standards in Haematology (BCSH) guidelines state, that for successful immunoprophylaxis, anti-D should be given as soon as possible after the sensitising event, but always within 72 hours\textsuperscript{17}. However they also advise that if it is not given before 72 hours every effort should still be made to administer the anti-D because a dose given within 7-10 days may provide some protection.

- As all three of the laboratory errors occurred during the night, it may be prudent to process samples which lead to the issue of anti-D the following morning, when there is less risk of human error. However, this needs to be balanced against the fact that patients are now being discharged earlier following delivery so it is important that systems are in place to ensure that these patients are not missed.

- The BCSH guidelines recommend that all pregnant women should be re-tested once for group and antibody screen between 28–36 weeks gestation\textsuperscript{17}. 


Serious Adverse Reactions including Severe Acute Anaphylactoid/ Anaphylactic and Acute Haemolytic and other Severe Acute Transfusion Reactions - 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.\(^{14}\)

- Each hospital must have a policy in place for the management of an acute transfusion reaction, which should include the medical and nursing management of the patient’s symptoms and the investigations necessary to complete the transfusion reaction investigation.

- SD treated plasma or FFP should be used in accordance with guidelines and should only be used for rapid reversal of over-anticoagulation in patients with serious bleeding or before emergency surgery (See Appendix 1).

- Protocols for management of severe allergic/anaphylactoid transfusion reactions should be in place in each hospital (See Appendix 4).

- Prophylactic cover should be given if there is a history of previous allergic reactions to transfusions or a history of allergy.

- Where there is a previous history of anaphylaxis, the patient will require specialist haematology and immunology support, including washing of the component, if further transfusion is required.

- In the event of fever, both the patient and the transfused unit or units should be cultured to exclude bacterial contamination. Classical allergic or anaphylactoid reactions do not routinely require culture of the patient or component pack. However, where the symptoms are not classical, culture of patient and pack to exclude sepsis either from the component or the line should be undertaken. This is particularly important where platelets are involved, as they are stored at room temperature and have a greater risk of bacterial contamination.

Transfusion Associated Circulatory Overload - Recommendations

- The risk of TACO is increased with the very small, the elderly and the cardiac or respiratory compromised patient. Strategies to prevent TACO include individual assessment of each patient prior to transfusion and identification of those ‘at risk’. Transfusing slowly (1ml/kg of body weight/hour) to these patients with the use of diuretics may be necessary.

- All patients, but particularly the elderly and those at greater risk of TACO, must be individually assessed prior to the first unit and carefully observed during transfusion. They should be reassessed before starting a subsequent unit. Where possible, when transfusing elderly patients with more than one unit, it may be prudent to transfuse only one unit in each 24-hour period.

- Non urgent transfusions should be avoided at night. It is desirable where possible, to only transfuse when adequate staff are on duty.

- An estimation of the patient’s hydration status should be made prior to the transfusion of any blood component, especially those patients considered to be at increased risk of circulatory overload. Patients in positive fluid balance should be treated with a diuretic prior to commencing transfusion. The choice of route of administration, i.e. oral or
intravenous (IV) will depend on the degree of pre-existing congestive cardiac failure or overload.

- It may be prudent to transfuse at risk patients in the day care setting with no more than two units per day together with a prophylactic diuretic.

- Written information should be provided for day care patients receiving blood transfusion, outlining possible adverse transfusion reactions and providing a contact telephone number in the event that symptoms develop.

Delayed Haemolytic Transfusion Reactions - Recommendations

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

- Careful history taking in relation to transfusion and pregnancies by the requesting physician is important. However, up to 12% of patients do not realise that they have had a transfusion\(^18\), therefore access to and checking of previous transfusion records are essential.

- Use of three cell screening panels, sensitive antibody screening techniques and satisfactory participation in external quality assurance schemes such as the National External Quality Assurance Scheme (NEQAS), should minimise failures to detect weak antibodies.

- As antibodies can develop rapidly, patients being repeatedly transfused, depending on the interval between transfusions, should have a fresh sample submitted within 24-72 hours of a planned transfusion in accordance with BCSH Guidelines\(^19\).

- When investigating a DHTR a serum sample should be used for antibody detection as some antibodies, particularly weakly complement binding antibodies not detectable in plasma specimens may be detected in serum samples\(^20\).

Pre-deposit Autologous Donor (PAD) Incidents - Recommendations

- Careful pre-operative assessment of the elective surgical patient with detection and correction of underlying anaemia and reversal of sub-clinical iron deficiency with iron supplements may reduce the need for any transfusion\(^21\).

- Donor selection criteria for the autologous donor are not as rigid as for the allogeneic donors. As a consequence, such donors already compromised from underlying disease processes, may develop complications considered innocuous in healthy individuals which may be of greater significance in this donor population\(^22\). Care therefore is required during the pre-donation assessment to elicit any underlying problems. Hospitals should have specific criteria for donor acceptability.

- Particular caution must be exercised during the assessment and donation of patients taking betablockers. Volume replacement should be considered for patients on treatment with betablockers and/or ACE inhibitors as their ability to respond to a reduction in blood volume may be compromised by their treatment\(^23\).

- Promotion of PAD programmes should be carefully targeted to ensure that only patients who are likely to require transfusion are recruited. Regular audit of the usage of blood collected under PAD programmes should be performed.
• Autologous transfusion carries the same risk as allogeneic transfusion, i.e., transfusing the wrong component to the wrong patient. There is also the possibility of bacterial contamination, which although rare, has been reported as somewhat more common in autologous donors than in allogeneic donors.

• Systems must be in place to ensure that autologous blood is only transfused to the intended recipient.

**Transfusion-Related Acute Lung Injury - Recommendations**

• Any respiratory distress occurring during, or within six hours following, blood or blood component transfusion could potentially be TRALI. A chest x-ray should be performed as it may help to exclude or support the diagnosis. The differential diagnosis includes TACO, anaphylactic transfusion reaction, bacterial contamination of the transfused blood component and acute respiratory distress syndrome (ARDS).

• Where there is a case fitting the clinical picture of TRALI, the supplying blood centre should be notified of the unit numbers of the components transfused to facilitate the removal of any components from this donation which remain on the shelf and the temporary deferral of these donors, pending investigation.

• Adherence to the guidelines for the appropriate use of blood components containing significant amounts of plasma is important in helping reduce the incidence of this complication.
INCORRECT BLOOD COMPONENT TRANSFUSED: 2002

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. This category accounted for 56% of incidents reported (87 of 155).

Figure 1a - NHO Incidents (n= 155)

Figure 1b
Site of first error – IBCT Cases (87)

Supply Centre 12% (10)
Unclear 3% (3)
Prescription &/or Request 37% (32)
Hospital Transfusion Laboratory 26% (23)
Administration 9% (8)
Site of Collection 5% (4)
Sampling 8% (7)

IBCT
A/A
TACO
AHOSTR
PAD
TRALI
TTI
DHTR
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 sequelae. 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. Incidents 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.

There were 41 cases (47%) reported in this period classified as level 1 incidents.

**Level 2**
Incidents such as failure to give cytomegalovirus (CMV) antibody 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 leucodepletion 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 2002 there were 32 cases (37%) 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 recommend that any such breakdown should be investigated and corrected even if the recipient of the transfusion is unharmed.

During this reporting period, 13 cases (15%) fulfilled the criteria for level 3 incidents. One case was not stratified, as it was an illustrative incident rather than an error.

Some subjectivity is inherent in individual incident classifications and not everyone may agree with the classification in all cases. Comments and feedback would be most welcome.
IBCT Incidents Relating to Blood Components Transfused
For the purpose of this report the IBCT anti-D incidents will be presented in a separate section at the end of this chapter.

Findings and Recommendations:

- Six Level I incidents related to blood components of the wrong ABO or Rh D blood group being given.

- In three cases, (IBCT Cases 1-3) the wrong patient’s blood was sampled leading to blood of a different ABO group being given to the patient. In one of these cases, (IBCT Case 2) there was a transposition of the patient’s samples at phlebotomy. In IBCT Case 1 where failure to access previous transfusion records compounded the problem, the hospital involved has introduced a new internal medical record computer system.

- In one case (IBCT Case 5), a unit of red cells destined for another patient was collected in error and the patient received red cells of a different ABO and Rh D type.

- In another case (IBCT Case 6) an error in the entry of laboratory results together with a communication failure meant the patient received plasma of an incorrect Rh D type.

- In a further case (IBCT Case 4), the blood group of the unit was incorrectly assigned by the laboratory computer system to that of a blood component previously issued due to a software problem. This allowed the issue of platelets of the incorrect ABO group to a patient. Donation identity numbers are reused over a four-year cycle. This has become a problem with the introduction of computerisation where the previous transfusion records have not been archived. The IBTS is progressing with the implementation of introducing the Information Standard for Blood Transfusion (ISBT) 128, a 12 digit unique non-reusable number, which will give each unit a unique identifier. Some hospitals may require changes to their software systems to accommodate this.

- Fortunately the one case (IBCT Case 3) where an ABO incompatible component was transfused involved plasma. The four wrong ABO red cell transfusion cases (IBCT Cases 1, 2, 5 and 7) were by chance ABO compatible.

- Two cases involved the administration of the wrong factor concentrate product (IBCT Cases 72 and 73)

Positive patient Identification

- The importance of positive patient identification at sampling is highlighted.

- Hospitals must have secure procedures to cover blood sampling and transfusion

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

- A number of manual systems designed to reduce blood transfusion errors also exist. These blood recipient identification systems, such as Typenex®, consist of tamper-evident ID bands for identifying blood recipients and the corresponding units of crossmatched blood, thus minimising the potential for an incompatible transfusion. Such a system provides hospital staff with a consistent and permanent patient crossmatch request record and allows the patient, sample tube, paperwork and units to be transfused to be linked. Pre-printed prompts are offered on the sample tube label that help the user
to be more thorough. However, one incident (IBCT Case 1) shows that such systems cannot protect against all errors and correct procedures must be followed.

- Four Level 3 incidents (IBCT Cases 48, 52, 66 and 71) involving Typenex bands also show that the security afforded by the bands depends on correct adherence to guidelines provided and rigorous checking procedures being in place.

- The patient must have a secure ID band in place at the time of pre-transfusion sampling and administration. This ID band must contain three identifiers, full name, date of birth and a unique identification number.

- The National Blood Users Group recommend that patients who are unconscious or confused; patients undergoing general anaesthesia, young children or patients whose first language is not English, should have two ID bands applied, e.g. wrist and ankle bands.

- When collecting blood components/products prior to transfusion, adequate checking systems must be in place at the site of collection, as illustrated in IBCT Case 5.

- Two people must confirm verification of the identity, ABO and Rh D group of the patient and unit at the bedside. The patient must be involved where possible.

- Because of this requirement it is desirable where possible to only transfuse when adequate staff are on duty and to avoid nighttime transfusion. In one of the Level 2 cases (IBCT Case 46) the transfusion was commenced when only two nurses were on duty and as the ward was divided in two sections, the unit was checked in the nurse’s station which is common to both sections.

**Transfusion /Hospital Records**

- In one case (IBCT Case 1) the situation was exacerbated by the fact that previous medical records were not available.

- Although full medical records may not be available, it should be possible to access previous the MRN and give a new MRN on a 24-hour basis.

- Previous transfusion records should be available and checked at all times. The transfusion records of patients who may have been transfused in another hospital should be confirmed with the original hospital, wherever possible.

**Communication Failures**

- In one case (IBCT Case 6) failure of adequate communication between laboratory staff led to the issue of Rh D positive plasma for an Rh D negative male patient.

- In two cases (IBCT Cases 14 and 15) the wrong component was transfused where platelets were issued instead of plasma and vice versa.

- In two additional cases (IBCT Cases 38 and 41) the failure to supply CMV antibody negative and irradiated component arose because the verbal request was either not recorded or not made.

- In one case (IBCT Case 7), the wrong Rh D group was given in a complex clinical situation due to lack of communication.

- Ideally all requests for components should be made in writing. In practice this can be difficult in the emergency setting and/or in a hospital where the transfusion laboratory is
geographically remote or off site. Hospitals need to develop protocols for such eventualities, such as a verbal request followed by a confirmatory written request, perhaps through the use of a vacuum system where they are in place, or through the hospital intranet.

- An electronic ordering system for blood components would overcome this and should be developed similar to systems already available for blood test ordering.

**Transfusion based on inaccurate/absent haematology results**
- There were six reported cases (IBCT Cases 17-22) where transfusion was based on old and/or inaccurate haematology results. One of these cases (IBCT Case 20) was stratified as level 2, the remaining as level 1.

**Findings:**
- Three cases (IBCT Cases 17-19) related to blood samples being taken from veins where IV fluids were infusing.
- In two cases (IBCT Cases 21 and 22), transfusions were prescribed based on ‘old’ Hb results taken some time earlier.
- In one further case (IBCT Case 20), a high Hb result was recorded post transfusion, suggesting that the low Hb result recorded pre-transfusion may have been incorrect.

**Recommendations:**
- The need for appropriate on-going education and training of medical and nursing staff in correct blood sampling techniques is emphasised.
- These cases highlight the importance of, where possible, taking blood samples from an alternative limb to the one where fluids are infusing, or where the sample must be taken from the same limb, stopping the infusion before taking the sample and choosing a vein distal to the infusion.
- As recommended in the NHO Annual Report 2000\(^2\) and 2001\(^3\), 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.
- Wherever practicable checking of Hb levels on a unit-by-unit basis should be carried out.

**Inappropriate Transfusions**
Ten transfusions were reported as inappropriate and raised a number of important education issues. Three of the incidents involved red cells, four plasma and three platelet transfusions.

**Red Cells**
Three cases involved red cells. One case (IBCT Case 25) illustrates the transfusion of an inappropriately large number of red cell units to an elderly female patient without checking post transfusion Hb levels, leading to polycythemia which may have contributed to morbidity.

**Plasma**
Two cases (IBCT Cases 29 and 30) highlight the inappropriate use of plasma for reversal of anticoagulant therapy.

In two other cases (IBCT Cases 31 and 32) plasma was transfused without any documented indication. In both cases coagulation studies were within normal range.
**Platelets**
Platelet concentrates are now issued as pools rather than individual units or as an apheresis unit from a single donor. Both are equivalent to a single adult dose. In two cases (IBCT Cases 27 and 28) inappropriately large numbers of platelets were given in error because of this misunderstanding. In addition, in both of these cases, the transfusion was inappropriate. The platelet count was spuriously low because of clumping in one case (IBCT Case 28) and in the other case (IBCT Case 27) the patient had idiopathic thrombocytopaenic purpura (ITP). In the third case (IBCT Case 26), the transfusion did not meet guidelines.

**Failure to prescribe and request**
In five of twelve cases where special requirements were not met there was a failure to prescribe or request suitable components (IBCT Cases 35, 36, 37, 39 and 41).

**Recommendations:**
- All clinical staff involved in transfusion must be familiar with guidelines for use of components. When transfusing more than one unit, regular monitoring of post transfusion Hb levels is strongly recommended ideally on a unit by unit basis.

- The number of cases reported in this category re-emphasises the need for ongoing education and training of staff involved in prescribing, ordering and administering transfusions. Best transfusion practice should also be an integral part of all induction training and education programmes for new staff.

- Systems and procedures need to be put in place to ensure that patients with special transfusion requirements e.g CMV negative and irradiated cellular components, receive the required components. This is particularly the case where care is shared between two centres.

**Laboratory Related Incidents**
The hospital transfusion laboratory was the site of first error in 23 (26%) incidents. Eight of these were level one incidents. In one case (IBCT Case 6) as previously mentioned, a transcription error when entering laboratory results onto the computer system together with a communication failure meant the patient received plasma of an incorrect Rh D type.

**Wrong blood given through transposition of units**
One case (IBCT Case 45) involved a transposition of units where the red cells crossmatched for one patient were labelled for another patient as a result of being processed and issued at the same time. Fortunately the group of both patients was the same.

**Antigen negative blood not selected**
In one case (IBCT Case 16), antigen negative units were not selected for a patient with a history of alloantibodies.

**Special requirements not met**
Eight of the twelve cases where special requirements were not met involved the laboratory. Five cases involved the hospital laboratory (IBCT Cases 38, 40, 41, 42 and 43), and three the supply centre (IBCT Cases 33, 34 and 44). A computer warning was overridden in the laboratory in two cases (IBCT Cases 38 and 41) and went unnoticed in another (IBCT Case 40). In two of the cases (IBCT Cases 42 and 43) although the mistake was detected there was a failure to withdraw incorrect products which had been issued earlier from the hospital laboratory.
Incorrect Factor Concentrate administered
In one case (IBCT Case 72) the incorrect product was requested by the clinical team but the laboratory computer warning was also overridden.

Storage of blood components
The storage of blood suitable for issue in the same fridge as blood unsuitable for issue is not recommended practice. In one case (IBCT Case 48) a patient was transfused with a unit of red cells, which was for disposal, as it was incorrectly placed on the issue shelf of the fridge.

Unit transfused outside expiry date/delayed transfusions
The American Association of Blood Banks (AABB) recommends that transfusion should be completed prior to component expiration. In two cases (IBCT Cases 61 and 62), units which were issued close to expiry, were in fact not transfused until some hours after expiry. Laboratories should endeavour 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.

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 service records and each unit of blood or component. Only units for one patient should be labelled up at any one time. As with all laboratory tasks, interruptions should be kept to a minimum.

• There is a need to review laboratory practices to highlight the importance of checking units against written and/or verbal request prior to issue.

• Automated systems for labelling and checking would enhance the security of the process.

• Three cases in this report (IBCT Cases 38, 41 and 72) relate to failures to heed computer warnings. As recommended in the NHO Annual Report 2001, computer systems should be designed with audible alarms/alerts to minimise opportunities to override screen warnings. Preferably any such overrides should require a reason or explanation as this should lead to questioning the need to override. An audit trail of any overrides should also be kept.

• Once a clinically significant red cell antibody has been detected in the past, the patient should in future 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.
## Incorrect ABO and Rh D Group Transfused: Table 1 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 1*</td>
<td>89 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Three units of red cells</td>
<td>No symptoms</td>
<td>Pre-transfusion sample taken from wrong patient. Unique MRN not available outside normal working hours. Emergency Typenex band used instead, historical records not checked. Error detected when further transfusion prescribed. Repeat pre-transfusion testing performed. Historical records checked and patient found to be group A Rh D positive.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 2*</td>
<td>71 yrs</td>
<td>F</td>
<td>Group AB Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Three units of red cells</td>
<td>No symptoms</td>
<td>Remote labelling of the sample and failure to positively identify the patient resulted in the pre-transfusion sample being taken from the wrong patient.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 3*</td>
<td>70 yrs</td>
<td>M</td>
<td>Group O Rh D negative</td>
<td>Group B Octaplas</td>
<td>Six units of SD plasma</td>
<td>No symptoms, No sequelae</td>
<td>Patient had been grouped as B Rh D positive five months earlier. Six units of group B Octaplas transfused based on the incorrect historical group. Error discovered when further pre-transfusion testing confirmed patient as group O Rh D negative.</td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
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<td>1</td>
<td>IBCT Case 5*</td>
<td>55 yrs</td>
<td>F</td>
<td>Group A Rh D negative</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms, No sequelae. Patient died of underlying disease unrelated to transfusion.</td>
<td>Incorrect units collected from blood bank fridge. Positive patient identification not confirmed. Error detected by nursing staff during the pre-transfusion checking procedure of the second unit.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 6*</td>
<td>70 yrs</td>
<td>M</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D positive</td>
<td>Two units of FFP.</td>
<td>No symptoms, No sequelae.</td>
<td>Two units of group O Rh D positive FFP thawed, in error, for group O Rh D negative patient. Error noted prior to issue, and units left aside for use if required for another patient. Correct units thawed and issued. When further FFP was required for this patient, it was assumed that O Rh D negative FFP was out of stock and previously thawed Rh D positive units were issued. Discrepancy identified during bedside check but clinical staff also assumed there was a supply problem and proceeded with the transfusion.</td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
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<tr>
<td>1</td>
<td>IBCT Case 4*</td>
<td>18 yrs</td>
<td>F</td>
<td>Group B Rh D positive</td>
<td>Group B Rh D positive</td>
<td>One unit of apheresis platelet concentrate</td>
<td>No symptoms</td>
<td>The patient’s group was B and the component was group B. This unit was scanned into the hospital computer system as group O. All subsequent electronic and paper reference identified this unit as group O and as the transfusion was group compatible the computer system allowed the unit to be issued.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 7*</td>
<td>31 yrs</td>
<td>F</td>
<td>Group A Rh D negative</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms</td>
<td>Patient post bone marrow transplant, blood group A Rh D negative received one unit of group O Rh D positive red cells instead of group O Rh D negative. Transfusion protocol for this patient was not available in intensive therapy unit (ITU). Senior laboratory staff discovered the error during routine checking of patient’s haematology/oncology notes.</td>
</tr>
</tbody>
</table>
Incorrect ABO and Rh D Group Transfused
There were six level one incidents where the patient received blood components of the wrong ABO or Rh D group; these cases are described in detail.

Sample Errors
Level 1 IBCT Case 1
This elderly female patient, with underlying cardiac disease, presented to the Accident and Emergency (A&E) Department with a gastrointestinal (GI) bleed, breathlessness and tachycardia - Hb 7.1g/dl. The hospital administration system does not allow issue of a unique MRN outside of normal working hours, so the patient received an emergency Typenex band for identification purposes, as is hospital policy. This band contained the patient's full name, date of birth and unique Typenex number, but no hospital number. Although it was known that this patient had been previously transfused at this hospital, the hospital laboratory policy stated that historical records are not checked when a Typenex number is used for crossmatch purposes. Three units of group O Rh D positive red cells were crossmatched, labelled and issued based on the blood group of the sample submitted. The three units were transfused over the following three days, one unit per day. Following transfusion of the third unit, a further transfusion was prescribed and a repeat pre-transfusion sample was required. On this occasion, a Typenex number was not required as the unique MRN was by now available. The sample was taken and labelled using the patient's full name, date of birth and unique MRN, and so on this occasion, historical records were checked. This time the patient was found to be group A Rh D positive. A repeat sample was requested which confirmed this. Historical records were also checked and the patient was found to have been group A Rh D positive previously. As the transfused red cells were group O Rh D positive, there were no complications to this incorrect transfusion. Following investigation it was revealed that hand-written details from another A&E patient were underneath the Typenex label on the original pre-transfusion sample tube.

This case illustrates a series of errors:
Error 1  The wrong pre-transfusion sample was labelled with the patient's details.
Error 2  Historical transfusion records were not checked at the time of crossmatching, although these could have been accessed, as the correct full name and date of birth were available.
Error 3  Three units were transfused over three days, by which time the MRN was available to allow transfusion records to be checked.
Error 4  Failure of the hospital administration system to allow access to hospital records outside normal working hours.

The hospital has acted as a consequence of this event and is in the process of introducing a new patient administration system (PAS), which is an internal medical record computer system. This system will replace the existing Typenex system so that all medical records can be accessed. Old charts will also be updated.
Level 1 IBCT Case 2
This elderly female patient was crossmatched for three units of red cells pre-operatively. She grouped as O Rh D positive, antibody screen negative. She was a new patient to this hospital and so there was no historical record. Three units of group O Rh D positive red cells were issued and transfused intra-operatively, with no associated problems. Two days later, a further transfusion was necessary for post-operative anaemia - Hb 6.9 g/dl. This time the pre-transfusion sample grouped as AB Rh D positive, antibody screen negative. A repeat sample confirmed that this patient was, in fact, group AB Rh D positive. Investigation revealed that there had been transposition of samples during phlebotomy. While positive patient identification was confirmed verbally, the sample tube was labelled remote from the bedside and the ID band was not checked.

Level 1 IBCT Case 3
This elderly male patient with disseminated malignancy was given a transfusion of six units of SD treated plasma to reverse over anticoagulation prior to an elective surgical procedure. Five months earlier the patient had been grouped as B Rh D positive. Six units of group B Octaplas were therefore issued and transfused uneventfully. Three days later when a repeat group and crossmatch was requested, the patient grouped as O Rh D negative. When the medical scientist tried to enter this information onto the computer it was discovered that the blood group on record was different. As it was five months later it was not possible to determine how the original error occurred. As the INR was 1.7 and the procedure was elective, this transfusion was deemed to be inappropriate.

Collection Errors
Level 1 IBCT Case 5
This middle-aged female patient, group A Rh D negative, required an emergency transfusion in the A&E Department following a massive haemorrhage. Four units of group O Rh D negative emergency uncrossmatched red cells were transfused and a further six crossmatched units requested. The pre-transfusion blood sample was taken from the correct patient. She was not wearing an ID band although she was unconscious and unable to identify herself. The sample details were taken from her medical records and correct in all respects. Three units of group O Rh D positive red cells which were crossmatched, labelled and issued for a different patient were collected in error from the blood bank refrigerator for this patient, without formal checking. The first of these units was checked by two people and administered while the patient was being intubated. The patient was then transferred to the operating theatre, with this unit in progress and accompanied by the remaining two units. The error was discovered when checking the second unit prior to transfusion in the operating theatre. The patient subsequently died from her underlying illness, not related to the transfusion. As a result of this incident, the hospital is putting in place written procedures for blood component collection and in addition, a specific member of the nursing team will be designated to co-ordinate blood management in each massive transfusion episode in the A&E Department.

Laboratory Errors
Level 1 IBCT Case 6
This elderly male patient who was on anticoagulants - INR of 9.8 - was admitted with a suspected intra-cranial bleed and was prescribed two units of FFP. The patient grouped as O Rh D negative but this result was incorrectly recorded as group O Rh D positive on the laboratory records and two units of group O Rh D positive FFP were thawed for use. The medical scientist noted this error prior to issue and two further units of group O Rh D negative FFP were thawed issued and transfused. The medical scientist, who was due to go off duty, removed the issue labels from the two group O Rh D positive thawed units of FFP and left them available on the bench in case they
may be needed later for a different patient. The report form, which contained details of both the patient and the units, was not discarded. Neither was an explanation for the two thawed units given to the on-call staff. Later that evening a request for two further units of FFP was made for the same patient. The on-call medical scientist assumed that group O Rh D negative FFP was low in stock and proceeded to issue the two previously thawed units of group O Rh D positive FFP left on the bench beside the report form. During the bedside checking procedure the nurses noticed the Rh D incompatibility of the plasma but understood this to be appropriate, as previously when supplies were low, Rh D positive FFP had been transfused to Rh D negative patients. The error was identified the following day when laboratory on-call work was checked.

Unit blood group incorrectly interpreted by computer system
Donation identity numbers are reused over a four-year cycle and this has become a problem with the introduction of computerisation. The IBTS is examining the implementation of ISBT 128, a 12 digit unique non-reusable number, which will give units a unique identifier. Some hospitals may require changes to their software systems to accommodate this.

Level 1 IBCT Case 4
This patient with a malignant haematological disorder required a transfusion of CMV negative and irradiated apheresed platelets. The patient's blood group was B, and the component was group B. However this unit had been scanned into the hospital computer system on receipt as a group O. This happened because the donation ID numbers used by the IBTS are re-used every four to five years. This unit number had been issued some years previously from the IBTS as a group O unit. The hospital still had records from the previous cycle on the computer system, which had not been archived due to a software problem and the blood group of the unit was not manually checked when scanned into hospital stock. All subsequent electronic and paper reference identified this unit as group O and as the transfusion was group compatible the computer system allowed the unit to be issued. The error was not detected prior to collection or at administration. During laboratory processing of the second unit, the group discrepancy was discovered. The patient suffered no sequelae as a result of this incident but it has emphasised the need to ensure that archiving of old unit numbers occurs.

Level 2
Failure of Communication
Level 2 IBCT Case 7
This young female patient who was Rh D negative post allogenic bone marrow transplant from an Rh D positive donor, required a transfusion of one unit of red cells for anaemia. Following transplant a transfusion protocol was issued for this patient, which stated both the bone marrow donor’s and the recipient’s group/Rh D status. It also included clear instructions to transfuse with group O Rh D negative red cells and, if required, Rh D negative platelets/plasma, until ABO antibody to donor type red cells were no longer detectable and donor red cells had engrafted. This protocol was disseminated widely among relevant clinical staff including staff of the transfusion laboratory. On this occasion one unit of red cells was requested during the night. A medical scientist, who does not regularly work in the transfusion laboratory, carried out the crossmatching and issuing procedure. The patient was being cared for in the ITU at this time and not in the Haematology/Oncology unit where staff would be more aware of specific transfusion needs in the peri-transplant period. The transfusion protocol was not included in the patient’s notes. One unit of group O Rh D positive red cells was issued and transfused instead of group O Rh D negative red cells. A senior medical scientist discovered the error during routine weekly checking of haematology/oncology patient’s laboratory computer records. The patient suffered no complications to this transfusion.
**Weak D not detected on Donor Units**

When testing donors for Rh D status it is important to ensure that Rh D positive donors are not incorrectly typed as Rh D negative, as transfusion of such blood can give rise to sensitisation in a Rh D negative recipient.

Most donors can be readily classified by current automated technology as Rh D positive or Rh D negative and as results are electronically transmitted, errors in blood grouping of donors are very rare.

However there is a category of individuals who have very weak expression of the Rh D antigen on their red cells, so called ‘weak’ D, which is often difficult to detect as detection may vary with the reagents used. It is important for the IBTS to be able to identify such weak D individuals and classify the donor as Rh D positive to avoid the risk that it could be given to a Rh D negative patient who could become sensitised. This risk is in practice small because of the weak expression of Rh D\(^26\). These donors are becoming easier to identify with the use of new testing reagents and technology which can help distinguish these weak Rh D donors from Rh D negative donors, however testing problems can still arise.

Five **Level 2** incidents (IBCT Cases 8, 9, 10, 12 and 13) involving three donations incorrectly identified at the supply centre as Rh D negative occurred. These incidents involved the transfusion of five components. In all three cases, semi automated grouping technology was not sufficiently sensitive to detect weak Rhesus D positive donations. In one case an additional manual test was not undertaken, in the second the additional manual test was negative and in the third the historical record which previously identified weak D was not available on the donor database. Procedural changes put in place during 2002 a result of these incidents included, additional manual testing, use of gel methodology and review of manual historical files for previous grouping results. An upgrade to fully automated technology is also currently being addressed.

In one of the cases (IBCT Case 9), a pooled platelet concentrate was issued to a Rh D negative women of childbearing potential. The level of red cell contamination in platelets is very small and there has been no evidence of sensitisation on follow-up of the recipient.
### Weak D not detected on Donor Units: Table 2

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Gender of patient</th>
<th>ABO and Rh D Group of IBCT</th>
<th>Component Transfused</th>
<th>Implications / Sequelae</th>
<th>Cause of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>IBCT Case 8</td>
<td>F post menopausal</td>
<td>Group O Rh weak D positive component issued as Group O Rh D negative.</td>
<td>Red cells</td>
<td>Tested negative for antibodies at five months.</td>
<td>Failure of semi automated grouping technology to detect weak D reaction. Manual test for weak D tested negative.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 9</td>
<td>F childbearing potential</td>
<td>Group O Rh weak D positive component in a platelet pool, incorrectly grouped as Rh D negative and was in fact Rh weak D positive.</td>
<td>Platelets</td>
<td>Tested negative for antibodies at five months.</td>
<td>Failure of semi automated grouping technology to detect weak D reaction. Manual test for weak D tested negative.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 10</td>
<td>M</td>
<td>Group O Rh weak D positive component issued as Group O Rh D negative.</td>
<td>Red cells</td>
<td>Minimal sensitisation potential</td>
<td>Failure of semi automated grouping technology to detect weak D reaction. Historical record for identifying weak D not available on IT system (held on manual system as pre dated record transferred to IT system).</td>
</tr>
<tr>
<td></td>
<td>IBCT Case 11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IBCT Case 11 excluded - Haemovigilance number assigned in error.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 12</td>
<td>M</td>
<td>Group O Rh weak D positive component issued as Group O Rh D negative.</td>
<td>Red cells</td>
<td>Minimal sensitisation potential.</td>
<td>Failure of semi automated grouping technology to detect weak D reaction. Weak D test not performed.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 13</td>
<td>F post menopausal</td>
<td>Group O Rh weak D positive component in a platelet pool, incorrectly grouped as Rh D negative and was in fact Rh weak D positive.</td>
<td>Platelets</td>
<td>No evidence of sensitisation on testing.</td>
<td>Failure of semi automated grouping technology to detect weak D reaction. Weak D test not performed.</td>
</tr>
</tbody>
</table>
## Wrong Component Transfused: Table 3 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 14*</td>
<td>80 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Two units of platelet concentrate pooled</td>
<td>No symptoms</td>
<td>No sequelae.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 15*</td>
<td>70 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O SD treated Plasma</td>
<td>Four units of SD treated Plasma</td>
<td>No symptoms</td>
<td>No sequelae.</td>
</tr>
</tbody>
</table>
Wrong Component Transfused
This section covers two cases (IBCT Cases 14 and 15) where the wrong component was transfused. Both cases occurred due to verbal communication failures.

Level 1 IBCT Case 14
This elderly male patient on oral anticoagulant therapy – INR 2.56 - presented to the A&E Department with a large cerebral haemorrhage and was prescribed an urgent transfusion of two units of SD treated plasma. The written prescription stated plasma. However a verbal order to the laboratory by a different member of the medical team stated two pools of platelets. There was no written request to the laboratory. This same incorrect verbal order was also given to the nursing staff. Two pools of platelet concentrate were issued and delivered to the clinical area. Two staff nurses checked the two units of platelets at the bedside but did not check the prescription in accordance with hospital policy so the error was unnoticed and the transfusion proceeded. Platelet concentrates do in fact contain plasma but the SD treated plasma prescription was never filled. There was no post transfusion INR performed. The TSO discovered the error during routine surveillance.

Level 1 IBCT Case 15
This elderly patient with a malignant haematological disorder was to receive one adult dose of platelets for thrombocytopenia - platelet count 15x10^9/L. The verbal request was made to the laboratory for platelets but the following errors occurred:

- Due to a reliance on verbal channels of communication, no prescription was written, nor was a record of the intention to transfuse made in the patient’s medical notes. Later that evening the on-call intern was asked to prescribe “one pool of platelets” and this was duly recorded on the blood transfusion prescription record.
- The entry in patient’s medical notes read “for one pool/unit of FFP”.
- The verbal request to the laboratory was recorded as “four units of FFP”.
- The name of the person making the request was not recorded, as is normal practice. Four units of SD treated plasma were thawed and issued.
- The note in the medical record, not the transfusion prescription, was used as the prescription when transfusing the units.

The laboratory staff contacted the clinical staff to advise that one unit of pooled platelet concentrate was also available for this patient. This unit was also transfused using the blood transfusion record as the prescription. The error was discovered the following day when the primary care team noted and questioned the transfusion of SD treated plasma.
Antigen negative blood not selected: Table 4 * Included as a full case history

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 16*</td>
<td>75 yrs</td>
<td>F</td>
<td>Group B Rh D positive. Was anti-C positive in the past but no longer detectable</td>
<td>Group B Rh D positive. Antigen negative blood not selected</td>
<td>Three units of red cells not antigen typed</td>
<td>No symptoms No sequelae</td>
<td>Non-antigen typed red cells issued in error by on-call medical scientist not regularly working in the transfusion laboratory. Error discovered the following morning during a routine check of on-call work.</td>
</tr>
</tbody>
</table>
Antigen negative blood not selected
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.

Level 1 IBCT Case 16
This elderly female patient presented with anaemia secondary to GI bleeding - Hb 5.0 g/dl - and required a transfusion of three units of red cells. A medical scientist, who does not normally work in the hospital transfusion laboratory, processed the pre-transfusion sample outside normal working hours. This was reported as group B Rh D positive, antibody screen negative. When checked, historical records indicated that the patient had an anti-C antibody which had not been detected since 1997. Laboratory guidelines were not adhered to and four units of standard red cells, not antigen typed, were crossmatched and issued. Three of these units were transfused uneventfully during the night, before the error was discovered when checking on-call work the next day. The fourth unit was then returned to the hospital transfusion laboratory. The medical scientist had assumed that since the antibody was no longer detectable it was not necessary to select antigen negative blood. There was no evidence of delayed haemolysis and the patient suffered no sequelae as a result of this incorrect transfusion.
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Case</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 IBCT Case 17*</td>
<td>Case 17*</td>
<td>84 yrs</td>
<td>F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>Four units of red cells</td>
<td>Patient, who was already very ill, died from underlying condition two days later.</td>
<td>The sample was taken from a vein where IV fluids were infusing rapidly, resulting in a haemodiluted sample and a spuriously low Hb result. Emergency group O Rh D negative red cells were transfused unnecessarily.</td>
<td></td>
</tr>
<tr>
<td>1 IBCT Case 18*</td>
<td>Case 18*</td>
<td>78 yrs</td>
<td>M</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Two units of red cells</td>
<td>No symptoms No sequelae</td>
<td>The sample was taken from a vein proximal to the vein where an IV fluids were infusing, resulting in a haemodiluted sample and a spuriously low Hb result. This led to an unnecessary transfusion.</td>
<td></td>
</tr>
<tr>
<td>1 IBCT Case 19*</td>
<td>Case 19*</td>
<td>88 yrs</td>
<td>M</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Unnecessary transfusion based on haemodiluted pre-transfusion sample.</td>
<td></td>
</tr>
<tr>
<td>2 IBCT Case 20</td>
<td>Case 20</td>
<td>83 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Transfusion possibly based on incorrect Hb result.</td>
<td></td>
</tr>
<tr>
<td>1 IBCT Case 21*</td>
<td>Case 21*</td>
<td>84 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Unnecessary transfusion based on old Hb result. The more recent result was 11.1g/dl. Error discovered by TSO during routine audit.</td>
<td></td>
</tr>
<tr>
<td>1 IBCT Case 22*</td>
<td>Case 22*</td>
<td>68 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Three units of red cells</td>
<td>Became wheezy &amp; breathless during transfusion. Required diuretic and chest x-ray. Hospitalised for extra 24 hrs.</td>
<td>Three units of red cells transfused based on Hb result taken one month earlier by GP. Current Hb result 10.1 g/dl.</td>
<td></td>
</tr>
</tbody>
</table>
Transfusion based on inaccurate/absent haematology results
This year, there were six reported cases all involving red cells where transfusion was based on inaccurate or old haematology results.

Findings:
- Three cases (IBCT Cases 17, 18 and 19) related to blood samples being taken from veins where IV fluids were infusing.
- In two cases (IBCT Cases 21 and 22), transfusions were prescribed based on ‘old’ Hb results taken some time earlier.
- In one further case (IBCT Case 20), a high Hb result was recorded post transfusion, suggesting that one low Hb result recorded pre-transfusion may have been incorrect.

Recommendations:
- These cases highlight the importance of, where possible, taking blood samples from an alternative limb to the one where fluids are infusing, or where the sample must be taken from the same limb, stopping the infusion before taking the sample and choosing a vein distal to the infusion.
- The need for appropriate on-going education and training of non-consultant medical and nursing staff in correct blood sampling techniques is also emphasised.
- The most recent Hb result must be checked prior to prescribing and administering a transfusion.
- The NHO recommends that, where practicable, Hb levels should be checked after each unit.

We report five cases in detail.

Haemodiluted samples
Level 1 IBCT Case 17
This elderly female patient with chronic renal impairment, hypertension and non-insulin dependant diabetes mellitus was transfused with four units of emergency group O Rh D negative red cells – apparent Hb 2.5 g/dl and deteriorating clinical condition. The blood sample was taken from a vein where IV fluids were infusing rapidly. The Hb was 9.7 g/dl six hours previously and, when rechecked post transfusion, was 11.0g/dl. The error was identified when it was noticed that the electrolyte results were also very abnormal, by which time four units had transfused.

Level 1 IBCT Case 18
This elderly patient presented to the A&E Department following a road traffic accident (RTA) with multiple fractures. The Hb fell from 13.5 g/dl to 7.6 g/dl over a five-hour period. Three units of red cells were prescribed. Following administration of two units a repeat Hb was checked and found to be 11.4 g/dl. Investigation revealed that the Hb sample had been taken from a vein proximal to the IV site through which four litres of a crystalloid solution had been infusing and was therefore considered to be haemodiluted.
Level 1 IBCT Case 19
This elderly male patient had a history of pulmonary embolus and was on warfarin - INR 8.04. The Hb was reported to be 5.7 g/dl. This result was considered with suspicion as all other parameters were abnormal, there were no obvious signs of bleeding and there was an IV infusion in progress although it is unknown from which vein the sample was taken. A repeat Hb was requested and sent to the laboratory without delay. However three units of red cells were prescribed and issued pending the results. The first unit was transfused before the repeat result was available. The repeat Hb was 10.8g/dl indicating that the first sample was haemodiluted. The repeat result was telephoned to the clinical area and the remaining two units were returned to the laboratory.

Level 1 IBCT Case 21
This elderly patient with a malignancy was being assessed by the anaesthetist re suitability for surgery. On reviewing the medical notes, the anaesthetist took a Hb result of 9.5 g/dl, which had been reported three months earlier, to be the most recent result and prescribed one unit of red cells “in view of the patient’s age”. This patient had a more recent Hb taken two days earlier, which was also filed in the medical notes but was not seen by the anaesthetist. This more recent Hb result was 11.1 g/dl. The patient received an unnecessary transfusion of one unit of red cells. The error was discovered during routine TSO audit.

Level 1 IBCT Case 22
This patient, with underlying severe restrictive lung disease and a bone marrow disorder, was referred to the Out-Patient Department (OPD) for assessment by her GP. The GP had checked the FBC one month previously and found the Hb to be 9.5g/dl. The admitting doctor prescribed and requested three units of red cells on this Hb result. The Hb was repeated on admission when taking the pre-transfusion sample. Three units of red cells were crossmatched, issued and transfused over four to six hours each before the result of the Hb was reported to the clinical staff. The admission Hb was actually 10.1 g/dl. Following three units of red cells the post transfusion Hb was 12.1 g/dl. The medical staff discovered the error during a review of the notes prior to discharge. The patient became wheezy and dyspnoeic during the third unit. She remained normotensive, oxygen saturation (pO₂) was maintained at 95% on room air and there was no associated fever. Oral frusemide 40mgs was given and the transfusion was completed. The intake and output chart was not recorded so it is not known what diuresis, if any, followed. The patient remained in hospital for an additional day and a chest x-ray was performed the following morning. The chest x-ray findings excluded TRALI. Because of the severe underlying lung disease it is difficult to say if the symptoms were transfusion related or as a result of the existing disease, however Transfusion Associated Circulatory Overload cannot be excluded.
### Inappropriate/Unnecessary Transfusions: Table 6 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 23*</td>
<td>26 yrs</td>
<td>M</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One unit of red cells</td>
<td>No symptoms</td>
<td>No sequelae</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 25*</td>
<td>84 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Eight units of red cells</td>
<td>Deteriorating renal function (urea raised to 15 mmols/L) and peripheral oedema (not present pre-transfusion). Patient died five days later.</td>
<td>Patient over-transfused. No Hb monitoring between units during transfusion. Post transfusion Hb 17.9 g/dl.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 24*</td>
<td>80 yrs</td>
<td>M</td>
<td>Group B Rh D positive</td>
<td>Group B Rh D positive (two units) and Group B Rh D negative (one unit)</td>
<td>Three units of red cells</td>
<td>No symptoms</td>
<td>No sequelae</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 29*</td>
<td>65 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O SD treated plasma</td>
<td>Two units of group O SD treated plasma</td>
<td>Transfusion continued uneventfully.</td>
<td>Due to a failure to follow local policy on the appropriate use of SD plasma, patient's anti-coagulant medication was not discontinued, instead, without checking INR, two units of SD treated plasma were prescribed. Laboratory staff queried this transfusion suggesting that vitamin K may be more appropriate.</td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
<td>ABO and Rh D Group of IBCT</td>
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<td>Symptoms and Outcome</td>
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</tr>
<tr>
<td>2</td>
<td>IBCT Case 30</td>
<td>69 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O SD treated plasma</td>
<td>Two units of SD treated plasma. Vitamin K administered pre-transfusion.</td>
<td>No symptoms No sequelae</td>
<td>Transfusion of SD treated plasma was considered inappropriate, as it did not meet with hospital guidelines. INR 6.7 and no bleeding or emergency invasive procedure planned. INR the next day was 1.2. Error identified by laboratory staff post transfusion and reported to TSO.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 31*</td>
<td>71 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O SD treated plasma</td>
<td>One unit of SD treated plasma</td>
<td>No symptoms No sequelae</td>
<td>The patient was not actively bleeding. One unit of SD treated plasma administered with no documented reason. There was no record of anticoagulant therapy.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 32*</td>
<td>46 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O SD treated plasma</td>
<td>One unit of SD treated plasma</td>
<td>No symptoms No sequelae</td>
<td>This patient was transfused with one unit of SD treated plasma with no documented reason. Coagulation studies were within normal range.</td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
<td>ABO and Rh D Group of IBCT</td>
<td>Volume of Incorrect Blood Component or Product Transfused</td>
<td>Symptoms and Outcome</td>
<td>Cause of Error</td>
</tr>
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</tr>
<tr>
<td>1 IBCT</td>
<td>Case 26</td>
<td>66 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of pooled platelet concentrate</td>
<td>No symptoms No sequelae</td>
<td>Possible unnecessary donor exposure. Reason for transfusion unclear. Platelet count 91x10^9/l.</td>
</tr>
<tr>
<td>1 IBCT</td>
<td>Case 27*</td>
<td>39 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Four units of pooled platelet concentrate</td>
<td>No symptoms No sequelae</td>
<td>Large volume request for platelets. Unnecessary donor exposure.</td>
</tr>
<tr>
<td>1 IBCT</td>
<td>Case 28*</td>
<td>37 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Three units of apheresis platelet concentrate</td>
<td>No symptoms No sequelae</td>
<td>Platelet count reported verbally as “49x10^9/l – history of clumping”. The significance of clumping was not explained to clinical staff. It was not appreciated that a single unit is now sufficient for an adult dose. Due to the “low” platelet count three units of apheresed platelets were ordered, issued and transfused unnecessarily.</td>
</tr>
</tbody>
</table>

Inappropriate/Unnecessary Transfusions: Table 6 continued
Inappropriate/Unnecessary Transfusions
We received 10 reports of inappropriate/unnecessary transfusions. Patients received inappropriate or unnecessary transfusions of red cells in three cases (IBCT Cases 23-25), platelets in three cases (IBCT Cases 26-28) and plasma in four cases (IBCT Cases 29-32). One case (IBCT Case 25), which involved red cells was associated with mortality.

All clinical staff involved in transfusion must be familiar with guidelines for use of components. When transfusing more than one unit, regular monitoring of post transfusion Hb levels is strongly recommended, ideally on a unit by unit basis.

We describe eight cases in detail, demonstrating a number of issues presented in the recommendations.

Red Cells
Level 1 IBCT Case 23
This patient presented to the A&E Department with a GI bleed - Hb 12.7 g/dl. During nursing “hand-over” crossmatching of red cells was mentioned, but not for this patient. There was in fact no prescription or verbal order for blood transfusion for this patient. One of the nursing staff incorrectly interpreted that this patient was for transfusion of one unit of red cells, took a pre-transfusion sample and requested blood from the laboratory. The transfusion proceeded even though other members of nursing staff questioned the need for transfusion. The consultant, during ward rounds, identified the error when the transfusion was in progress, which was then discontinued. There were no complications to this transfusion. As a result of this error retraining of staff has taken place.

Level 1 IBCT Case 25
This elderly female patient with a history of congestive cardiac failure presented with peptic ulcer disease and melaena - Hb 7.9 g/dl - and was admitted to the ITU. Two units of red cells were prescribed for “Rectal bleeding” and further requests for six more units were later made over a 12-hour period. Laboratory staff considered the patient to be actively bleeding and did not question the orders. The nursing staff, who did not normally work in ITU, did not question the unusually high volume of red cells transfused to a patient who was haemodynamically stable. The Hb concentration was not monitored at any stage during the eight-unit transfusion. Post-transfusion the Hb was 17.9 g/dl. There were signs of deteriorating renal function with a urea of 15 mmols/L and peripheral oedema, which were not present pre-transfusion. The laboratory staff detected the unusually high post transfusion Hb and discussed it with the TSO. Investigation revealed that the Hb immediately post transfusion was 17.9 g/dl, 36 hours post transfusion 18.5 g/dl and 84 hours post transfusion 17.5 g/dl. The patient died on the date of this last Hb measurement. Coupled with the patient’s age and underlying condition it is likely that this over transfusion contributed to mortality.

Level 1 IBCT Case 24
This elderly male patient presented to the A&E Department with a wound to the hand and minimal blood loss - Hb 7.9 g/dl. The patient was asymptomatic but three units of red cells was prescribed and transfused. Subsequent haematology review diagnosed iron deficiency anaemia. The patient suffered no sequelae following this inappropriate transfusion.
Plasma
Level 1 Case 29
This patient, who was on oral anticoagulant medication, was scheduled for an elective surgical procedure. There was no pre-transfusion INR checked and the oral anticoagulant was not discontinued. Pre-operatively, two units of SD Plasma were prescribed, following which the INR was to be checked. Laboratory staff suggested seeking haematology advice, as they felt in view of the routine nature of the surgery, that vitamin K may be more appropriate. However, haematology advice was not sought and the patient received two units of SD Plasma uneventfully. Subsequently the haematology team considered that vitamin K would have been the treatment of choice. Prior to this event there had been considerable educational input into the appropriate use of SD Plasma and the indication for this transfusion did not comply with local guidelines.

Level 1 IBCT Case 31
This elderly post-operative patient was bleeding from wound sites and required six units of red cells over a period of one month. He was not on any anticoagulant therapy and coagulation studies were within normal range. One unit of SD treated plasma was prescribed and transfused. There was no documented reason for this transfusion but it was thought that it might aid in reducing the “oozing”. There was no noticeable improvement in the patient’s condition. The TSO discovered this inappropriate transfusion during routine audit.

Level 1 IBCT Case 32
This patient received four units of red cells for vaginal bleeding. Coagulation studies were checked pre-transfusion and were within normal range. The following day one unit of SD treated plasma was administered with no documented reason for transfusion. The patient was discharged home uneventfully and suffered no sequelae as a result of this transfusion. The TSO discovered the error during routine audit.

Platelets
Platelets are now issued by the IBTS as either a unit of apheresis platelets or as a pooled concentrate from four donors which constitutes a single adult dose. In two cases (IBCT Cases 27 and 28), the clinicians ordering the platelets were unaware that this was the case and ordered an inappropriately large dose thinking that each unit was a single donor unit. Guidelines for use of platelets were not followed in two of these cases (IBCT Cases 26 and 27). In the first case the transfusion did not follow guidelines for use of platelets (IBCT Case 26) in surgery and in the second case (IBCT Case 27) the patient had ITP. In another case (IBCT Case 28) the low platelet count was artefactual. We describe in detail two of the three cases.

Level 1 IBCT Case 27
This patient was being given platelets for ITP, platelet count 2x10^9/L with petechial rash and gum bleeding. A request for 10 pools of platelets was made to the supply centre during the night. This was on the assumption by the clinician that the platelets were being issued as single units. However the IBTS has been issuing pooled platelets since 2000, where one pool made up of platelets from four donors constitutes an adult dose. Following discussion between medical staff at the hospital and laboratory staff at the supply centre, who were concerned at the unusually large request, five units of pooled platelet concentrate were issued. Subsequently four units were transfused over four hours each although a unit of platelets should usually be transfused over 30 to 60 minutes. Patients with ITP do not require platelet support unless there is serious bleeding. This transfusion exposed the patient to 16 donors.
Clumping of Platelets giving rise to an artefactually low platelet count
Level 1 IBCT Case 28
This lady had a history of low platelet counts during pregnancy which was identified as “clumping—numbers appear normal”. Clumping of platelets in the anticoagulant ethylenediaminetetraacetic acid (EDTA) can give an artificially low platelet count, or pseudothrombocytopenia. is of no clinical significance except that it may lead to an incorrect diagnosis of thrombocytopenia. During labour, the verbal platelet count report was “45x10⁹/L and history of clumping”. There was a communication breakdown between laboratory and clinical staff as the significance of clumping was not made clear and a platelet count of 45x10⁹/L during labour is considered low. This fact was not conveyed to clinical staff who then ordered three packs of apheresed platelets, as they were under the impression that each pack was a single unit of platelets. A basic grade medical scientist permanently working in the hospital transfusion laboratory processed this request. A senior medical scientist in the haematology laboratory identified the error the following day. As the platelet count was in fact normal, this was an unnecessary transfusion.
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 IBCT Case 33</td>
<td>15 yrs</td>
<td>M</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D negative</td>
<td>One unit of irradiated pooled platelet concentrate</td>
<td>CMV status of patient not known, not checked post transfusion</td>
<td>No symptoms No sequelae</td>
<td>Component issued by supply centre was irradiated but not CMV antibody negative as requested. Error not detected despite multiple checking procedures pre-transfusion.</td>
</tr>
<tr>
<td>2 IBCT Case 34*</td>
<td>16 days</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of pooled platelet concentrate.</td>
<td>No symptoms No sequelae</td>
<td>Incorrect component issued from supply centre, correct component issued to another hospital. Error not identified in hospital transfusion laboratory prior to issue or at bedside prior to transfusion.</td>
<td></td>
</tr>
<tr>
<td>2 IBCT Case 36</td>
<td>42 yrs</td>
<td>F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One unit of pooled platelet concentrate</td>
<td>No symptoms No sequelae</td>
<td>Failure to request CMV antibody negative and irradiated cellular components following autologous peripheral blood stem cell (PBSC) transplant. Error not identified during bedside checking procedure.</td>
<td></td>
</tr>
<tr>
<td>2 IBCT Case 37*</td>
<td>23 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Two units of red cells</td>
<td>No symptoms No sequelae</td>
<td>Failure to request CMV antibody negative and irradiated cellular component. Error discovered by TSO during routine audit.</td>
<td></td>
</tr>
<tr>
<td>2 IBCT Case 38*</td>
<td>28 yrs</td>
<td>F</td>
<td>Group O Rh D positive.</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Failure to issue CMV antibody negative and irradiated cellular component. Hospital laboratory computer warning overridden. Pre-transfusion checking procedures failed to identify the error.</td>
<td></td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
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</tr>
<tr>
<td>2</td>
<td>IBCT Case 39*</td>
<td>15 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Less than 100mls of red cells</td>
<td>Apprehension, feeling of doom, chills, itching, urticaria and rigors. Patient recovered with no sequelae. Both the patient and unit cultured negative.</td>
<td>Failure to request CMV antibody negative and irradiated component for this patient with a newly diagnosed malignant haematological disorder.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 40*</td>
<td>34 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Six units of red cells</td>
<td>No symptoms</td>
<td>No sequelae</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 41*</td>
<td>36 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Less than 50 mls of red cells</td>
<td>No symptoms</td>
<td>No sequelae.</td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
<td>ABO and Rh D Group of IBCT</td>
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<td>Symptoms and Outcome</td>
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</tr>
<tr>
<td>2 IBCT Case 42*</td>
<td>17 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of standard red cells</td>
<td>No complications to this transfusion</td>
<td></td>
<td>Initial transfusion cancelled pending further investigation. Issued units still available in issue fridge. A malignant haematological disorder was diagnosed requiring CMV antibody negative and irradiated red cells. The original crossmatched units, which were not CMV antibody negative or irradiated, and had been left in issue fridge were collected and transfused in error. Bedside check failed to identify the error.</td>
</tr>
<tr>
<td>2 IBCT Case 43*</td>
<td>21 yrs</td>
<td>M</td>
<td>Group B Rh D positive</td>
<td>Group B Rh D positive</td>
<td>One unit of non-irradiated red cells</td>
<td>No symptoms No sequelae</td>
<td></td>
<td>Irradiated components requested. Two units of non-irradiated red cells issued. Error discovered prior to transfusion and clinical staff informed, but incorrect units were left in issue fridge. Two further irradiated units were issued, and one transfused uneventfully. When second unit was being collected one of the non-irradiated units was collected and transfused in error.</td>
</tr>
<tr>
<td>2 IBCT Case 44*</td>
<td>1 mth</td>
<td>M</td>
<td>Group AB Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One unit of platelet concentrate apheresis</td>
<td>No symptoms No sequelae</td>
<td></td>
<td>Supply centre issued group O Rh D negative standard platelets. Baby should have received washed group O Rh D negative platelets if group A Rh D negative platelets were not available. Hospital transfusion laboratory assumed that the correct component had been issued. Error identified the following day.</td>
</tr>
</tbody>
</table>
Special Requirements not met

There were 12 cases reported in this category classified as level 2 incidents. In some cases there may not have been a strict clinical requirement for irradiated CMV antibody negative cellular components but because they were requested and not issued they have been included as incidents.

- Eleven cases reported failure to supply CMV antibody negative and irradiated cellular components.

- In one case standard platelets were supplied instead of washed platelets (IBCT Case 44).

- Five cases occurred due to prescription and/or request errors without stating any special requirements or without giving a clinical history, which would have raised the laboratory awareness to the requirement (IBCT Cases 35, 36, 37, 39 and 41).

- In one case (IBCT Case 39) the patient developed symptoms of an adverse transfusion reaction, which led to an investigation. Although not related to the reaction, the investigation revealed that there had been a failure to administer CMV antibody negative and irradiated cellular components. This highlights the importance of auditing all transfusion reactions.

- In three cases (IBCT Cases 38, 40 and 41) in this category, errors in the hospital transfusion laboratory led to the issue of units which did not meet special requirements. In one of these cases (IBCT Case 41) the clinical team had also not requested the correct component.

- In two cases (IBCT Cases 42 and 43) the errors related to a failure to withdraw incorrect components from circulation that had been issued earlier by the hospital transfusion laboratory. These cases demonstrate that it is not sufficient to correct the error and re-issue the correct component, the incorrect component must be physically removed from the issue fridge.

- Three errors occurred in the supply centre (IBCT Cases 33, 34 and 44). In two of these cases the supply centre failed to provide CMV antibody negative components as requested. Multiple checking procedures at both IBTS and hospital level failed to identify the error. The third case (IBCT Case 44) involved a neonate where the supply centre issued standard, instead of washed platelets.

- In two cases (IBCT Case 38 and 41) a computer warning, which prompted that CMV antibody negative and irradiated components had been issued for this patient in the past, was overridden. In a further case (IBCT Case 40) the information was available on screen, but went unnoticed.

Recommendations

- The number of cases reported in this category re-emphasises the need for ongoing education and training of staff involved in prescribing, ordering and administering transfusions. The significance and importance of the bedside checking procedure cannot be over-emphasised.

- There is a need to review laboratory practices to highlight the importance of checking units against written and/or verbal request prior to issue.

- A number of cases in this report, as in last years, relate to failures to heed computer warnings (IBCT Cases 38, 40, 41 and 72). As recommended in the NHO Annual
Report 2001\(^3\), computer systems should be designed with audible alarms/alerts to minimise opportunities to override screen warnings. Preferably any such overrides should require a reason or explanation as this should lead to questioning of the need to override. An audit trail of any overrides should also be kept.

- Two cases (IBCT Case 37 and 39) show the importance of providing clinical details on transfusion request forms.

We describe nine cases in detail that typically describe the types of error associated with this category and demonstrate a number of issues addressed in the recommendations.

**Level 2 IBCT Case 37**
This patient was recently diagnosed with a malignant haematological disorder and had symptomatic anaemia requiring a transfusion of two units of red cells - Hb 6.1 g/dl. Two units of CMV antibody negative and irradiated red cells were prescribed as per hospital policy. The requesting doctor then completed the request form but failed to state the special component requirements. The request form simply stated ‘anaemia’ as the reason for transfusion and as this patient had no historical record it was not possible to detect the error. Two units of unknown CMV antibody status and non-irradiated red cells were issued. The pre-transfusion bedside checking procedure failed to identify the error. There were no complications to this transfusion. The error was discovered by TSO during routine audit.

**Level 2 IBCT Case 39**
This adolescent patient with a newly diagnosed malignant haematological disorder required a transfusion of one unit of red cells for symptomatic anaemia - Hb 5.7g/dl. Following transfusion of less than 100 mls, symptoms of urticaria, apprehension, chills and rigors developed. The transfusion was discontinued. Both the patient and unit were cultured and no organisms were isolated. IV hydrocortisone 100mgs was given. There was a full recovery within hours and the patient was transferred to a tertiary care centre for further management. During investigation of the adverse reaction it was discovered that the patient should have received CMV antibody negative and irradiated cellular components. It was found that there was a failure to state these special requirements on the prescription and at the time of requesting. As anaemia was the only clinical information given on the request form, the laboratory staff did not suspect the need for special requirements. Nursing staff failed to identify the need for these special requirements and as they were not prescribed, the bedside checking procedure failed to identify this error.

**Laboratory Errors**  
**Level 2 IBCT Case 38**
This young patient was suspected to have an underlying haematological disorder, and was anaemic - Hb 5.4 g/dl. Three units of CMV antibody negative and irradiated red cells were prescribed. The patient had been transfused previously with CMV antibody negative and irradiated red cells at this hospital. In this hospital the pre-transfusion sample is delivered to the hospital transfusion laboratory with the "Group and Hold" form only. Further requests are made by telephone. In this case the special requirements were requested verbally by telephone. Two units of standard red cells were crossmatched, labelled and issued. The computer warning was overridden and the verbally requested special requirements went unnoticed. There was a change of shift at this point and a second medical scientist crossmatched, labelled and issued the third unit of red cells, this time meeting the special needs. One of the incorrect units was handed over personally by laboratory staff who formally checked it for identity, but failed to recognise that the special requirements were not met. Subsequent pre-transfusion checking procedures failed to identify the error. The second unit collected
was CMV antibody negative and irradiated. On receiving this unit, the nursing staff realised the error. There were no complications following this incorrect transfusion. As a result of this error, the laboratory have introduced an audible computer warning alarm to compliment the already existing visual alarm.

Level 2 IBCT Case 34
This premature infant was septic and thrombocytopenic, with multiple associated problems and required a transfusion of one unit of CMV antibody negative apheresed platelet concentrate. The correct component was requested by telephone from the supply centre. Where possible neonates are issued with apheresed platelet concentrate in an effort to reduce donor exposure. However the correct apheresed unit was issued in error to another hospital and one unit of pooled platelet concentrate, of undetermined CMV status, was despatched to the hospital. The unit label clearly stated ‘pooled platelet concentrate’, but did not indicate ‘CMV antibody negative’. The unit was delivered to the hospital transfusion laboratory outside normal working hours. The medical scientist on duty did not normally work in the transfusion laboratory. Despite numerous checking procedures throughout the transfusion process, neither the absence of a CMV antibody negative label nor the fact that it was a pooled platelet concentrate were identified. The supply staff identified the error later that night, by which time the transfusion had commenced. The transfusion was then discontinued and the correct unit was despatched and transfused. There are no complications to this transfusion.

Level 2 IBCT Case 40
This severely immunocompromised patient required a perioperative transfusion of six units of CMV antibody negative and irradiated red cells for anaemia - Hb 6.2g/dl. Appropriate components were prescribed, however non-irradiated CMV antibody negative red cells were issued from the hospital transfusion laboratory. The crossmatch took place outside normal working hours by an on-call medical scientist who regularly worked in the hospital transfusion laboratory. Special requirements for this transfusion had been entered into the laboratory computer but were not noticed on the computer screen. These units were then transfused in the operating theatre where the anaesthetic team was unaware of the special requirements needed. The patient suffered no ill effects.

Level 2 IBCT Case 41
This patient, with a malignant haematological disorder, required a transfusion of one unit of CMV antibody negative and irradiated red cells for associated anaemia - Hb 8.2 g/dl. The request was made verbally, as is hospital policy, but without stating the special requirements. A computer warning prompting that CMV antibody negative and irradiated components had been issued for this patient in the past was overridden and one unit of standard red cells was issued. Multiple checking procedures failed to identify the error. The unit was checked remote from the bedside against patient documentation and the transfusion was administered without a written prescription. The nursing staff discovered the error while the transfusion was in progress, less than 50mls had transfused, and the transfusion was discontinued. As a result of this incident changes to the computer software have been introduced. The special requirements warning is now in bold on the computer screen and audible warnings have also been introduced to highlight all warnings and to draw attention to those patients requiring special components. The importance of only transfusing against written prescriptions was re-emphasised to nursing staff.
Failure to withdraw product

In two cases, although the mistake was rectified in the hospital transfusion laboratory and the correct component was issued, there was a failure to physically remove the wrong component from the issue fridge leading to the transfusion of the wrong component.

Level 2: IBCT Case 42
This patient was to be transfused for the first time with three units of red cells for anaemia - Hb 7.4 g/dl. One unit of standard red cells was crossmatched and issued. The transfusion was postponed, pending results of diagnostic investigations. A malignant haematological disorder was subsequently diagnosed and it was decided to proceed with the transfusion, but to transfuse CMV antibody negative and irradiated components. The prescription was amended to reflect this and the hospital transfusion laboratory was informed of the special requirements by telephone, as the request form for the initial transfusion was still in date and was already in the laboratory. Three units of CMV antibody negative and irradiated red cells were crossmatched and issued. However, the original units were not removed from the issue fridge, and the porter collecting the blood selected one of these units for delivery to the clinical area. This error was not identified during the bedside checking procedure prior to commencing the transfusion. Laboratory staff identified the error when checking stock levels at end of shift, by which time one unit of non-CMV antibody negative and non-irradiated red cells had been transfused. There were no complications to this transfusion.

Level 2: IBCT Case 43
This patient with anaemia of malignancy required two units of CMV antibody negative and irradiated red cells. The appropriate component was prescribed and requested. Two units of non-irradiated red cells were issued in error and placed in the satellite fridge for use. The laboratory staff discovered the initial error and informed the clinical area. The compatibility report form was returned to the laboratory but the incorrect units were not withdrawn from the satellite fridge. Two further units of irradiated red cells were issued and placed in the satellite fridge for transfusion. One irradiated unit was then transfused uneventfully. When the second unit was being collected the incorrect units were still available and one of these non-irradiated units was collected in error. At the time of collection it was noted that the unit number was not listed on the available compatibility report form and the laboratory staff were contacted. The on-call staff in the laboratory reassured the nursing staff that this unit was safe to transfuse. A duplicate copy of the compatibility report form was still available at the satellite fridge and this was used to confirm identity of the unit in the pre-transfusion bedside checking procedure. The on-call medical scientist discovered the error some time later when he/she remembered receiving instructions on the withdrawal of the two non-irradiated red cell units and contacted the clinical area, by which time this one incorrect unit had been transfused. There have been no complications to this incorrect transfusion. Changes have been introduced where components for recall must be withdrawn from issue/satellite fridge immediately.
**Standard instead of washed platelets**
Where feasible platelets should be of the same ABO group as the patient to prevent haemolysis of the patient’s red cells from haemolysin in the donor plasma. Where this is not feasible and group O platelets must be given to group A or B recipients, only group O platelets, which are haemolysin negative should be transfused. In the case of babies, it may be preferable to transfuse washed platelets or platelets re-suspended in saline.

**Level 2 IBCT Case 44**
This baby with sepsis and associated coagulopathy and thrombocytopenia – platelet count 12x10⁹/l - grouped as AB Rh D negative. One unit of apheresed platelet concentrate was prescribed and requested. The baby had been transfused seven times previously with washed group O Rh D negative apheresed platelet concentrate as no group AB or A Rh D negative platelets were available. On this occasion, washed group O Rh D negative platelets should have been issued as again no group A Rh D negative platelets were available. However, in error, the supply centre issued standard group O Rh D negative platelets. The hospital medical scientist on-call, who did not regularly work in the transfusion laboratory, assumed the supply centre had issued the correct component and processed and issued the platelets during the night. The error was identified when checking on-call work the following morning. There were no complications to this transfusion.

**Recommendation:**
Group A platelets would be preferable to Group O platelets due to the lower risk of haemolysis associated with anti-B present in group A donor plasma. Washing of platelets can diminish the platelet increment and efficacy significantly. In this case very poor increments were obtained with group O washed platelets. The IBTS are increasing the number of group A apheresis donations collected that are suitable for neonatal use to ensure that, where possible, group A neonatal recipients receive ABO identical platelets. See Appendix 3 for recommendations on the selection of platelets.
### Transposition of unit labels: Table 8 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 45*</td>
<td>42 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells.</td>
<td>No symptoms, No sequelae</td>
<td>Transposition of issue labels during issuing procedure. Error not identified during pre-transfusion checking procedures.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 46*</td>
<td>56 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>One unit of CMV negative and irradiated red cells</td>
<td>No sequelae. Hospital considering introducing automated tracking system.</td>
<td>Transposition of issue labels on blood packs during laboratory processing– unit numbers on the front and back of packs were different. Error discovered during pre-transfusion checking of second unit.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 47*</td>
<td>32 yrs</td>
<td>F</td>
<td>Group B Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Two different issue labels on one unit of red cells. Nursing staff noticed discrepancy during bedside checking procedure. Laboratory staff advised that transfusion could proceed.</td>
</tr>
</tbody>
</table>
Wrong blood transfused due to transposition of compatibility labels
There were two cases where there was transposition of compatibility labels between units. One of these cases involved the transposition of compatibility labels between units for different patients (IBCT Case 45). The second case involved the transposition of compatibility labels between units for the same patient (IBCT Case 46). In one case (IBCT Case 47) there was more than one compatibility label attached to one unit of red cells.

Transposition of compatibility labels between units for different patients
Level 1 IBCT Case 45
This female patient (Patient X) was actively bleeding and was to be transfused with two units of red cells for symptomatic anaemia - Hb 7.2 g/dl. She grouped as O Rh D positive, antibody screen negative. The medical scientist was processing two crossmatch requests simultaneously where co-incidentally both patients were group O Rh D positive. During the issuing procedure a transposition error occurred and the issue label of Patient X’s unit was placed on Patient Y’s unit and vice versa. Patient X was subsequently transfused with the unit intended for patient Y, patient Y did not require transfusion. Multiple pre-transfusion checking procedures, including the bedside checking procedure, failed to identify the error. Laboratory staff discovered the error when scanning the IBTS label of the unused unit destined for patient X in order to return it to stock. The computer records showed that this unit had already been transfused to Patient X. The empty pack of the transfused unit was retrieved and retrospective crossmatching confirmed its compatibility for Patient X. Units are now labelled for only one patient at a time. Ongoing education of nursing staff continues to highlight the importance of a thorough pre-transfusion checking procedure. There were no complications to this transfusion.

Transposition of compatibility labels between units for the same patient
Level 2 IBCT Case 46
This patient, with a malignant haematological disorder, required two units of red cells for associated anaemia - Hb 7.5 g/dl. Two units of CMV antibody negative and irradiated red cells were prescribed and requested. The two units were crossmatched according to hospital policy but the issue labels for the blood component packs were transposed during processing, i.e. label for unit X was placed on unit Y and vice versa. The transfusion was commenced during lunchtime when only two nurses were on duty and as the ward is divided in two sections, neither nurse being able to leave his/her section, the unit was checked in the nurse’s station which is common to both sections. The error was not identified during this remote pre-transfusion checking procedure of the first unit. There was no ID band in place. The error was detected during the bedside pre-transfusion checking procedure prior to commencing the second unit and the laboratory was informed. The second unit was returned to the laboratory and the error corrected. The patient suffered no sequelae.

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 service records and each unit of blood or component\(^{15}\). Only units for one patient should be labelled up at any one time. As with all laboratory tasks, interruptions should be kept to a minimum.
• There is a need to review laboratory practices to highlight the importance of checking units against written and/or verbal request prior to issue.
• Automated systems for labelling and checking would enhance the security of the process.
More than one compatibility label attached.
Level 3 HV Case 47
This woman with a postpartum haemorrhage - Hb 7.0g/dl - required two units of red cells. Two units of crossmatched compatible group O Rh D positive red cells were issued. One unit had two different issue labels attached. In this hospital it is practice to crossmatch the same unit for two patients when supply difficulties are encountered. Normally laboratory staff remove the issue label for the patient who is not to receive the unit prior to collection. On this occasion, the unit was handed over by laboratory staff and delivered to clinical area with both issue labels attached. During the bedside checking procedure nursing staff noted this discrepancy and contacted the laboratory for advice. They were reassured that it was safe to transfuse the unit with two unit labels attached. The unit was transfused uneventfully. However, as nursing staff were unhappy about such a situation arising again, they contacted the TSO the following day.

Recommendation:
In hospitals where it is the practice to crossmatch and reserve the same unit of red cells for more than one patient at a time, it is recommended that a procedure is in place to ensure the additional label is removed prior to issue of such units. This would result in less confusion at the bedside and could also act to alert the laboratory staff that a unit is no longer available for the other patient. Further crossmatching may be required for the second patient.
### Incorrect Red Cell storage: Table 9 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 48*</td>
<td>93 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Unit out of controlled storage for more than 30 minutes and returned to laboratory for disposal, as patient was not wearing ID band. Unit handed over to laboratory staff, and placed on issue shelf of fridge in error. Time of return not documented. Patient was issued with new ID band and repeat sample taken. Original unit was collected in error and not identified at the bedside check. Laboratory staff discovered error when checking the returns ledger.</td>
</tr>
</tbody>
</table>
Incorrect Red Cell Storage
One case involved the incorrect storage of red cells as described below.

Level 2 IBCT Case 48
This elderly patient with symptomatic anaemia - Hb 7.1 g/dl - required a transfusion of one unit of red cells. During the bedside checking procedure the nursing staff discovered the patient's Typenex bracelet on the bedside locker and followed hospital policy by not proceeding with the transfusion. At this point the unit had been out of controlled storage for more than 30 minutes, so a repeat crossmatch was requested and a care assistant was asked to return the unit to the laboratory for disposal. There is only one blood fridge in this laboratory, which is divided into two sections - the top part contains stock and crossmatched units and the bottom shelf contains units unsuitable for use, e.g. returned and expired. The unit was handed to a member of laboratory staff who placed it on the issue shelf of the fridge. The time of return of the unit was not documented in the ledger. A new Typenex bracelet was placed on the patient and a repeat sample was taken. A new unit of red cells was crossmatched. However, the porter collected the original unit with the old Typenex number and the issue label, which had been returned unsuitable for transfusion and but still available on the issue shelf of the fridge, and delivered it to the clinical area. The bedside check failed to detect that the Typenex number on the patient's ID band did not match the Typenex number on the unit and antibody compatibility form. Furthermore the number on the compatibility report form did not match the number on the unit. The transfusion proceeded. The error was discovered when the TSO investigated the return of a unit for disposal, which had not been entered into the returns ledger.

Recommendations:
It is preferable to have a designated fridge for allocated units and a separate fridge for units intended for issue i.e. stock. In circumstances where this is not practicable, it is recommended that separate space should be reserved for:
- units for issue i.e stock
- units selected for certain patients i.e allocated units
- units kept in quarantine awaiting completion of testing
- outdated and discarded units
- autologous donations

The space for each of these component types should be clearly indicated. Blood and blood components that have been returned to the blood bank or transfusion service shall only be re-issued if they have been maintained at the appropriate temperature.
### Transfusion using standard fluid administration set: Table 10 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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</td>
<td>69  yrs</td>
<td>F</td>
<td>Group B Rh D positive</td>
<td>Group B Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms</td>
<td>Blood transfused through a fluid administration set without a filter. Final bedside check failed to detect the discrepancy. Similarity of packaging on fluid and blood administration sets has been raised with the manufacturers.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 50*</td>
<td>71 yrs</td>
<td>F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>Two units of red cells</td>
<td>No symptoms</td>
<td>Two units of red cells transfused via a standard fluid administration set. Both fluid and blood administration sets are stored on same shelf in Treatment Room and packaging is similar.</td>
</tr>
</tbody>
</table>

* Included as a full case history
Transfusions using standard fluid administration set
Blood components should always be transfused through a standard blood giving set with a 170-200 micron filter. We received two reports of transfusions using standard fluid administration sets instead of blood administration sets. The packaging for fluid administration sets and blood administration sets are similar and this issue has been brought to the attention of the manufacturers.

We describe one case.

Level 2 IBCT Case 50
This elderly patient, with symptomatic iron deficiency anaemia - Hb 7.0 g/dl - was prescribed two units of red cells. At completion of the second unit, nursing staff noticed that a standard fluid administration set was in use. The incident was reported to the TSO. On investigation, it was found that standard fluid and blood administration sets were stored on the same storage shelf and the packaging was almost identical. There were no complications to this transfusion.

Recommendation:
Blood administration sets should be stored separately from fluid administration sets.
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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</td>
<td>72 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Two units red cells</td>
<td>No sequelae.</td>
<td>Patient chart used to check two units. No crossmatch report used to crosscheck first two units.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT</td>
<td>80 yrs</td>
<td>M</td>
<td>Group B Rh D positive</td>
<td>One unit of group O Rh D negative and one unit of group B Rh D negative</td>
<td>Two units of red cells</td>
<td>No symptoms, No sequelae. Patient died of underlying injuries.</td>
<td>Staff considered one patient identifier and a note in the patient's medical record to be sufficient patient identification. An additional transfusion four days later was based on original specimen results despite staff being aware of error.</td>
</tr>
</tbody>
</table>
Name discrepancy unresolved
Hospital laboratories should have a SOP or policy for acceptance and/or rejection of incorrectly labelled samples. This policy should cover amendments, which are acceptable, and those which are unacceptable and require a further sample to be taken.

Level 2 IBCT Case 52
This patient was admitted to ITU via the A&E Department with multiple injuries following an RTA. He was semiconscious and an incorrect first name and date of birth were obtained and recorded on the medical records. A sample for group and hold was taken in the A&E Department using these incorrect data and a Typenex band and hospital ID band were put in place. The following day the correct first name and date of birth were obtained and the medical notes were amended, but not the Typenex band, the ID band or the laboratory request forms. Four days later two units of red cells were prescribed for anaemia – Hb 8.0 g/dl. The original serum sample was used to process the request. A new specimen was not obtained although the clinical staff were aware of a reference in the patient’s notes regarding the identification error on admission. Subsequently the transfusion proceeded using the incorrect first name and date of birth but correct surname and hospital number. Staff considered that one complete correct identifier was sufficient and that the reference in the medical notes supported this. There were no complications to this transfusion, however the patient subsequently died of underlying injuries.

Transfused without proper checking procedures

Level 2 IBCT Case 51
This patient with melaena - Hb 6.2 g/dl - required a transfusion of three units of red cells. In this hospital blood components are released for issue on the basis of a laboratory report form (for laboratory use only) and a standard compatibility report form. On collection of the first two units a compatibility report form was not used to confirm identity of the patient and the unit. Instead the patient’s medical record was used to confirm the identity of the patient, but no transfusion documentation was used. Two nurses checked the units at the time of collection and again at the bedside, prior to administration. The error was discovered when the nurse collecting the third unit was unable to find the compatibility report form and the medical scientist refused to release it. There were no complications to this transfusion. However, as a result of this incident transfusion guidelines have now been put in place in this hospital.
**Antibody acquired from transfusion Table: 12 *Included as a full case history*  

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 IBCT</td>
<td>Case 53*</td>
<td>74 yrs</td>
<td>F</td>
<td>Group AB Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Two units of apheresed platelet concentrate</td>
<td>No symptoms No sequelae.</td>
<td>There were no group AB platelets available at the supply centre, so the requesting doctor ordered group O platelets instead. These were transfused uneventfully. Post transfusion direct antiglobulin test (DAT) was positive.</td>
</tr>
<tr>
<td>2 IBCT</td>
<td>Case 54*</td>
<td>22 yrs</td>
<td>M</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One unit pooled platelet concentrate</td>
<td>Subsequent testing after this transfusion episode revealed that the patient now had anti-D antibodies passively acquired from the platelet transfusion.</td>
<td>Incident reported to and investigated by QA/QC Department at supply centre. One donor used in the platelet pool had previous anti C+D.</td>
</tr>
</tbody>
</table>
Issues due to antibody in the transfused components

Level 2: IBCT Case 53
This elderly lady with symptomatic thrombocytopenia – platelets 28x10^9 - and sepsis secondary to a malignant haematological disorder, required transfusion with two units of platelets. Pre-transfusion testing results showed the patient to be group AB Rh D positive, antibody screen negative and direct antiglobulin test (DAT) negative. A clinical decision was made by the hospital haematology team to transfuse group O Rh D positive platelets as these were the only platelets available from the supply centre at that time. The platelets tested negative for high titre anti-A and anti-B. Two units of group O Rh D positive apheresis platelets were transfused uneventfully. Subsequently, the patient was to be further transfused. This time the pre-transfusion antibody screen was again negative, but the DAT was positive and the eluate demonstrated anti-A_1 specificity. The DAT remained positive for four days and on the fifth day was negative. There were no ill effects and the patient recovered with no sequelae. Subsequent transfusions were uneventful.

Recommendation:
In the event of a difficulty with the supply of ABO compatible platelets it may be necessary to administer ABO non-identical platelet transfusions. While this is acceptable transfusion practice there may be poor increments, and in some rare cases, haemolysis. Group O platelets should only be issued for group A, B and AB patients if they have been tested and labelled as negative for high titre anti-A and anti-B. Hospitals should be aware that there is no generally agreed discriminatory test for high titre anti-A and anti-B and no precise guidelines for testing. Clinical users should therefore be aware of the possible occurrence of haemolysis especially where large volumes of incompatible plasma are transfused or in the case of paediatric patients who have smaller blood volumes. It may therefore be preferable to only transfuse one unit of group O platelets at a time to such patients. Group AB patients should receive group A or B platelets, as group AB are generally not available. See Appendix 3 for recommendations on selection of platelets where ABO/Rh D identical platelets are not available.

Level 2 IBCT Case 54
This young male patient, who was thrombocytopenic and anaemic secondary to malignancy, required blood and platelet transfusions. He was group O Rh D negative, antibody screen negative and was transfused uneventfully with two units of crossmatch compatible red cells and one unit of compatible pooled platelet concentrate. During subsequent pre-transfusion testing, he again grouped as O Rh D negative, but with a positive antibody screen, with anti-D detected. Repeat group and antibody screen confirmed that the patient had passively acquired anti-D from transfusion. During subsequent pre-transfusion testing of the recipient three months later the antibody screen was negative and transfusion was uneventful. The QA/QC Department of the supply centre was notified and, during their investigations, it was discovered that one donor used in the platelet pool had previous anti C and D antibodies detected. As a result of this complaint lists of donors with a previous history of antibodies are reviewed daily and their donations re-tested to confirm suitability for issue. Donors whose antibody titres are greater than those acceptable for issue are removed from the active donor panel.
### Neonatal /Paedipacks transfused in error: Table 13 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 55*</td>
<td>23 days</td>
<td>M</td>
<td>Mother Group A Rh D positive</td>
<td>Group O Rh D negative</td>
<td>10 mls of one aliquot of a paedipack (red cells)</td>
<td>No symptoms No sequelae</td>
<td>Neonatal pack of partially packed, CMV antibody negative red cells in CPDA1, kept in stock for neonatal resuscitation was inappropriately made available for this non-emergency transfusion. The error was discovered six days later when a further transfusion was requested. The infant had one unnecessary donor exposure.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 56*</td>
<td>1 day</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of a paedipack (red cells)</td>
<td>No sequelae.</td>
<td>A paedipack aliquot intended for another infant was crossmatched, issued and transfused to this infant.</td>
</tr>
</tbody>
</table>
Paediatric Transfusions
Neonates are the longest living survivors of blood transfusion. To reduce donor exposure a single unit, called a paedipack, can be reserved for an individual baby and divided into five separate portions and used for top-up transfusions for this baby to the end of its shelf life. A paedipack takes approximately one hour to prepare in the supply centre. When requesting a paedipack consideration needs to be given for distance and the time required to complete compatibility testing on its arrival.

Level 2 IBCT Case 55
This premature neonate required a transfusion for anaemia - Hb 7.7 g/dl. The prescription was for 50 mls of blood and the request form stated 50 mls of blood suitable for neonates. The on-call medical scientist processing the request was new to the transfusion laboratory and contacted the doctor to advise him/her that due to distance it would take approximately six hours to arrange for a paedipack to be delivered as there was none in stock. A neonatal pack of plasma reduced, leucodepleted, CMV antibody negative red cells in citrate-phosphate-dextrose-adenine (CPDA1) for neonatal use, which was normally kept in stock for neonatal resuscitation was requested by the attending doctor, as it was considered unacceptable to wait so long. However, as this was a non-acute, non-emergency transfusion, it would have been acceptable practice to wait for the paedipack to be delivered. When a further transfusion was requested six days later, the error was discovered and a paedipack was allocated for the baby. It transpired that the doctor did not understand the significant difference between a paedipack and CPDA1 product. As a result, this baby had one unnecessary donor exposure but suffered no sequelae.

Level 2 IBCT Case 56
This baby required a transfusion for anaemia of prematurity - Hb 9.6g/dl. Contrary to laboratory policy, the aliquot crossmatched for this baby was taken from a paedipack which had been allocated and crossmatched for another baby. Fortunately neither baby required further transfusions and the baby suffered no sequelae as a result of this incident.
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 57*</td>
<td>20 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D negative</td>
<td>Two units of red cells</td>
<td>No symptoms</td>
<td>Presented to A&amp;E with penetrating wound, query ruptured spleen. Two units of uncrossmatched group O Rh D negative red cells were prescribed over four hours each and one of these units was transfused the following day.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 58*</td>
<td>30 yrs</td>
<td>F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One unit of emergency un-crossmatched red cells transfused when crossmatched red cells were available.</td>
<td>No symptoms</td>
<td>One unit of un-crossmatched emergency group O Rh D negative red cells was transfused over two hours when crossmatched units were available shortly after the transfusion commenced.</td>
</tr>
</tbody>
</table>
Emergency uncrossmatched red cells transfused
Hospitals need to have protocols to cover massive transfusions\textsuperscript{16}. These should include timeframes for the provision of crossmatched, group specific and uncrossmatched blood taking into account the specific physical location of the hospital transfusion laboratory/blood fridges and clinical areas. If emergency uncrossmatched blood is needed, once the patient is stabilised, he/she should be returned to group specific or crossmatched blood to conserve blood supplies. The first instance is a clear case of inappropriate transfusion and use of emergency uncrossmatched blood. The second reflects failure of communication.

Level 2 IBCT Case 57
This incident involved the inappropriate transfusion of un-crossmatched group O Rh D negative red cells to a young male patient who presented to the A & E Department with a penetrating wound with a suspected ruptured spleen. Two units of un-crossmatched group O Rh D negative blood were prescribed over four hours each. The patient was oozing but was otherwise haemodynamically stable. One of the units was transfused the following day, despite crossmatched blood being available. This was also very probably a case of inappropriate transfusion as the Hb was 14.8g/dl before the first unit of uncrossmatched blood was transfused.

Level 2 IBCT Case 58
This patient had a postpartum haemorrhage - Hb 6.5g/dl - and required two units of red cells. The laboratory received an urgent request for these units. The person collecting the blood had difficulty gaining access to the laboratory as it was out-of-hours. At the request of the obstetrician, two units of un-crossmatched group O Rh D negative red cells were collected from a satellite fridge, one of which was transfused immediately and completed within two hours. However, two units of crossmatched red cells were available almost immediately afterwards. The second unit of un-crossmatched red cells was returned to the laboratory. This practice reflects poor communication within the multidisciplinary team and inappropriate use of group O Rh D negative red cells.
## Unit number incorrectly transcribed: Table 15 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 65</td>
<td>83 yrs</td>
<td>M</td>
<td>Group B Rh D positive</td>
<td>Group B Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms</td>
<td>No sequelae</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Blood was being issued manually as computer software was being upgraded. A transcription error occurred leading to a single digit discrepancy in unit number. Multiple checking procedures failed to identify the error.</td>
</tr>
</tbody>
</table>

| 3     | IBCT Case 66* | 75 yrs | M      | Group AB Rh D positive       | Group A Rh D negative     | One unit of red cells                                  | No symptoms         | No sequelae     |
|       |              |       |        |                               |                           |                                                        |                     | Medical record number not available, full name, date of birth and Typenex number used as identifiers. The Typenex number was incorrectly transcribed onto the issue label on the blood component pack. |

## Unit details transposed: Table 16 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 68*</td>
<td>75 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms</td>
<td>No sequelae</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wrong unit details were recorded when unit was collected from storage. Multiple checking procedures failed to identify the error. Error detected by laboratory staff when checking stock.</td>
</tr>
</tbody>
</table>
Level 3 Cases – Minor Incidents
Thirteen incidents were classified as minor, but reflect the necessity for careful monitoring of the transfusion process. In three cases the recommended transfusion time was exceeded (IBCT Cases 59, 60 and 64). In two cases units were transfused outside their expiry date (IBCT Cases 61 and 62). In one case the unit details were transposed (IBCT Case 68).
Five cases involved undetected single digit changes in hospital number or date of birth (IBCT Cases 52, 65, 66, 67 and 69). Two cases involved undetected single letter changes in patient name (IBCT Cases 70 and 71). As previously mentioned, hospital laboratories should have a policy for accepting and/or rejecting inaccurately labelled samples.
We describe two of the incidents in detail.

Typenex number Incorrectly transcribed

Level 3 IBCT Case 66
This elderly male patient presented to the A&E Department with symptomatic chronic anaemia - Hb 6.2g/dl - and required transfusion with two units of red cells. The MRN was not available as it was outside of normal working hours, so the full name, date of birth and Typenex number were used as identifiers, according to hospital policy. Patient data on the request form and sample tube were correct in all respects. The patient grouped as AB Rh D positive, antibody screen negative. Two units of group A Rh D negative red cells were crossmatched and issued. During the processing procedure in the hospital transfusion laboratory the Typenex number was incorrectly transcribed onto the issue label on the blood component pack. The first unit was collected from storage, delivered to the clinical area and checked pre-transfusion for identity of the patient and unit without noting the error. The error was discovered during the pre-transfusion checking procedure for the second unit. There were no complications to this incorrect transfusion.

Unit details transposed

Level 3 IBCT Case 68
This elderly male patient was bleeding - Hb 7.0 g/dl - and required a transfusion of two units of red cells outside normal working hours. The details of both units to be transfused were recorded on each issue label and stuck on the back of the pack as is standard policy in this hospital, i.e. each unit contains details of all units crossmatched on this occasion. When the first of unit was collected from storage, details of the second unit were recorded on the laboratory register in error. The details of the second unit were used throughout the transfusion process despite pre-transfusion checking procedures. The pre-transfusion checking procedure was carried out at the bedside by one person only and again the donation number for the second unit was used. The second unit was never transfused. The laboratory staff detected the error during routine checking. There were no complications to this transfusion. This incident led to the review of the issuing process to ensure that only one number, that of the actual unit being checked, will appear on the issue label in the future.
<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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</td>
<td>73 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms, No sequelae</td>
<td>Unit administered after expiry date. Commenced at 23.45hrs. Unit expired at 24.00hrs.</td>
</tr>
<tr>
<td>3</td>
<td>Case 62*</td>
<td>82 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms, No sequelae</td>
<td>During bedside check, nursing staff noticed component had expired. On-call medical scientist advised to proceed with the transfusion. Error discovered by TSO.</td>
</tr>
</tbody>
</table>
Unit Transfused outside expiry date/delayed transfusions

In two cases (IBCT Cases 61 and 62), units, which were issued close to expiry, were in fact not transfused until some hours after expiry. While blood stock management to avoid wastage due to outdating of units is an important aspect of laboratory practice, hospital transfusion laboratories should endeavour 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.

The AABB recommends that transfusion should be completed prior to component expiration. In individual cases where this arises, 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.

We describe one case, which illustrates this issue.

Level 3 IBCT Case 62

This elderly patient with an underlying malignancy required a non-emergency transfusion of one unit of red cells for anaemia - Hb 7.6 g/dl. During the bedside checking procedure it was noted that this unit had expired at midnight, it was now 01.30hrs. The transfusion laboratory staff was contacted and reassurance was given that it was safe to proceed with transfusion. The unit was subsequently transfused uneventfully. During a routine audit, the TSO discovered the incident. A medical scientist not normally working in the transfusion laboratory had issued this unit earlier that evening.
**Transfusion time exceeded: Table 18**

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 IBCT Case 59</td>
<td>58 yrs</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Approximately 100 mls of red cells</td>
<td>This patient developed fever shortly after the transfusion commenced, it was temporarily discontinued. Temperature returned to normal within one hour. Transfusion then recommenced.</td>
<td>5½ hours had elapsed from time of removal from controlled storage to completion of transfusion, exceeding recommended time by 1½ hours. TSO noted error during routine audit.</td>
<td></td>
</tr>
<tr>
<td>3 IBCT Case 60</td>
<td>46 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>A low-grade fever developed five hours after start of transfusion. Transfusion discontinued six hours after commencement. Neither patient nor pack cultured. The patient suffered no sequelae as a result of this incident.</td>
<td>Unit in progress for more than five hours when symptoms developed.</td>
<td></td>
</tr>
</tbody>
</table>
## Unit out of controlled temperature in excess of recommended time: Table 19

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 63</td>
<td>NA</td>
<td>N/A</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>11 units of red cells</td>
<td>All 11 units were transfused uneventfully</td>
<td>Eleven units of red cells issued by supply centre having been stored at an unacceptable temperature range for a period of over nine hours.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 64</td>
<td>52 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of red cells</td>
<td>No symptoms No sequelae</td>
<td>Unit out of controlled storage for four and a half hours by completion of transfusion. Hospital policy states blood should be transfused within four hours of removal from controlled storage. Error discovered by TSO during routine audit.</td>
</tr>
</tbody>
</table>
### Date of Birth discrepancy: Table 20

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 69</td>
<td>77 yrs</td>
<td>M</td>
<td>Group B Rh D positive</td>
<td>Group B Rh D positive</td>
<td>Three units of red cells</td>
<td>No symptoms No sequelae</td>
<td>Date of birth discrepancy on patient’s ID band identified during bedside check and repeat specimen requested. The new ID band contained the incorrect information. This was identified pre-transfusion but laboratory staff advised to proceed with transfusion.</td>
</tr>
</tbody>
</table>

### Incorrect spelling of forename: Table 21

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 70</td>
<td>27 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Four units of red cells</td>
<td>No symptoms No sequelae</td>
<td>Transcription error in laboratory created ‘new’ first name. Continued undetected throughout the transfusion process despite multiple checking procedures.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 71</td>
<td>26 yrs</td>
<td>F</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D positive</td>
<td>Three units of red cells</td>
<td>No symptoms No sequelae</td>
<td>Incorrect spelling of forename entered onto computer. Error noted by nursing staff, laboratory staff advised that transfusion could proceed.</td>
</tr>
</tbody>
</table>
### Incorrect Hospital Number: Table 22

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 Case 67</td>
<td>2 wks</td>
<td>M</td>
<td>Group A Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of paedipack - red cells for neonatal use</td>
<td>No symptoms</td>
<td>No sequelae</td>
</tr>
</tbody>
</table>
### Incorrect Factor Concentrate Administered: Table 23 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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 72*</td>
<td>12 yrs</td>
<td>M</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>3000 units (one vial) of Benefix (Factor IX) given instead of Refacto (Factor VIII).</td>
<td>No sequelae.</td>
<td>Benefix (Factor IX) requested instead of Refacto (Factor VIII). A series of multiple errors allowed the error to progress along the chain to administration, including computer system warning overridden and no formal checking procedure being carried out. The error was identified when further factor concentrate was requested some days later.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 73*</td>
<td>39 yrs</td>
<td>M</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>3000 IU units (3 vials) of Recombinate given instead of Refacto.</td>
<td>No adverse effects.</td>
<td>Patient with severe Factor VIII deficiency received 3,000 units of Recombinate in error, instead of Refacto.</td>
</tr>
</tbody>
</table>
Incorrect Factor Administered
As noted in the NHO Annual Report 2001, the risk of errors when administering factor concentrate therapy to patients is a constant hazard, particularly if staff are unfamiliar with the different products. To minimise this, secure systems need to be put in place to ensure the administration of the correct product to the correct patient. The National Centre for Hereditary Coagulation Disorders (NCHCD) has produced a standard protocol for staff administering factor concentrates. This is available from the NCHCD, located at St James Hospital, Dublin 8.

There were two cases (IBCT Cases 72 and 73), which involved the administration of the wrong product to the right patient. Both have been scored as level 1 incidents and are included as full case histories.

In one case (IBCT Case 72), computer warnings designed to avoid errors were overridden and resulted in a Factor VIII deficient patient receiving Factor IX in error. This type of incident was also reported in the NHO Annual Report 2001. In the second case, the wrong type of Factor VIII was given.

The two cases are described in detail:

Level 1 IBCT Case 72
This patient, with Factor VIII deficiency, was prescribed Refacto (Recombinant Factor VIII) in the non-emergency, in-patient setting. The request form, which was handwritten, stated Benefix (Recombinant Factor IX) in error. The laboratory computer system alerted issuing staff that this patient previously had Refacto, but the warning was overridden and Benefix was issued. It was then administered and signed by two staff nurses without formal checking for identity of product or patient, or reference to the prescription. A series of errors allowed this event to occur - the laboratory computer warning was overridden, hospital policy was not adhered to and there was no ID band in place. The error was identified when further factor concentrate was requested some days later.

Level 1 IBCT Case 73
This patient with severe Factor VIII deficiency presented with bleeding into his right knee joint. The patient normally received recombinant Factor VIII (Refacto). On this occasion 3,000 units of Refacto were prescribed. Three vials of Recombinate (also a Recombinant Factor VIII product) were removed from the storage site but signed out of the fridge as Refacto. The patient’s factor concentrate treatment sheet also documented that 3,000 units of Refacto had been administered. Bedside checking was not carried out and 3,000 units of Recombinate were given in error. The error was detected when the patient was receiving his next dose of factor concentrate. The previous batch numbers recorded were different from the Refacto batch numbers currently being administered. All three vials of Recombinate were from the same batch.
INCORRECT BLOOD COMPONENT
TRANSFUSED - INCIDENTS INVOLVING
ANTI-D IMMUNOGLOBULIN: 2002

The NHO collects administration incidents involving errors or omissions relating to anti-D or factor concentrates, as they reflect on transfusion practice. Adverse reactions to anti-D immunoglobulin or factor concentrates are reportable directly to the IMB under the Pharmacovigilance Scheme, and if received by the NHO are forwarded to them. Therefore these are not covered in this report.

Findings:
- There were 15 cases relating to anti-D immunoglobulin administration.
- None of the patients suffered any sequelae, although the period of follow up is too short to exclude sensitisation arising from delays in administration.
- Ten cases involved inappropriate administration, two (IBCT Anti-D Cases 1 and 2) of which involved anti-D being given to the wrong patient, one of whom was Rh D positive. In addition, a further three cases (IBCT Anti-D Cases 7 – 9) involved the inappropriate administration of anti-D to Rh D positive women due to failure to accurately confirm their Rh D status.
- There was one case (IBCT Anti-D Case 11) where anti-D was omitted, and in four cases (IBCT Anti-D Cases 12 – 15) there was delay in giving anti-D within the recommended 72 hour period.
- We have included one incident in which no error actually occurred to illustrate the types of problems that can arise when patients are not aware about the need for anti-D under certain circumstances during the antenatal period (IBCT Anti-D Case 15).
- Some of these incidents have led to reappraisal and changes in practice and many hospitals have developed specific anti-D guidelines to help improve practice in this area.

Clinical Area Findings:
- In two cases (IBCT Anti-D Cases 1 and 2), anti-D was administered to the wrong patient. One of these patients (IBCT Anti-D Case 1) was Rh D positive. In one case (IBCT Anti-D Case 2) the product was not checked by a second person as per hospital policy. In both cases the patients were wearing ID bands but these were not checked prior to administering the product.
- In two cases (IBCT Anti-D Cases 7 and 8), anti-D was administered inappropriately to Rh D positive women. In both of these cases, records were not checked to confirm the Rh D status of the mother prior to administration. In one case (IBCT Anti-D Case 8), there was an incorrect assumption made that the mother was Rh D negative because cord blood samples had been taken. In the other case (IBCT Anti-D Case 7), the request form had been completed incorrectly leading the laboratory to process the request as a cord blood sample and issue anti-D. Poorly
designed systems for identification of new-borns and for requesting anti-D contributed to both events.

- In three cases (IBCT Anti-D Cases 4, 6 and 10), wrong clinical reasoning lead to administration of anti-D where the patient had previously been alloimmunised. In one of these cases (IBCT Anti-D Case 6), the patient was alloimmunised but this was not detected until delivery as no antibody testing had been carried out at 28-36 weeks gestation.

- One case (IBCT Anti-D Case 9) involved a patient who had previously grouped as Rh D negative but with the use of more recent laboratory reagents was found to be Rh D positive (weak D) and therefore did not require anti-D. However, an old Rh D negative result in the patient’s medical notes was read and acted on when there were three more recent and correct results available in the same chart.

Delay - Clinical / Laboratory Interface Findings:
- Four cases involved a delay in administration within the recommended 72-hour timeframe (IBCT Anti-D Cases 12 - 15). The length of delay ranged between 24 hours and 15 days.

- Communication difficulties between the laboratory and the clinical areas were responsible in three of these cases (IBCT Anti-D Cases 12 - 14).

- In one case (IBCT Anti-D Case 14), the patient was receiving shared care between the GP and Obstetrician and an incorrectly transcribed Rh D group on admission, followed by a series of clinical and laboratory errors, led to a delay in the patient receiving anti-D until seven days post delivery.

Laboratory Area Findings:
- Three cases involved errors at laboratory level, (IBCT Anti-D Cases 3, 5 and 11). One case (IBCT Anti-D Case 11), involved a result which was incorrectly recorded on the computer system, a second case (IBCT Anti-D Case 5) was due to transposition of sample tubes and the third case (IBCT Anti-D Case 3) was where a patient was grouped incorrectly. All three of these events occurred while being processed ‘on-call’, outside normal working hours.

Recommendations:
- Each hospital should have clear policies on prescription and administration of anti-D and the management of Rh D negative women during pregnancy.

- Some hospitals monitor requirements and issue anti-D through the laboratory as they have access to both the mother and baby’s group and antibody records and the product can be issued and labelled on a named patient basis. This seems very appropriate and would reduce the risk of errors.

- Systems must be in place to ensure that there is easy access to current laboratory results, either in written or electronic format. Both the prescriber and the person administering anti-D should always check the most recent report of the patient’s Rh D and antibody screen to assess the need for the product prior to administration. Transcribed Rh D results must not be accepted; the original reports must always be consulted.
• All babies must have an ID band with a unique MRN immediately post delivery. All samples should be processed using the baby’s own unique identifying details.

• Where cord blood samples are received for processing in the laboratory and group as Rh D positive, clinical or laboratory staff should not assume that the mother is Rh D negative. The mother’s Rh D status must be confirmed before anti-D is issued.

• The BCSH guidelines state, that for successful immunoprophylaxis, anti-D should be given as soon as possible after the sensitising event, but always within 72 hours. However they also advise that if it is not given before 72 hours every effort should still be made to administer the anti-D because a dose given within 7-10 days may provide some protection.

• As all three of the laboratory errors occurred during the night, it may be prudent to process samples which lead to the issue of anti-D the following morning, when there is less risk of human error. However, this needs to be balanced against the fact that patients are now being discharged earlier following delivery so it is important that systems are in place to ensure that these patients are not missed.

• Effective communication between clinical and laboratory staff relating to antibody screening and the issuing of anti-D, both in the antenatal and postnatal period is vital in preventing errors. This is particularly important where patients are receiving shared care between their GP and Obstetrician.

• The BCSH guidelines recommend that all pregnant women should be re-tested once for group and antibody screen during 28–36 weeks gestation.
### Anti-D - Inappropriate Administration: Table 24 All cases are included as full case histories

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age and Gender</th>
<th>ABO and Rh D Group of Mother</th>
<th>ABO and Rh D Group of Baby</th>
<th>Volume of Incorrect Product Transfused</th>
<th>Summary of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 1</td>
<td>35 yrs F</td>
<td>Group O Rh D positive</td>
<td>Not applicable</td>
<td>One dose of anti-D</td>
<td>Anti-D intended for another patient on the same ward collected from laboratory and administered in error. Remote checking was carried out and ID band not checked prior to administration. Error detected immediately following administration.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 2</td>
<td>29 yrs F</td>
<td>Group A Rh D negative</td>
<td>Group A Rh D negative</td>
<td>One dose of anti-D</td>
<td>Anti-D administered to the wrong mother due to failure to crosscheck the product or to check mother’s ID band at bedside as per hospital policy.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 3</td>
<td>20 yrs F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One dose of anti-D</td>
<td>Cord blood grouped as Rh D weak positive when in fact it was group O Rh D negative. Anti-D was given unnecessarily.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 4</td>
<td>27 yrs F</td>
<td>Group AB Rh D negative (with D &amp; E antibodies)</td>
<td>Group AB Rh D positive</td>
<td>Two doses of anti-D</td>
<td>Two inappropriate doses of anti-D given. Rh D negative mother with anti-D+E antibodies throughout pregnancy. Baby grouped as Rh D positive. Mother’s antibody screen not checked. Standard dose of anti-D given, based on cord blood result. A further dose was also given five days later.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 5</td>
<td>32 yrs F</td>
<td>Group O Rh D negative</td>
<td>Group B Rh D negative</td>
<td>One dose of anti-D</td>
<td>Transposition of cord blood samples in the hospital transfusion laboratory leading to O Rh D negative mother receiving anti-D following delivery of group A Rh D negative baby.</td>
</tr>
</tbody>
</table>
### Anti-D- Inappropriate Administration: Table 24 continued

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age and Gender</th>
<th>ABO and Rh D Group of Mother</th>
<th>ABO and Rh D Group of Baby</th>
<th>Volume of Incorrect Product Transfused</th>
<th>Summary of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 6</td>
<td>36 yrs F</td>
<td>Group O Rh D negative (with c + D antibodies)</td>
<td>Group O Rh D positive</td>
<td>One dose of anti-D</td>
<td>During fourth pregnancy antibody screen was negative at booking. No further group or antibody screen taken until presenting for planned caesarean section, when antibody screen was positive for anti-c and anti-D. Cord blood grouped as O Rh D positive. Anti-D given unnecessarily.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 7</td>
<td>17 yrs F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One dose of anti-D</td>
<td>Request form and sample were sent to laboratory from a three-day-old baby. The request form was incorrectly completed, leading the laboratory to process it as a cord blood sample. A series of errors ensued which led to the administration of an unnecessary dose of anti-D.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 8</td>
<td>20 yrs F</td>
<td>Group O Rh D positive</td>
<td>Group A Rh D positive</td>
<td>One dose of anti-D</td>
<td>Anti-D given in error due to staff making an incorrect assumption that the mother was Rh D negative as they received a positive cord blood result from the baby.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 9</td>
<td>32 yrs F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One dose of anti-D</td>
<td>This patient had grouped as Rh D negative on three occasions during this pregnancy. On the fourth occasion she grouped as weak D positive and was reported as Rh D positive. This was confirmed at a reference centre. Two further Rh D positive results were obtained. However, in the postnatal ward an old report stating she was Rh D negative was read in error and anti-D was given inappropriately.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 10</td>
<td>38 yrs F</td>
<td>Group O Rh D negative with anti-C+D antibodies</td>
<td>Not Applicable</td>
<td>One Dose of anti-D</td>
<td>Anti-D administered for bleeding at 10 weeks gestation unnecessarily. Patient had already developed anti-D from a previous pregnancy. Group and antibody screen not checked on presentation. Anti-D administered on the basis of a verbal Rh D status given by the mother.</td>
</tr>
</tbody>
</table>
Anti-D Administered Inappropriately

Level 1 IBCT Anti-D Case 1
This postnatal mother, group O Rh D positive, received anti-D inappropriately. The error occurred when anti-D intended for another patient on the same ward was collected from the laboratory and delivered to the clinical area. The two midwives did not check the product at the bedside. One of the midwives then went to the bedside of the wrong patient and administered the product without checking the patient's ID band. The error was detected immediately after administration. Hospital policies and procedures relating to bedside administration have been reinforced with all staff since this event.

Level 1 IBCT Anti-D Case 2
This Rh D negative lady (Patient X) delivered a Rh D negative baby. There was another Rh D negative lady (Patient Y) on the same ward who delivered a Rh D positive baby and required anti-D. Both of these patients were wearing ID bands. The person administering the anti-D did not adhere to hospital policy and check the product with a colleague nor did he/she take written confirmation of the mother's and infant's group and Rh D status to the bedside. He/she proceeded to the bedside of Patient X and without checking the patient's ID band, administered anti-D to the wrong patient. Ward staff detected the error and the intended patient, Patient Y, then received anti-D.

Level 1 IBCT Anti-D Case 3
This mother grouped as O Rh D negative. A cord blood sample was taken from the baby post-delivery and was processed out-of-hours. The staff member processing the sample read the result incorrectly as group O Rh D positive (weak D) and anti-D was issued and administered. The error was discovered the following day during routine checking of on-call work when it was identified that the cord blood was in fact, Rh D negative and anti-D had already been given unnecessarily.

Level 1 IBCT Anti-D Case 4
This mother grouped as AB Rh D negative, antibody screen positive with anti-D and anti-E antibodies on five occasions during this pregnancy. She had developed the D and E antibodies during a previous pregnancy. Following delivery by emergency Caesarean section the cord blood was group AB Rh D positive and a standard dose of anti-D was prescribed and given despite the fact this lady had already developed anti-D. Five days later, a further dose of anti-D was prescribed and administered “to mop up any further Rh D cells that may be present”. The event was highlighted when the clinical nurse manager reported the second unnecessary dose of anti-D. Anti-D is not issued from the laboratory in this hospital but is signed out of a drug fridge in the maternity ward. New anti-D guidelines have been drawn up as a result of this event.

Level 1 IBCT Anti-D Case 5
This mother grouped as O Rh D negative. The cord blood was taken from the correct baby and labelled correctly but as the delivery was outside normal working hours, the sample was processed on-call. Due to an error in the laboratory, transposition of sample tubes occurred in the rack and the baby’s sample tube got switched with another tube. As a result this baby was reported to be Group B Rh D positive and anti-D was given to the mother accordingly. The error was discovered the following morning during routine retrospective checking of all on-call work in the laboratory. The baby was re-grouped as group B Rh D negative. This mother had received an unnecessary dose of anti-D by this time.
Level 1 IBCT Anti-D Case 6
This lady, having her fourth baby was having combined care between her obstetrician and the GP. On the first antenatal visit to the hospital the lady grouped as O Rh D negative, antibody screen negative. There was no further group and antibody screen performed until the lady presented for elective Caesarean section. On this occasion the antibody screen was positive for anti-c and anti-D antibodies. The baby’s cord blood group was O Rh D positive, and showed evidence of mild haemolytic disease. Anti-D was then prescribed and administered to the mother based on the cord blood group, although the patient was already alloimmunised. There are no transfusion guidelines on the use of anti-D in this hospital. As a result of this incident the development of such guidelines is being discussed.

Level 1 IBCT Anti-D Case 7
This lady grouped as O Rh D positive on admission and the written report of this was recorded correctly on the patient’s medical record. No cord blood was taken post delivery, as it was not indicated. Three days later due to worsening jaundice, bloods were taken from the baby who was being nursed in the neonatal unit. The request form was inaccurately completed, and was labelled “baby of ” which would normally indicate to the laboratory a cord blood sample, not a routine sample from a three-day-old baby. The baby’s MRN was not recorded either on the sample tube or on the request form as hospital policy states that only sick babies who require intervention receive an MRN. ‘Jaundice’ was stated on the form as the indication for the test. The medical scientist processing the sample did not regularly work in the transfusion laboratory and processed the sample as a cord blood sample. Hence the result was delivered to the postnatal ward and not to the neonatal unit. The result read “Cord blood - Group O Rh D positive, DAT negative”. The midwives receiving the report assumed the mother of this baby to be Rh D negative and were anxious to administer anti-D as it was nearing the recommended 72-hours. Anti-D was then prescribed and administered without confirming the mother’s Rh D status. The following day the midwives realised their error and reported the incident to the TSO. Complete review of the protocol for administration of anti-D and identification of neonates in this hospital has occurred since this event. All babies are now issued with their own unique MRN number, and all blood samples from the baby are processed using only the baby’s details, not the mother’s.

Level 1 IBCT Anti-D Case 8
When this Rh D positive mother gave birth, the medical record was unavailable, so a temporary medical record was in use. The only record of the mother’s group and Rh D status in this temporary file was a hand-written note stating that the mother was Rh D positive. In order to confirm that this result was correct a repeat sample was taken and sent to the laboratory along with a cord blood sample from the baby in case the positive result turned out to be incorrect. The samples were processed and the mother again grouped as Rh D positive. The laboratory telephoned the result of the baby’s cord blood, which was group A Rh D positive, to the ward. The clinical staff taking the call presumed incorrectly that as they were receiving a Rh D positive cord blood result, the mother must be Rh D negative. Without either medical or nursing staff checking the mother’s Rh D status, anti-D was then prescribed and administered. A doctor noted the error when examining the mother and baby prior to discharge. A new hospital prescription and administration record sheet has been devised since this incident, stating that an official copy of both the mother and baby’s blood group must be seen before prescribing anti-D.
Level 1 IBCT Anti-D Case 9
On three occasions during her pregnancy this lady grouped as O Rh D negative at this hospital. On the fourth occasion, using different technology, she grouped as O Rh weak D and was reported as Rh D weak positive. This Rh D status was confirmed at a reference centre. Two further Rh D positive results were subsequently obtained. The baby was delivered and also grouped as Rh D positive. However, prior to discharge from the delivery suite, clinical staff checked the woman’s Rh D status from an old report, which stated that she was Rh D negative and administered anti-D. The error was discovered later that day by ward staff reading the mother’s medical notes; the three most recent reports were then seen, confirming the mother to be Rh D positive. Policy in this hospital allows midwives to administer anti-D within agreed written protocols. The laboratory does not issue the anti-D and clinical staff collect it with no patient specific label attached when required.

Level 1 IBCT Anti-D Case 10
This Rh D negative patient presented to the A&E department at 10 weeks gestation with bleeding, abdominal cramps and pain. The notes from previous admissions were not available but the woman stated that she was Rh D negative. The doctor then prescribed and administered anti-D on this verbal result without checking any historical records. A group and antibody screen was not performed. The following week she presented to the antenatal clinic where a routine group and screen was performed. Historical records in the laboratory for this patient were then seen showing that the patient had anti-D and anti-C detected since 1996 and identified that an unnecessary dose of anti-D had been given. Several problems have been highlighted as a result of this incident. There were no written guidelines for the administration of anti-D, or for the management of Rh D negative women during pregnancy in this hospital. Anti-D was not issued by the laboratory, but a small stock was kept in the maternity wards. Having access to old medical records at all times could also have averted this event. BCSH guidelines currently do not recommend use of anti-D where there is bleeding in the first trimester with a viable pregnancy as shown by ultrasound\textsuperscript{17}. However, the use of anti-D may be prudent where bleeding is heavy or repeated, or where it is associated with abdominal pain, particularly if the event occurs when gestation is approaching 12 weeks\textsuperscript{17}. 
### Anti-D not administered: Table 25 All cases are included as full case histories

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age and Gender</th>
<th>ABO and Rh D Group of Mother</th>
<th>ABO and Rh D Group of Baby</th>
<th>Summary of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 11</td>
<td>31 yrs F</td>
<td>Group O Rh D negative</td>
<td>Not applicable</td>
<td>This woman’s Rh D negative group and antibody screen result was incorrectly recorded on the computer system as Rh D positive. Error identified and corrected on computer by laboratory staff the following morning when checking on-call work but not communicated to clinical staff, leading to omission of prophylactic anti-D.</td>
</tr>
</tbody>
</table>
Delay in Administering Anti-D: Table 26 All cases are included as full case histories

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age and Gender</th>
<th>ABO and Rh D Group of Mother</th>
<th>ABO and Rh D Group of Baby</th>
<th>Time period between birth &amp; administration of Anti-D</th>
<th>Summary of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 12</td>
<td>32 yrs F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D positive</td>
<td>15 days</td>
<td>Failure to administer anti-D following intrauterine death at 28 weeks due to a breakdown of communication between clinical staff. Anti-D administered 15 days later when mother was readmitted for delivery of the stillborn infant.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 13</td>
<td>37 yrs F</td>
<td>Group A Rh D negative</td>
<td>Group O Rh D positive</td>
<td>96 hrs</td>
<td>Anti-D issued from transfusion laboratory and clinical area informed. Due to system errors the anti-D was not collected or prescribed. Daily checking procedure failed to identify that anti-D had not been given. Error identified by laboratory staff four days post delivery.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Anti-D Case 14</td>
<td>36 yrs F</td>
<td>Group O Rh D negative</td>
<td>Group O Rh D positive</td>
<td>7 days</td>
<td>Due to incorrect Rh D results being transcribed onto a handwritten note, anti-D not administered until seven days post delivery. Error discovered at discharge when lady informed midwife that she had received anti-D following a previous pregnancy.</td>
</tr>
<tr>
<td>N/A</td>
<td>IBCT Anti-D Case 15</td>
<td>24 yrs F</td>
<td>Group O Rh D negative</td>
<td>Not applicable</td>
<td>12 days</td>
<td>Anti-D given 12 days following antenatal bleed as lady left hospital against medical advice prior to results being made available. This may have been due to lack of knowledge on the patient’s behalf about the importance of receiving anti-D, following certain circumstances, during pregnancy.</td>
</tr>
</tbody>
</table>
Failure to Administer Anti-D

Level 1 IBCT Anti-D Case 11
This antenatal woman, eight to ten weeks gestation, was admitted with vaginal bleeding. She was correctly grouped (on-call) as O Rh D negative but the result was incorrectly recorded on the computer system as group O Rh D positive. Evacuation of retained products of conception was necessary and the patient, who was aware of her Rh D status, queried if she was to receive anti-D. Nursing staff accessed and printed the result from the computer while the incorrect data was on the system and hence advised that this would not be necessary. The following day, when checking on-call work, laboratory staff identified the error and corrected the information on the system, but failed to communicate the corrected result to the clinical staff. Following discharge from hospital, the woman again queried her Rh D status with the hospital laboratory, explaining that she had beenRh D negative in the past. This information prompted an investigation and the error was identified. A clinical decision was made not to administer anti-D at this point, due to the low risk of sensitisation in early pregnancy. The availability of unauthorised results via the computer system to clinical staff is under review in this hospital as a result of this event.

Delay in Administering Anti-D

Level 1 IBCT Anti-D Case 12
This Rh D negative woman experienced an intrauterine death at 28 weeks. A sample was sent, out-of-hours, to the laboratory for group and antibody screen with a request form for Kleihauer testing but with no accompanying sample. For reasons that remain unclear, the sample was stored for routine work on Monday morning. The senior medical scientist processing the sample contacted the ward to inform them that the patient had grouped as Rh D negative. He/she indicated that this lady should receive anti-D and would also need a sample for Kleihauer testing as he had previously received a request form with no accompanying sample. Later that afternoon when the senior medical scientist had still not received any request for anti-D or a sample for Kleihauer testing he/she again contacted the ward to find that the patient had been discharged earlier that day. It was now 72 hours post possible sensitisation. On investigation it was discovered that this incident occurred due to a breakdown of communication between the multidisciplinary team. Following the delivery of the stillborn infant 15 days later a request for anti-D was received. This incident has prompted a review of hospital guidelines.

Level 2 IBCT Anti-D Case 13
This Rh D negative lady delivered a Rh D positive baby. On day one postpartum, laboratory staff informed the clinical area of the positive result and issued anti-D for the mother, outside of normal working hours. Practice in this hospital is for ward staff to collect the anti-D from the laboratory and then arrange for medical staff to prescribe it. However, on this occasion the anti-D was not collected and was not prescribed. It is also practice in this hospital for staff to check the medical notes of all patients on a daily basis to confirm the Rh D status and ensure Rh D negative patients receive anti-D appropriately. However on this occasion this practice was not adhered to and the omission was not identified. On day four postpartum, the laboratory staff noticed that the anti-D for this patient had not been collected. The postnatal ward were informed and the anti-D was given at 96 hours post delivery, i.e. 24 hours outside the recommended 72-hour administration time frame. As a result of this incident anti-D is now routinely prescribed prior to collection form the laboratory in this hospital.
Level 1 IBCT Anti-D Case 14
This lady was having combined care between her GP and consultant obstetrician. The GP took the booking bloods, which were sent to the hospital, for processing and was grouped as O Rh D negative. This result was correctly recorded in the GP notes. The lady saw both her obstetrician and her GP during the remainder of her pregnancy. On presenting to the hospital for an elective Caesarean section she gave the midwife a letter from her GP with a ‘post it’ note stating her ABO and Rh D group. The Rh D result had been incorrectly transcribed as Rh D positive on the note. It remains unclear whether the transcription error occurred in the GP surgery or in the obstetrician’s rooms. The midwife then transcribed the incorrect result from the ‘post it’ note onto all the documentation for the labour ward. A repeat group and antibody screen was taken on admission but for reasons which remain unclear, the laboratory report was not received by the ward until seven days post delivery. The lady gave birth to a Rh D positive baby but anti-D was not administered, as the staff believed her to be Rh D positive. The error was discovered just prior to discharge, when the lady informed the midwife that she had received anti-D following a previous pregnancy and queried if she needed it on this occasion. Repeat sampling and historical records confirmed that the lady was in fact Rh D negative and anti-D was administered seven days post delivery.

IBCT Anti-D Case 15
This woman presented to the A&E Department at 19 weeks gestation with vaginal spotting. This lady had already booked for antenatal care at another hospital and had not been to this hospital before, so there were no historical records available. Following medical assessment a blood sample was taken to determine the blood group and Rh D status and the need for anti-D prophylaxis. The woman would not wait for the results and left the hospital against medical advice. She subsequently grouped as O Rh D negative and was contacted with the result and the need for anti-D prophylaxis. The woman’s husband assured the midwife that he would take his wife to her original booking hospital as soon as possible to have the anti-D administered. However, she did not go to her booking hospital and therefore did not receive anti-D prophylaxis. The omission was discovered when the lady presented to her booking hospital for a routine antenatal appointment 12 days later and informed the staff of the vaginal bleed and the fact she had not received the anti-D that had been recommended by this hospital. The anti-D was then given, 12 days after the possible sensitising event.

We describe this incident not because any error occurred in either of the hospitals but to illustrate problems that can arise. All Rh D negative women should be given information at booking about the need for anti-D under certain circumstances during the antenatal period and post delivery.

The manufacturers of anti-D issue a patient information leaflet explaining about Rh D groups and Rh haemolytic disease. This, or similar information leaflets, should be available and distributed in all maternity units.
SEVERE ACUTE ANAPHYLACTOID OR ANAPHYLACTIC TRANSFUSION REACTION: 2002

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.

This category accounted for 20% (31 of 155) of incidents reported during this reporting year. In most cases the symptoms described were not considered severe and patients usually recovered without sequelae within a short time frame. For the purposes of this report all incidents have been included in the tables. In addition, a number of individual cases are described in full.

Findings:

• There were 31 reports received in total. Of these 18 (58%) were due to platelet transfusions, seven (23%) were due to red cell transfusions and five (16%) to plasma transfusions. Of the plasma transfusion reactions, three were associated with FFP and two with SD treated plasma. There was one case (Case 5) where multiple components were transfused during a massive transfusion setting and it is unclear which component caused the reaction.

• In one case (Case 28) it is unclear if the symptoms are related to an anaphylactoid transfusion reaction or to volume overload and/or underlying illness.

• The number of reactions reported associated with plasma, five in total, has decreased when compared with previous years. This may reflect the introduction of SD treated plasma in March 2002. SD treated plasma is a pooled virally inactivated frozen plasma product sourced from the United States of America. It is made from an SD treated pool size of 1500 donors and appears to be associated with reduced numbers of acute transfusion reactions due to the dilution of allergic proteins from individual donors during the pooling process. Plasma pooling also reduces human leucocyte antibody (HLA) levels to below detectable limits.

• Most of the reactions reported were associated with platelet concentrates, 18 out of 31 reports (58%). Thirteen of these (72%) were associated with pooled platelet concentrates. These reactions appear to be related to the presence of chemokines/cytokines in stored platelets and allergens in donor plasma.

• Of the 18 reports associated with platelets, six had anaphylactoid/anaphylactic symptoms which were not accompanied by rash (Cases 4, 17, 20, 29, 30 and 31). In three of these cases (Cases 4, 17 and 20) the symptoms were consistent with allergic/anaphylactoid reactions with the presence of wheeze, stridor, and/or chest tightness. In the other three cases, (Cases 29 - 31) the features were more in
keeping with symptoms of a severe acute non-haemolytic transfusion reaction. In one of these cases, (Case 30) there was an underlying sepsis, not related to transfusion. In all three cases there was no evidence of bacterial contamination of the unit following culture and the patients recovered with no ill effects. Each of these patients has been subsequently transfused with pre-medication cover uneventfully.

- During this reporting year, more female patients experienced allergic/anaphylactoid transfusion reactions than did male patients. There were 20 (65%) female patients and 11 (35%) male patients.

- Eighteen (58%) of the patients who suffered an allergic/anaphylactoid transfusion reaction were transfusion-dependent secondary to malignant disease and were on multiple medications including multiple IV antibiotics and/or chemotherapy. This can make it difficult to be certain what caused the reaction.

- IgA deficiency with anti IgA antibodies can cause severe anaphylactoid reactions and anaphylaxis. In the 11 cases where IgA levels were checked they were found to be normal. There was one further case (Case 13) where IgA levels were found to be low, but the patient was receiving immunosuppressant therapy when the levels were checked. From the perspective of transfusion medicine practice, only persons with serum IgA <0.05g/dl can be considered IgA deficient31.

- In one case (Case 8) the patient had a history of bee sting anaphylaxis. In another (Case 14), the patient had a history of multiple medication allergies. Two cases involved patients with a history of asthma (Cases 19 and 25) and there was one case (Case 12) where the patient had a medication allergy and had also experienced a reaction to a red cell transfusion following the birth of her child, many years previously.

- In 19 cases (61%) an early response to chlorpheniramine and/or steroids was documented. However, in two cases (Cases 9 and 27) recovery was delayed up to 24 hours, and in one case (Case 24), full recovery took 48 hours. There was one further case (Case 22) where adrenaline was required to control the symptoms.

- Five patients (16%) required washed platelets as a result of anaphylactoid/anaphylactic reactions.

- There was an additional case of anaphylactoid transfusion reaction recorded in the IBCT category (IBCT Case 39).

- One of the plasma transfusions was inappropriate and Vitamin K should have been prescribed (Case19).
Recommendations:

- Most allergic/anaphylactic transfusion reactions respond to chlorpheniramine and steroids. However more severe reactions may require use of adrenaline (as in Case 22).

- Protocols for management of severe allergic/anaphylactoid reactions should be in place in each hospital (See Appendix 4).

- IgA deficiency with anti IgA antibodies can cause severe anaphylactoid reactions and anaphylaxis. Since the transfused product may contain appreciable quantities of IgA, where possible, samples taken pre-transfusion should be used to check for IgA levels.

- Prophylaxis should be given if there is a previous history of allergy or reactions. As reactions are more common with pooled platelets than with apheresis platelets, apheresis platelets should be used whenever possible in patients with a previous history of reactions to platelets.

- Where there is a previous history of anaphylaxis, the patient will require specialist haematology and immunology support, including washing of the component, if further transfusion is required.

- Washed components for the management of allergic reactions are only appropriate for patients with a history of anaphylactic or severe anaphylactoid transfusion reactions. A poorly justified requirement for washed components may cause serious, 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 \textit{in vivo} incremental rises\(^3\).

- Classical allergic or anaphylactoid reactions do not routinely require culture of the patient or component pack. However, where the symptoms are not classical, culture of patient and pack to exclude sepsis should be undertaken (as in Case 30). This is particularly important where platelets are involved, as they are stored at room temperature and have a greater risk of bacterial contamination.

- Adherence to guidelines for the use of components in particular for the use of plasma will avoid unnecessary reactions (Appendix 1).
Anaphylactoid/Anaphylactic Transfusion Reaction to Platelets: Table 27 * Included as a full case history

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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>55 yrs F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to malignant haematological disorder and sepsis. Platelet count - 35x10^9/L.</td>
<td>Urticaria, dyspnoea, restlessness and anxiety. Vital signs remained stable.</td>
<td>IgA level normal.</td>
<td>Following completion of transfusion.</td>
<td>Pre-medicated with IV chlorpheniramine. Oral morphine given with relief of symptoms.</td>
<td>Recovered with no ill effects. Pre-medication cover given prior to next transfusion with no effect. Subsequent transfusions with washed platelets have been uneventful.</td>
</tr>
<tr>
<td>AA Case 2*</td>
<td>39 yrs F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to haematological disorder. Invasive procedure planned. Platelet count 15x10^9/L.</td>
<td>Urticaria, stridor, wheeze, cyanosis, flushing and facial oedema.</td>
<td>Pack cultured - no organisms isolated. Patient not cultured. IgA level not checked. Lungs clear on chest x-ray.</td>
<td>Following completion of transfusion.</td>
<td>Pre-medicated with IV chlorpheniramine 10 mgs. Repeat IV chlorpheniramine 10 mgs and hydrocortisone 100 mgs given with effect.</td>
<td>Patient recovered with no ill effects. Subsequent platelet transfusions with a pre-medication of chlorpheniramine have been uneventful.</td>
</tr>
</tbody>
</table>
### Anaphylactoid/Anaphylactic Transfusion Reaction to Platelets: Table 27 Continued

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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>Sequelea/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 4*</td>
<td>31 yrs F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to malignant haematological disorder – platelet count 28x10⁹/L.</td>
<td>Dyspnoea, stridor, wheeze, restlessness, anxiety, chest tightness, hypertension and tachycardia.</td>
<td>Patient cultured – no organisms isolated. Unit cultured - negative. IgA level normal.</td>
<td>During transfusion when almost 200 mls had transfused.</td>
<td>Transfusion discontinued. IV hydrocortisone, chlorpheniramine and Salbutamol nebulizer given with relief of, symptoms within two hours.</td>
<td>Recovered with no ill effects. Subsequent transfusions of apheresis platelet concentrate with pre-medication of IV chlorpheniramine and hydrocortisone have been uneventful.</td>
</tr>
<tr>
<td>AA Case 8*</td>
<td>70 yrs F</td>
<td>Two units of pooled platelet concentrate.</td>
<td>Thrombocytopenia of unknown origin - platelet count 22x10⁹/L.</td>
<td>Urticaria, hypertension, dyspnoea, stridor, wheeze and facial swelling.</td>
<td>IgA level normal.</td>
<td>During second unit when more than 100 mls had transfused.</td>
<td>Transfusion discontinued. IV hydrocortisone and chlorpheniramine given with effect.</td>
<td>Recovered with no ill effects, and has since been referred to a specialist haematology centre. No further transfusions have been required to date.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age and Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Stage Transfusion Reaction developed</td>
<td>Treatment</td>
<td>Sequeleae/Recommendations for future transfusions</td>
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</tr>
<tr>
<td>AA Case 9</td>
<td>61 yrs F</td>
<td>One unit of apheresis platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder – platelet count 8x10⁹/L.</td>
<td>Urticaria, dyspnoea, restlessness anxiety and weakness of upper limbs.</td>
<td>Patient and pack cultured – no organisms isolated. IgA level normal.</td>
<td>During transfusion when less than 100 mls had transfused.</td>
<td>Due to a history of similar reactions a pre-medication of hydrocortisone &amp; chlorpheniramine had been given. Transfusion discontinued. Repeat IV hydrocortisone &amp; chlorpheniramine given with effect.</td>
<td>Recovered with no ill effects within 24 hours. Subsequent transfusion with washed platelets and pre-medication cover has been uneventful.</td>
</tr>
<tr>
<td>AA Case 10*</td>
<td>6 yrs F</td>
<td>One unit of apheresis platelet concentrate.</td>
<td>Thrombocytopenia secondary to a haematological disorder and underlying sepsis - platelet count 18x10⁹/L.</td>
<td>Urticaria, dyspnoea, restlessness, anxiety and facial and tongue swelling. Falling pO₂ – 84% in room air.</td>
<td>IgA levels were not checked.</td>
<td>Transfusion was almost complete.</td>
<td>Transfusion discontinued. IV hydrocortisone &amp; chlorpheniramine given. Nasal oxygen given with relief of symptoms.</td>
<td>IgA levels to be checked if future transfusions are required.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age and Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
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<td>Treatment</td>
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</tr>
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</tr>
<tr>
<td>AA Case 12</td>
<td>61 yrs F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopaenia secondary to malignancy - platelet count 19x10⁹/L.</td>
<td>Urticaria, dyspnoea, wheeze, falling pO₂, restlessness, anxiety and angioedema.</td>
<td>Unit cultured – no organisms isolated. Patient not cultured. IgA level normal.</td>
<td>During transfusion when more than 100 mls had transfused.</td>
<td>Transfusion discontinued. IV hydrocortisone &amp; chlorpheniramine given. Nebulisers also given.</td>
<td>Symptoms resolved within two hours. Subsequent red cell transfusions with antihistamine cover have been uneventful. Apheresis platelet concentrate with antihistamine cover has been recommended for future transfusions – no platelet transfusions needed to date.</td>
</tr>
<tr>
<td>AA Case 13</td>
<td>29 yrs F</td>
<td>One unit of apheresis platelet concentrate.</td>
<td>Thrombocytopaenia secondary to a haematological disorder – platelet count less than 10x10⁹/L.</td>
<td>Urticaria and a burning sensation on skin.</td>
<td>IgA level 0.37g/l - checked while on immuno-suppressive therapy.</td>
<td>Following completion of the transfusion.</td>
<td>Pre-medication of chlorpheniramine had been administered. IV hydrocortisone and chlorpheniramine repeated.</td>
<td>There was a full recovery within 12 hours. Subsequent transfusions of washed apheresis platelets with a pre-medication of chlorpheniramine have been uneventful.</td>
</tr>
</tbody>
</table>
### Anaphylactoid/Anaphylactic Transfusion Reaction to Platelets: Table 27 Continued

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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 15</td>
<td>47 yrs M</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder.</td>
<td>Urticaria, hypotension dyspnoea, wheeze, substernal discomfort, chills and nausea.</td>
<td>Patient cultured - staphylococcus epidermidis which had been present pre-transfusion. Pack not cultured. IgA levels not checked. On multiple concomitant medications.</td>
<td>During and following the transfusion.</td>
<td>Transfusion initially slowed and IV chlorpheniramine given. Symptoms resolved, and transfusion recommenced. Symptoms recurred once transfusion complete.</td>
<td>Symptoms resolved within three hours with no sequelae. Subsequent transfusions of both pooled and apheresis platelets following pre-medication of chlorpeniramine have been uneventful.</td>
</tr>
<tr>
<td>AA Case 16</td>
<td>75 yrs F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to sepsis and underlying illness platelet count – 19x10⁹/L.</td>
<td>Urticaria and erythematous rash, hypotension - 80/42 mmHg - and low grade fever - 37.5°C.</td>
<td>Patient cultured – staphylococcus aureus (MRSA) isolated, which had been present pre-transfusion. Unit not cultured. IgA levels were not checked.</td>
<td>Following completion of transfusion.</td>
<td>IV hydrocortisone 100 mgs 8 hourly.</td>
<td>Patient was extremely ill and subsequently died unrelated to transfusion.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age and Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Stage Transfusion Reaction developed</td>
<td>Treatment</td>
<td>Sequelea/Recommendations for future transfusions</td>
</tr>
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</tr>
<tr>
<td>AA Case 17</td>
<td>26 yrs M</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder - platelet count $14 \times 10^9/L$.</td>
<td>Dyspnoea with falling $pO_2$. Chest pain and tightness with tachycardia.</td>
<td>Neither patient nor unit cultured. IgA level not checked.</td>
<td>During transfusion when less than 50 mls had transfused.</td>
<td>Transfusion discontinued temporarily. IV hydrocortisone &amp; chlorpheniramine given. Transfusion then recommenced and completed without further symptoms.</td>
<td>Recovered with no sequelae. No further platelet transfusions required. It has been recommended that apheresis platelet concentrate be transfused if needed.</td>
</tr>
<tr>
<td>AA Case 20</td>
<td>18 yrs F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder – platelet count $56 \times 10^9/L$.</td>
<td>Dyspnoea, apprehension, substernal discomfort, nausea and vomiting.</td>
<td>Both patient and unit cultured – no organisms isolated. IgA levels not checked.</td>
<td>Following completion of the transfusion.</td>
<td>Due to history of allergic transfusion reactions a pre-medication of chlorpheniramine had been given. Unable to confirm what treatment was given following this episode.</td>
<td>Recovered with no sequelae and received further transfusion of red cells uneventfully.</td>
</tr>
</tbody>
</table>
### Anaphylactoid/Anaphylactic Transfusion Reaction to Platelets: Table 27 Continued

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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 21</td>
<td>18 yrs M</td>
<td>One unit of apheresis platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder - Platelet count &lt;10 x 10⁹/L.</td>
<td>This was the 4⁰th episode of urticaria following platelet transfusions despite pre-medication with antihistamine and hydrocortisone.</td>
<td>IgA levels not checked.</td>
<td>Following completion of transfusion.</td>
<td>Had been pre-medicated with hydrocortisone &amp; chlorpheniramine due to history of urticarial reaction to platelets. No further treatment given.</td>
<td>Subsequent transfusions with washed platelets and an antihistamine pre-medication have been uneventful.</td>
</tr>
<tr>
<td>AA Case 26</td>
<td>18 yrs F</td>
<td>One unit pooled platelet concentrate.</td>
<td>Thrombocytopaenia secondary to a haematological disorder - platelet count 16x10⁹/L.</td>
<td>This was the 3rd episode of urticaria following platelet transfusions despite pre-medication with antihistamine.</td>
<td>IgA level was not checked.</td>
<td>Following completion of transfusion.</td>
<td>Had been premedicated with antihistamine due to history of urticarial reaction to platelets. IV hydrocortisone given for relief of symptoms.</td>
<td>Subsequent transfusions with washed platelets and an antihistamine pre-medication have been uneventful.</td>
</tr>
<tr>
<td>AA Case 27</td>
<td>8 yrs F</td>
<td>One unit pooled platelet concentrate.</td>
<td>Thrombocytopaenia secondary to malignancy – platelet count 9x10⁹/L.</td>
<td>Urticaria, fever (38.5°C), rigors and tachycardia.</td>
<td>Central line cultured - no organisms isolated. Pack not cultured. IgA levels not checked. No red cell or HLA antibodies detected.</td>
<td>Following completion of transfusion.</td>
<td>IV hydrocortisone and chlorpheniramine.</td>
<td>Recovered with no ill effects within one day. Subsequent transfusions have been uneventful.</td>
</tr>
</tbody>
</table>
Anaphylactoid/Anaphylactic Transfusion Reaction to Platelets: Table 27 Continued

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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>Sequeleae/ Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 29*</td>
<td>46 yrs M</td>
<td>One unit of apheresis platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder – platelet count 17x10^9/L.</td>
<td>Dyspnoea, chills, rigors and bradycardia.</td>
<td>Patient not cultured. Pack cultured – no organisms isolated. Post transfusion IgA level normal.</td>
<td>15 minutes following completion of transfusion.</td>
<td>IV pethedine and oxygen were given with relief of symptoms.</td>
<td>Recovered within one hour. Subsequent transfusions with antihistamine cover have been uneventful.</td>
</tr>
<tr>
<td>AA Case 30*</td>
<td>52 yrs M</td>
<td>One unit pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder – platelet count 28x10^9/L.</td>
<td>Fever (38.1°C), rigors, tachycardia, dyspnoea and coughing with falling pO₂.</td>
<td>Both patient and pack cultured – no organisms isolated. Chest x-ray clear. Pre-transfusion IgA levels within normal levels.</td>
<td>During transfusion when less than 50 mls had been transfused.</td>
<td>Transfusion discontinued. Oral paracetamol, IV chlorpheniramine and nasal oxygen given with effect.</td>
<td>Patient recovered with no ill effects. Subsequent transfusions with pre-medication cover have been uneventful.</td>
</tr>
<tr>
<td>AA Case 31</td>
<td>76 yrs M</td>
<td>Two units of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to a malignant haematological disorder – platelet count 8x10^9/L.</td>
<td>Facial flushing, rigor, nausea and tachycardia.</td>
<td>Both patient and unit cultured – no organisms isolated. IgA level not checked.</td>
<td>During transfusion when more than 100 mls of second unit had transfused.</td>
<td>Transfusion discontinued. Hydrocortisone 100 mgs given IV.</td>
<td>Patient recovered with no ill effects. Subsequent transfusions with chlorpheniramine as pre-medication have been uneventful.</td>
</tr>
</tbody>
</table>
Anaphylactoid/Anaphylactic Transfusion Reaction to Red Cells: Table 28 * Included as a full case history

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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>Sequeleae/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 7</td>
<td>53 yrs F</td>
<td>Red cells.</td>
<td>Anaemia of chronic illness and sepsis - Hb 6.8 g/dl.</td>
<td>Restlessness, anxiety, stridor, wheeze, nausea, hypertension and fever rise of greater than 2°C.</td>
<td>Patient cultured – no organisms isolated. Pack not cultured. Incompatible transfusion excluded. IgA level not checked.</td>
<td>During transfusion when more than 100 mls had transfused.</td>
<td>Transfusion discontinued. Metoclopramide 10 mgs and midazalam 2 mgs given IV. Paracetamol 1 gr and zydol 50 mgs given orally.</td>
<td>Recovered with no ill effects. Unclear if symptoms relate to transfusion or underlying illness. Difficult crossmatch due to the presence of multiple antibodies pre-transfusion. No further transfusions required.</td>
</tr>
<tr>
<td>AA Case 11*</td>
<td>66 yrs M</td>
<td>Two units of red cells.</td>
<td>Anaemia secondary to post operative sepsis – Hb 8.5g/dl.</td>
<td>Fever, extensive rash and poor incremental rise immediately following transfusion.</td>
<td>Pack cultured, no organisms isolated. Incompatible transfusion excluded although post-transfusion DAT positive but no antibodies detected.</td>
<td>40 minutes following completion of transfusion.</td>
<td>IV chlorpheniramine.</td>
<td>Patient recovered with no ill effects. No further transfusions required.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age and Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Stage Transfusion Reaction developed</td>
<td>Treatment</td>
<td>Sequeleae/Recommendations for future transfusions</td>
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<tr>
<td>AA Case 22*</td>
<td>73 yrs F</td>
<td>Two units red cells.</td>
<td>Intraoperative bleed.</td>
<td>Extensive urticaria, hypotension, tachycardia and wheeze with associated increased airway pressure and decreased tidal volume.</td>
<td>IgA levels within normal limits. Chest x-ray clear.</td>
<td>Immediately following completion of second unit.</td>
<td>Salbutamol nebuliser via endotracheal tube. IV fluids and IV adrenaline hydrocortisone and chlorpheniramine.</td>
<td>Patient recovered from this event with no sequelae. To be transfused with caution and pre-medication cover if future transfusions needed.</td>
</tr>
<tr>
<td>AA Case 23*</td>
<td>31 yrs M</td>
<td>One unit of red cells.</td>
<td>Anaemia secondary to trauma - Hb 6.2g/dl.</td>
<td>Urticaria, chills, fever and tachycardia.</td>
<td>Patient cultured no organisms isolated. Unit not cultured. IgA levels not checked.</td>
<td>During the transfusion when more than 100 mls had transfused.</td>
<td>Transfusion discontinued. Paracetamol only given.</td>
<td>Patient recovered from this event with no sequelae. No further transfusions required.</td>
</tr>
<tr>
<td>AA Case 24*</td>
<td>15 yrs F</td>
<td>One unit of red cells.</td>
<td>Post-operative anaemia - Hb 5.9g/dl.</td>
<td>Urticaria and periorbital oedema.</td>
<td>Both patient and pack cultured, no organisms isolated. IgA levels within normal limits.</td>
<td>During the first 15 minutes of transfusion when less than 100 mls had transfused.</td>
<td>Transfusion discontinued. Chlorpheniramine given orally.</td>
<td>Patient recovered from this event with no sequelae. No further transfusions required.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age and Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Stage Transfusion Reaction developed</td>
<td>Treatment</td>
<td>Sequelae/Recommendations for future transfusions</td>
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<tr>
<td>AA Case 25*</td>
<td>65 yrs F</td>
<td>One unit of red cells.</td>
<td>Anaemia associated with sepsis - Hb 7.3g/dl.</td>
<td>Fever, hypertension, increased airway pressure and pulmonary hypertension.</td>
<td>Pack cultured-no organisms isolated. Patient cultured - staphylococcus epidermis isolated, not transfusion related. Incompatible transfusion excluded. Chest x-ray showed no new changes. IgA level not checked.</td>
<td>During transfusion when more than 100 mls had transfused.</td>
<td>Transfusion discontinued. Glyceryl trinitrite (GTN) infusion and paracetomol.</td>
<td>Subsequent transfusions of standard red cells have been uneventful.</td>
</tr>
<tr>
<td>AA Case 28</td>
<td>70 yrs F</td>
<td>One unit of red cells.</td>
<td>Anaemia of malignancy - Hb 7.7 g/dl.</td>
<td>Dyspnoea.</td>
<td>Incompatible transfusion excluded. Neither patient nor pack cultured. IgA levels not checked.</td>
<td>During transfusion when less than 100 mls had transfused.</td>
<td>Transfusion discontinued. Hydrocortisone and chlorpheniramine given IV with effect.</td>
<td>Patient subsequently died of underlying condition, not related to transfusion.</td>
</tr>
</tbody>
</table>
### Anaphylactoid/Anaphylactic Transfusion Reaction to Plasma: Table 29 *Included as a full case history*

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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>Sequeleae/Recommendations for future transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 3</td>
<td>37 yrs M</td>
<td>One unit of FFP.</td>
<td>Hypogammaglobulinaemia requiring monthly plasma transfusions.</td>
<td>Dyspnoea, stridor, wheeze, shivering and facial flushing.</td>
<td>Neither patient nor pack cultured. IgA levels not checked.</td>
<td>During transfusion when more than 100 mls had been transfused.</td>
<td>Pre-medication not given. Transfusion discontinued. Oral prednisolone and chlorpheniramine given but not tolerated. IV hydrocortisone and chlorpheniramine given with effect.</td>
<td>Recovered with no ill effect. This patient has since been successfully treated with gammaglobulin and has not required plasma transfusions.</td>
</tr>
<tr>
<td>AA Case 6*</td>
<td>43 yrs F</td>
<td>Two units of SD treated plasma.</td>
<td>Plasma exchange for thrombotic thrombocytopenic purpura (TTP).</td>
<td>Urticarial rash, anxiety and restlessness.</td>
<td>Pre transfusion IgA levels within normal limits.</td>
<td>Within first 15 minutes of procedure.</td>
<td>Procedure abandoned. IV hydrocortisone and oral chlorpheniramine had been given as pre-medication.</td>
<td>Recovered with no sequelae. This patient has had no subsequent exchange transfusions.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age and Gender</td>
<td>Component</td>
<td>Reason for Transfusion</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Stage Transfusion Reaction developed</td>
<td>Treatment</td>
<td>Sequelae/Recommendations for future transfusions</td>
</tr>
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</tr>
<tr>
<td>AA Case 14*</td>
<td>51 yrs F</td>
<td>One unit of SD treated plasma.</td>
<td>Malignant disease with active bleeding - INR 1.45.</td>
<td>Urticaria, hypotension and falling pO₂ (81%). There was a low-grade fever pre-transfusion, which worsened during transfusion.</td>
<td>Patient not cultured. Unit cultured 19 hours post transfusion – positive culture considered to be a contaminant, not related to transfusion. IgA levels within normal limits.</td>
<td>During transfusion when less than 100 mls had transfused.</td>
<td>Transfusion discontinued. IV hydrocortisone and chlorpheniramine given.</td>
<td>Patient recovered fully within 12 hrs. Subsequent transfusion of two units of red cells has been uneventful.</td>
</tr>
<tr>
<td>AA Case 18*</td>
<td>38 yrs M</td>
<td>One unit of FFP.</td>
<td>Underlying infection INR 1.4 pre liver biopsy.</td>
<td>Urticaria, chest pain and fever - 38.6°C.</td>
<td>Patient and pack cultured – no organisms isolated. IgA level not checked.</td>
<td>During transfusion when less than 100 mls had transfused.</td>
<td>Transfusion discontinued and oxygen therapy commenced.</td>
<td>No subsequent transfusions necessary to date. Future transfusions to be administered cautiously and with antihistamine cover.</td>
</tr>
<tr>
<td>AA Case 19*</td>
<td>80 yrs M</td>
<td>Two units of FFP.</td>
<td>Obstructive jaundice INR 5.1 prior to an elective invasive procedure.</td>
<td>Tachycardia, rigors, dyspnoea, wheeze and hypertension.</td>
<td>Patient cultured - no organisms isolated. Pack not cultured. IgA levels not checked. Chest x-ray clear post transfusion.</td>
<td>Following completion of transfusion.</td>
<td>IV hydrocortisone and chlorpheniramine given with relief of symptoms.</td>
<td>Symptoms improved within two hours and recovered fully within four hours, with no sequelae.</td>
</tr>
</tbody>
</table>
### Anaphylactoid/Anaphylactic Transfusion Reaction to Multiple components: Table 30 *Included as a full case history*

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and 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 5</td>
<td>22 yrs F</td>
<td>Eight units of red cells, three units of pooled platelet concentrate, one unit of apheresis platelet concentrate, three units of FFP and 20 units cryoprecipitate</td>
<td>Massive GI bleed – Hb 5.4 g/dl, platelet count 13x10^9/L, PT 17 seconds and fibrinogen 0.85g/L.</td>
<td>Urticaria, nausea, facial and neck oedema and flushing.</td>
<td>Patient cultured – no organisms isolated. Pack not cultured. Post transfusion IgA levels within normal range. Platelet and HLA antibodies negative.</td>
<td>Within two hours of commencing massive transfusion.</td>
<td>IV hydrocortisone and zofran administered. Transfusion continued due to haemorrhage.</td>
<td>Patient admitted to ITU due to underlying disease. Recovered from this event with no ill effects.</td>
</tr>
</tbody>
</table>
We describe a number of interesting cases in detail.

Reactions associated with platelets

AA Case 1
This patient, with a malignant haematological disorder and associated sepsis, was thrombocytopenic – platelet count 35x10^9/L. She had a history of multiple transfusions with CMV antibody negative and irradiated cellular components with no associated problems. However, during her last platelet transfusion she had a mild allergic reaction. As a result she was pre-medicated with IV chlorpheniramine 10 mgs prior to this transfusion of one unit of CMV antibody negative and irradiated pooled platelet concentrate. Following the transfusion, despite pre-medication, symptoms of dyspnoea, urticaria, restlessness and anxiety developed. Vital signs remained stable throughout. Oral morphine 5 mg was given with relief of symptoms and the patient recovered with no ill effects. Post-transfusion IgA levels were normal. Pre-medication cover was again used prior to the next transfusion, but symptoms developed again. The use of washed platelets has been advised and subsequent transfusions of these washed platelets have been uneventful.

AA Case 2
This patient with a haematology disorder was thrombocytopenic – platelet count 15x10^9/L and required a platelet transfusion prior to a planned invasive procedure. An urticarial rash had developed following previous platelet transfusions which had been treated successfully with a pre-medication of IV chlorpheniramine 10mgs. In view of this history, IV chlorpheniramine 10 mgs was given prior to this transfusion. Following transfusion of one unit of CMV antibody negative and irradiated pooled platelet concentrate, symptoms of urticaria with stridor, wheeze, cyanosis, flushing and facial oedema developed. Following immediate medical review IV hydrocortisone 100 mgs and repeat chlorpheniramine 10 mgs were given and there was a full recovery. Chest x-ray was normal. IgA levels were not checked. This patient went on to receive two further transfusions of pooled and apheresis platelet concentrates with chlorpheniramine cover uneventfully.

AA Case 4
This patient with a malignant haematological disorder was thrombocytopenic – platelet count 28x10^9/L - and required a platelet transfusion. She had previously received multiple red cell and platelet transfusions uneventfully. During this transfusion of a pooled platelet concentrate, when approximately 200 mls had transfused, symptoms of dyspnoea, stridor/wheeze, restlessness/anxiety, chest tightness, hypertension and tachycardia developed. The transfusion was discontinued immediately and IV chlorpheniramine 10mgs and hydrocortisone 200 mgs were given. Nebulized salbutamol was also given with relief of symptoms. The patient was cultured, no organisms were isolated. The pack was also cultured, no organisms were isolated from the pack contents, segment line or administration line. The patient made a full recovery and has since been transfused uneventfully with apheresed platelet concentrate and pre-medication cover of hydrocortisone and chlorpheniramine.

AA Case 8
This elderly female patient with a history of epilepsy, hypertension and osteo-arthritis required a platelet transfusion for thrombocytopenia of unknown origin - platelet count 22x10^9/L. The first platelet transfusion some days earlier had been uneventful. During the second unit, when approximately 100 mls had been transfused, symptoms of urticaria, hypertension, dyspnoea, stridor/wheeze and facial swelling developed. The transfusion was discontinued immediately and IV hydrocortisone 200mgs and chlorpheniramine 10mgs were given. There was a full recovery within 24 hours.
Neither the patient nor the pack were cultured. Pre-transfusion IgA levels were normal. Following the transfusion reaction it was discovered that this patient had a history of bee-sting anaphylaxis and carried adrenaline in the event of a bee-sting. As a result she has been transferred to a specialist haematology centre for future transfusions where a diagnosis of ITP has been made. No further platelet transfusions have been required to date.

AA Case 10
This child with a haematological disorder and associated sepsis required a prophylactic platelet transfusion for thrombocytopenia – platelet count 18x10^9/L. There was a history of urticarial rash with previous platelet transfusions, which had been treated successfully with IV chlorpheniramine and hydrocortisone. On this occasion a pre-medication of IV chlorpheniramine and hydrocortisone was given as before. Despite this, symptoms of urticaria, dyspnoea, restlessness, anxiety and facial/tongue swelling with falling pO_2 (84%) in room air developed towards the end of the transfusion. The transfusion was discontinued and IV hydrocortisone and chlorpheniramine were repeated. Nasal oxygen was also given. Symptoms resolved within a few hours and the patient recovered with no ill effects. IgA levels were not checked on this occasion but will be if further transfusions are required. This patient was taking multiple concomitant medications, none of which had been recently commenced, so it is thought unlikely that these contributed to the cause of the symptoms.

AA Case 29
This patient with a malignant haematological disorder was thrombocytopenic – platelet count 17x10^9/L and required a prophylactic platelet transfusion. Fifteen minutes following completion of the transfusion symptoms of dyspnoea, chills, rigors and bradycardia developed. Nasal oxygen and IV pethedine were administered and symptoms resolved within one hour. The patient was cultured, no organisms were isolated. The pack was not cultured. Post transfusion IgA levels were within normal levels. A chest x-ray was not performed. This patient had experienced two similar episodes previously, neither during transfusion. However, the haematology team felt this particular episode was transfusion related. Subsequent transfusions using a pre-medication of chlorpheniramine have been uneventful.

AA Case 30
This patient with a malignant haematological disorder required a transfusion of platelets - platelet count 28x10^9/L. Forty-five minutes after the transfusion had commenced, when approximately 50 mls had transfused, symptoms of fever, rigors, tachycardia and dyspnoea developed. The transfusion was temporarily discontinued and medical review was sought over the telephone. Due to a delay in obtaining feedback the platelets were recommenced slowly by nursing staff, contravening recommended practice. After five minutes the patient began coughing and pO_2 fell. The transfusion was discontinued completely and nasal oxygen, IV chlorpheniramine and paracetamol were administered. Both the patient and pack were cultured and no organisms were isolated. The chest x-ray was clear and subsequent investigations confirmed an infection of the central line, which responded to a change in antibiotic therapy. Following review by the consultant haematologist it was concluded that this was an allergic reaction with an underlying sepsis. Future transfusions with pre-medication cover have been uneventful.
Anaphylaxis/Anaphylactoid Transfusion Reactions to Red Cells

AA Case 11
This patient required a transfusion of two units of red cells for anaemia, secondary to post-operative sepsis – Hb 8.5g/dl. Forty minutes following the completion of the transfusion, symptoms of fever and rash developed. A poor incremental Hb rise was also noted at this time. Following medical review, IV chlorpheniramine was administered. The patient made a full recovery within 24 hours. This reaction was initially reported as a DHTR but although the post transfusion DAT was positive no evidence of haemolysis or antibodies were detected and in view of the cutaneous manifestations it was considered to be an anaphylactoid transfusion reaction. The fever was ascribed to the underlying illness.

AA Case 22
This elderly patient required a transfusion of two units of red cells for an intraoperative bleed. The two units were transfused over two hours and 50 minutes and the patient was continuously monitored throughout. On completion of the second unit symptoms of extensive urticaria on arms, legs and trunk, hypotension, tachycardia and wheeze developed with associated increased airway pressure and falling tidal volume. The anaesthetist was present and nebulised salbutamol was administered via the endotracheal tube. IV Adrenaline, hydrocortisone, chlorpheniramine and a fluid bolus were also given. The patient recovered quickly without sequelae. IgA levels were normal and the chest x-ray was clear. No further transfusions have been required to date. It is recommended to transfuse with caution and to pre-medicate with an antihistamine and/or hydrocortisone should future transfusions be needed.

AA Case 23
This patient was anaemic – Hb 6.2 g/dl – following trauma and required two units of red cells. Two hours following completion of the first unit the patient became agitated and restless and complained of hallucinations. A psychiatric consult was sought which found no psychiatric abnormalities and attributed the symptoms to the trauma of the road traffic accident.

The following morning the second unit was commenced and during transfusion symptoms of urticaria, fever (38.7°C), chills and tachycardia developed. The transfusion was discontinued completely. The patient was cultured and no organisms were isolated. The unit was not cultured. An ABO incompatible transfusion was excluded. IgA levels were not checked. The patient recovered fully without sequelae. It is unlikely that the symptoms following the first unit were related to transfusion but this event has been captured as a severe allergic/anaphalactoid reaction due to the symptoms following the second unit.

AA Case 24
This young patient had pre-deposited one unit of whole blood prior to an elective surgical procedure. She had been transfused with this unit uneventfully the previous day. The next day a further unit of red cells was needed for persistent anaemia - Hb of 5.9g/dl. As there were no further autologous units available, one unit of allogeneic red cells was prescribed. During the first 15 minutes of transfusion, when less than 100 mls had transfused, symptoms of urticaria and severe periorbital oedema developed. The transfusion was discontinued and oral chlorpheniramine administered. Both the patient and the pack were cultured and no organisms were isolated. IgA levels were normal post transfusion. The patient required no further transfusions. The urticaria subsided within one day and periorbital oedema in two days.
AA Case 25
This patient was very ill with associated sepsis and ARDS and required one unit of red cells - Hb 7.3g/dl. There was a history of childhood asthma. The transfusion took place while the patient was being continuously monitored in the ITU. When more than 100 mls had transfused signs of increased airway pressure, pulmonary hypertension, raised blood pressure (240/80 mmHg) and a worsening fever (40.2°C) developed. The transfusion was discontinued, an infusion of GTN was commenced and paracetamol administered. The GTN infusion was weaned off within a short period and the patient was afebrile the next morning. Both the patient and the pack were cultured, the patient cultures isolated staphloccus epidermis, unrelated to transfusion, and no organisms were isolated from the pack. An incompatible transfusion was excluded. There were no new changes apparent on the chest x-ray. IgA levels were not checked. Subsequent transfusions of red cells have been uneventful.

Anaphylaxis/Anaphylactoid Transfusion Reactions to Plasma

AA Case 6
This patient required regular plasma exchanges for TTP. She had had 44 plasma exchanges over the previous eight years. There was a history of allergic-type symptoms during previous transfusion of FFP which had been successfully treated with chlorpheniramine and hydrocortisone. As a result a pre-medication of chlorpheniramine 8 mgs orally and hydrocortisone 200 mgs IV was routinely given prior to a plasma exchange procedure. This was the first plasma exchange using SD plasma. During the first 15 minutes of the procedure, when approximately 250mls had been transfused, symptoms of restlessness/anxiety and urticarial rash developed. The procedure was abandoned and the patient recovered with no ill effects within 30 minutes. The pre-transfusion IgA levels were normal. The patient has had no subsequent exchange transfusions.

AA Case 14
This patient with malignant disease was actively bleeding and had received 10 units of red cells over the previous 48 hours uneventfully. The 11th unit was given earlier the same day and was discontinued as the patient developed a fever, subsequently considered unrelated to transfusion. She had been having fluctuating fevers prior to transfusion and was on multiple antibiotics. Later that day, due to persistent bleeding, a transfusion of one unit of SD treated plasma was given – INR 1.45. The pre-transfusion temperature was 37.5°C. Approximately 15 minutes after commencement, when less than 100mls had transfused, symptoms of urticaria developed and the transfusion rate was slowed. Twenty minutes later the urticaria persisted and further symptoms of rising fever (38°C), hypotension and falling pO₂ (81%) developed. The transfusion was discontinued completely at this stage. IV hydrocortisone and chlorpheniramine were given, there was a full recovery within 12 hrs. The patient was cultured earlier that day and no organisms were isolated. The pack was cultured 19 hours post transfusion. Streptococcus was isolated at room temperature, but following review by a consultant microbiologist and haematologist this result was considered to be a contaminant, not related to transfusion. This patient has since received two units of red cells uneventfully. IgA levels were within normal limits. There was a history of multiple drug allergies.
AA Case 18
This patient with underlying infection was scheduled for a liver biopsy and was prescribed one unit of FFP - INR 1.4. During the first 100 mls of the transfusion, symptoms of urticaria, chest pain and fever (38.6°C) developed. The transfusion was discontinued and nasal oxygen administered. Both the patient and pack were cultured and no organisms were isolated. IgA levels were not checked. The patient made a full recovery and has required no further transfusions to date.

AA Case 19
This elderly patient with obstructive jaundice required two units of FFP prior to an elective invasive procedure - INR of 5.1. There was underlying hypertension and mild asthma. The two units were transfused over 65 minutes in total. Following the transfusion symptoms of wheeze, dyspnoea, hypertension, rigors and tachycardia developed. There was no associated fever. IV chlorpheniramine and hydrocortisone were given with relief of symptoms and a full recovery was made within four and a half-hours. The patient was cultured and no organisms were isolated. The pack was not cultured. No further transfusions have been necessary. The possibility of volume overload was considered but the chest x ray was clear. Although there was no cutaneous manifestations this reaction was considered to be an anaphylactoid transfusion reaction due to the respiratory symptoms and the rapid response to steroid and antihistamine medication. This was an inappropriate plasma transfusion to correct a raised INR prior to an elective invasive procedure where vitamin K would have been effective and appropriate.
**Transfusion Associated Circulatory Overload: 2002**

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.

This category accounted for 10 of 155 (7%) of incidents reported during this reporting year.

For patients with diminished cardiac reserve or chronic anaemia, rapid transfusion or massive transfusion poses a significant risk of circulatory overload. While infants and patients over 60 years of age are particularly susceptible, it can occur in any recipient of blood or blood components. Even low volumes can cause symptoms in susceptible patients, especially infants.

In a study of 382 orthopaedic surgery patients, the majority of whom were elderly females, four patients (1.05%) developed TACO postoperatively. The mean age of these patients was 84 years and symptoms were reversed with diuretics. Each received only 1-2 units of red cells prior to the onset of symptoms, and in two cases autologous blood was used. Each patient had a positive fluid balance (mean 2,480 mls) prior to the transfusion and symptoms resolved with diuretics. These researchers conclude that the use of conservative transfusion criteria and optimum fluid management may decrease the incidence of circulatory overload. TACO is closely associated with advanced age, longer length of hospital stays and increased healthcare costs.

The incidence of TACO in the Irish hospital context during the first three full years of reporting has been approximately 1:15,000 components issued. From the literature it would appear that this complication is significantly under-reported. Popovsky and Taswell (1985) found the frequency of diagnosis of TACO had increased from 1:3,168 to 1:708 patients transfused with red cells after the introduction of a ‘bedside consultation service’. They attributed this increase in reporting to the vigilance of the transfusion service and a raised awareness among the clinical staff.

In previous reports, it was noted that TACO was often related to the transfusion of FFP and hence during 2000 the NHO issued an information leaflet outlining the indications for its use, the associated risks and recommended rates of transfusion. During 2001 following the introduction of SD treated plasma this information leaflet was updated and re-issued to all acute care hospitals in the country. Since then there has been a reduced number of TACO incidents related to the transfusion of plasma reported to the NHO which may be as a result of increased awareness following the circulation of these information leaflets.
**Findings:**

- This year all episodes of TACO involved the transfusion of red cells, in contrast to the two previous years when the transfusion of plasma and/or platelets was associated with 42% of such episodes.

- All but one episode (Case 3) involved elderly patients.

- The patient who was younger, (Case 3) had pre-existing cardiac disease and the relationship of the TACO to the cardiac failure is unclear as the symptoms occurred four days following transfusion.

- Two patients (Cases 2 and 7) had no known respiratory, cardiac or renal disease, but both were over 80 years of age and weighed less than 60kgs.

- In one case (Case 6) the transfusion was followed by an IV infusion of crystalloid solution and as with many of the other cases, the symptoms could not be solely attributed to the transfusion but reflected a general circulatory overload of IV fluid of which red cells were a part. This patient had a positive fluid balance of 724 mls prior to commencing the transfusion and no prophylactic diuretic medication was prescribed.

- A fluid balance chart was not maintained prior to transfusion in eight (Cases 1-5, 7-9) of the ten cases. In the remaining two cases (Cases 6 and 10) where the fluid balance was known, there was a significant positive balance prior to commencing the transfusion which was not treated.

- One case (Case 9), where the patient had accompanying low grade fever, was originally reported to the NHO as a TRALI but further investigations indicated that the symptoms were more consistent with TACO.

- Only one patient (Case 1) was given prophylactic diuretic medication. This patient required two units of red cells and received an oral diuretic before the second was commenced, which was not sufficient to prevent circulatory overload.

- Two incidents (Cases 3 and 5) were associated with transfusion of three units of red cells in the day care setting where both patients were known to have existing cardiac disease and so could be considered to be at greater risk. In both cases each unit was transfused over 2-2½ hours and no prophylactic diuretic medication was prescribed. The transfusion episode had been uneventful and the patients were discharged before symptoms developed.

- Prolonged length of hospital stay and/or increased healthcare costs in the form of more intensive nursing and/or medical care were incurred in at least four of the cases (Cases 1, 3, 5 and 9). In the remaining cases it is not possible to say whether the reaction prolonged the length of hospital stay, but the symptoms experienced are associated with considerable unnecessary discomfort and risk for the patient. Fortunately no incident in this category was associated with mortality.
Recommendations:

- The risk of TACO is increased with the low weight, elderly and cardiac or respiratory compromised patient. Strategies to prevent TACO include individual assessment of each patient prior to transfusion and identification of those ‘at risk’. Transfusing slowly (1ml/kg of body weight/hour) to these patients with the use of diuretics may be necessary.

- All patients, but particularly the elderly and those at greater risk of TACO, must be individually assessed prior to the first unit and carefully observed during transfusion. They should be reassessed before starting another unit. Where possible, when transfusing elderly patients with more than one unit, it may be prudent to transfuse only one unit in each 24 hour period.

- Non urgent transfusions should be avoided at night. It is desirable where possible, to only transfuse when adequate staff are on duty.

- An estimation of the patient’s hydration status should be made prior to the transfusion of any blood component, especially those patients considered to be at increased risk of circulatory overload. Patients in positive fluid balance should be treated with a diuretic prior to commencing transfusion. The choice of route of administration ie oral or IV will depend on the degree of pre-existing congestive cardiac failure or overload.

- It may be prudent to transfuse at risk patients in the day care setting with no more than two units per day together with a prophylactic diuretic.

- In line with the recommendations of the National Blood User Group there is a need to provide written information for day care patients receiving blood transfusion, outlining possible adverse transfusion reactions and providing a contact telephone number in the event of symptoms developing.

- There were no reports received in this category relating to the transfusion of autologous blood. However, in order to ensure such reactions in this patient group are minimised, clinical staff should be aware that autologous transfusions carry the same risks for TACO as do allogeneic transfusions.

- Efforts must be directed at raising awareness among the clinical staff in the form of a hospital-wide transfusion education programme. Ongoing education and training by the hospital haemovigilance team in the area of transfusion practice is crucial to the recognition, reporting and prevention of transfusion-associated patient problems. Investigation and analysis of these problems will contribute towards continuous improvement of the transfusion service for the patient.
### Transfusion Associated Circulatory Overload (TACO): Table 31 All cases included as full case histories

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>Volume Transfused</th>
<th>Rate of Transfusion</th>
<th>Symptoms and Outcome</th>
<th>Pre-existing Problems</th>
<th>Comments</th>
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<tbody>
<tr>
<td>TACO Case 1</td>
<td>72 yrs</td>
<td>M</td>
<td>Symptoms developed when less than 100 mls of second unit of red cells had transfused.</td>
<td>Two units prescribed and transfused over four hours each.</td>
<td>Symptoms of dyspnoea, pulmonary oedema and severe chest pain with productive cough and blood stained sputum. Associated with hypertension and falling pO₂. Chest x-ray showed bilateral pulmonary oedema. Transfusion discontinued and diuretic medication administered with effect. Patient required ITU admission for two days.</td>
<td>There was significant cardiac history with unstable angina, impaired left ventricular function and hypertension. Symptomatic anaemia of chronic disease – Hb 8.2 g/dl.</td>
<td>The fluid balance was not monitored prior to transfusion. Oral diuretic was given prophylactically before the second unit commenced. Referred for specialist cardiac monitoring.</td>
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<td>TACO Case 2</td>
<td>84 yrs</td>
<td>F</td>
<td>Symptoms developed following the transfusion of three units of red cells.</td>
<td>Three units prescribed over 4 hours each. Transfused over 3-4 hours each.</td>
<td>Four hours post transfusion symptoms of fluid overload developed. Responded to IV diuretics and an oral sedative. Recovered with no ill effects. Received a further two units the following day uneventfully with diuretic cover prior to and following the transfusion.</td>
<td>There was no history of cardiac, renal or respiratory disease. Chronic anaemia of malignancy – Hb 7.1g/dl. Weight - 55 kgs.</td>
<td>The fluid balance was not monitored prior to or during transfusion.</td>
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<td>TACO Case 3</td>
<td>29 yrs</td>
<td>M</td>
<td>Symptoms developed following the transfusion of three units of red cells.</td>
<td>The prescription did not state the rate of the transfusion. Each unit transfused over 2 – 2½ hours.</td>
<td>Four days following transfusion symptoms of dyspnoea associated with falling pO$_2$ and rales on chest auscultation. Chest x-ray showed pulmonary oedema and cardiomegaly. IV frusemide 40 mgs and 100% nasal oxygen given. There was a good diuresis and the patient recovered without further treatment. Subsequently a diagnosis of cardiomegaly was made. pO$_2$ on room air remained low - 80% - four days later.</td>
<td>Multi-system disorders including bone marrow failure and cardiac dysfunction with slow atrial fibrillation. Anaemia of chronic disease with epistaxis – Hb 6.8 g/dl.</td>
<td>Due to the complicated medical history, it is unclear if this was an episode of TACO or if symptoms were as a result of the underlying disease.</td>
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<tr>
<td>TACO Case 4</td>
<td>76 yrs</td>
<td>F</td>
<td>Symptoms developed during the transfusion of one unit of red cells.</td>
<td>One unit prescribed and transfused over four hours.</td>
<td>During transfusion symptoms of acute breathlessness, pulmonary oedema, chest tightness and falling pO$_2$ developed. A chest x-ray was not performed. Commenced nasal oxygen 4L /min and IV frusemide 40 mgs given with good diuresis. Symptoms resolved within two hours.</td>
<td>Ischemic heart disease, atrial fibrillation, mitral regurgitation and angina - on regular diuretic medication. Symptomatic anaemia of chronic disease - Hb 8.2 g/dl.</td>
<td>Incomplete fluid balance chart only maintained prior to commencing the transfusion.</td>
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<td>TACO Case 5</td>
<td>74 yrs</td>
<td>M</td>
<td>Symptoms developed following the transfusion of three units of red cells.</td>
<td>Three units of red cells prescribed and transfused over 2½ hours each.</td>
<td>One hour following transfusion, en route home in a taxi, symptoms of dyspnoea, tachycardia, chest tightness and pulmonary oedema developed. Required admission to nearest hospital for IV diuretics and oxygen therapy, and in view of the cardiac history was monitored in the coronary care unit (CCU) for two nights.</td>
<td>Aortic stenosis with associated left ventricular hypertrophy. Symptomatic anaemia of malignancy – Hb 8.2 g/dl.</td>
<td>The fluid balance was not monitored prior to the transfusion, as the patient was a day case. Neither was a fluid balance chart maintained during the transfusion.</td>
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<tr>
<td>TACO Case 6</td>
<td>83 yrs</td>
<td>F</td>
<td>Symptoms developed following the transfusion of one unit of red cells.</td>
<td>Three units of red cells prescribed over four hours each on three consecutive days. The first unit transfused over four hours.</td>
<td>Three hours following transfusion of the first unit symptoms of dyspnoea, tachycardia, engorged neck veins and falling pO₂ developed. Evidence of a positive fluid balance and chest x-ray changes were suggestive of pulmonary oedema. Nasal oxygen and IV diuretics given with a good diuresis. There was a full recovery within two days. Subsequent transfusions with prophylactic diuretic pre-medication has been uneventful.</td>
<td>Presented with pneumonia and symptomatic anaemia of unknown cause - Hb 6.0 g/dl.</td>
<td>There was a positive fluid balance of 724 mls prior to commencing the transfusion. A prophylactic diuretic was not prescribed. This transfusion was followed by an IV fluid infusion which may also have contributed to the volume overload.</td>
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<td>TACO Case 7</td>
<td>88 yrs</td>
<td>F</td>
<td>Symptoms developed when almost 220 mls of the second unit had transfused, after 5 hours.</td>
<td>Two units of red cells prescribed and transfused over six hours each on two consecutive days.</td>
<td>When the transfusion was almost complete - 220 mls had transfused over 5 hours – when symptoms of breathlessness developed. IM diuretic and chlorpheniramine given with relief of symptoms. Subsequent transfusions with prophylactic diuretic pre-medication has been uneventful.</td>
<td>There was no known history of cardiac, renal or respiratory disease. Anaemia secondary to chronic peptic ulcer disease with active bleeding – Hb 5.2 g/dl.</td>
<td>The fluid balance was not accurately monitored prior to or during the transfusion.</td>
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<tr>
<td>TACO Case 8</td>
<td>95 yrs</td>
<td>M</td>
<td>Symptoms developed following the transfusion of two units of red cells.</td>
<td>Prescribed and transfused over four hours each.</td>
<td>Following completion of 2nd unit symptoms of breathlessness and a ‘heavy feeling in chest’ developed with hypertension and associated falling pO₂. Nasal oxygen and IV diuretic medication given with relief of symptoms. There was a full recovery.</td>
<td>There was evidence of left ventricular hypertrophy on electrocardiograph (ECG). Also a history of hypertension. Anaemia of unknown cause - Hb 7.2 g/dl.</td>
<td>The fluid balance was not monitored prior to or during transfusion. Weight 60.4 kgs.</td>
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<td>TACO Case 9</td>
<td>70 yrs</td>
<td>F</td>
<td>Symptoms developed when less than 100 mls of red cells had transfused over 20 minutes.</td>
<td>Prescribed over four hours.</td>
<td>During first 20 minutes of the transfusion symptoms of low grade fever, dyspnoea, cyanosis, falling PO₂ and tachycardia developed. Chest x-ray suggested pulmonary oedema secondary to left ventricular failure. Transferred to CCU and required IV frusemide, hydrocortisone, cyclimorph and amiodarone infusion. Sublingual GTN, nebulizers and assisted ventilation also required. Recovered fully within 48 hours.</td>
<td>There was significant cardiac history with 1st degree heart block on ECG. Transfused for symptomatic anaemia of malignancy – Hb 8.9 g/dl.</td>
<td>An accurate fluid balance was not available as it had been incompletely recorded.</td>
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<td>TACO Case 10</td>
<td>82 yrs</td>
<td>M</td>
<td>Symptoms developed when 50 mls of the second unit of red cells had transfused.</td>
<td>Prescribed and transfused over four hours each.</td>
<td>During first 50 mls of the second unit symptoms of dyspnoea, cyanosis, bronchospasm and chest tightness developed, associated with falling PO₂, tachycardia and hypertension. Chest x-ray changes were consistent with pulmonary oedema. Recovered fully within 4-6 hours.</td>
<td>There was significant respiratory and cardiac disease with pneumonia and sepsis.</td>
<td>There was a positive fluid balance of 1475 mls prior to transfusion.</td>
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</table>
Transfusion Associated Circulatory Overload

TACO Case 1
This elderly male patient, with a significant cardiac history including unstable angina, impaired left ventricular function and hypertension, required a transfusion of red cells for symptomatic anaemia of chronic disease – Hb 8.2 g/dl. He was already on regular diuretic therapy pre-transfusion. Two units of red cells were prescribed, each over four hours. Oral frusemide 40 mgs was given prophylactically after the first unit as prescribed. However a fluid balance chart was not commenced until then. During the second unit, when approximately less than 100 mls had transfused over three hours, symptoms of dyspnoea, pulmonary oedema and severe chest pain with productive cough and blood stained sputum developed. There was associated hypertension and falling pO2. The transfusion was discontinued and 100% nasal oxygen was commenced. The chest x-ray showed bilateral pulmonary oedema. The patient was transferred to the ITU and required IV cyclimorph 2.5 mgs and frusemide 80 mgs and infusions of isosorbide dinitrate and dopamine. The response to diuretic therapy was 1728 ml over 12 hours and the patient remained in ITU for two days. This patient has ongoing cardiac problems exacerbated by this transfusion and has been referred for regular specialist cardiac review.

TACO Case 2
This low weight elderly female - weight 55 kgs - with symptomatic anaemia of malignancy – Hb 7.1 g/dl - was prescribed three units red cells over four hours each. There was no known underlying respiratory, renal or cardiac disease. The three units were transfused consecutively over 11 hours in total. An oral diuretic was given prophylactically during and following the transfusion. The fluid balance was not monitored. The time the symptoms of fluid overload developed is not recorded in the nursing notes, but a medical review four hours following completion of the transfusion recorded that the patient had signs of fluid overload. Symptoms at this time included dyspnoea, chest tightness and chest pain with associated tachycardia. There was reduced air entry and audible crepes bilaterally. A chest x-ray was not performed. IV frusemide and an oral sedative were administered. There was a good diuresis and resolution of symptoms. The patient recovered with no ill effects and received a further two units of red cells the following day uneventfully, with IV diuretic cover pre and post transfusion.

TACO Case 3
This young male patient, with a chronic multi-system disorder, including bone marrow failure with underlying cardiac disease, was attending the Day Care Unit following an episode of epistaxis. He was transfused with three units of red cells - Hb 6.8g/dl. Prophylactic diuretic medication was not prescribed, neither was the rate of transfusion. Each unit was transfused over 2-2½ hours. The fluid balance was not monitored. All observations were within normal limits prior to, during and following the transfusion and the patient was discharged home. He presented again four days later with symptoms of dyspnoea associated with falling pO2 and rales on chest auscultation. He was admitted and the chest x-ray showed pulmonary oedema and cardiomegaly. IV frusemide 40 mgs and 100% nasal oxygen were given. There was a good diuresis – 2,250 mls of urine over four hours. Subsequently a diagnosis of cardiomegaly with cardiac failure was made following the event.

The patient recovered from this event without further treatment but, due to the complicated medical history, it is unclear if the transfusion was associated with the symptoms.
TACO Case 4
This elderly female patient with ischemic heart disease, angina, atrial fibrillation and mitral regurgitation was to be transfused for symptomatic anaemia of chronic disease – Hb 8.2 g/dl. One unit of red cells was prescribed and transfused over four hours. Although a fluid balance chart was maintained prior to commencing the transfusion it was not accurately recorded and there was no record of the patient's weight. The patient was on a regular oral diuretic prior to transfusion which she had received earlier that morning. Approximately half the unit had transfused when symptoms of acute breathlessness, hypertension, falling pO₂ and chest tightness developed. There was evidence of pulmonary oedema on chest auscultation but no chest x-ray performed. Nasal oxygen 4L/minute was commenced and IV frusemide 40 mgs was given with relief of symptoms. There was a full recovery within two hours and no further treatment was necessary.

TACO Case 5
This elderly male patient had been recently discharged from hospital following surgery. He was attending the day unit with symptomatic anaemia of malignancy -Hb 8.2 g/dl – and was to be transfused with three units of red cells. There was underlying severe aortic stenosis associated with left ventricular hypertrophy and he was on a regular diuretic which he had taken earlier that morning. No prophylactic diuretic medication was prescribed prior to, during or following the transfusion on this occasion and a fluid balance chart was not maintained. The three units of red cells were prescribed and transfused over 2½ hours each (7½ hours in total). The transfusion episode was uneventful. Approximately one hour later, while the patient was on his way home in a taxi, he developed symptoms of dyspnoea, tachycardia, chest tightness and pulmonary oedema. The taxi driver drove to the nearest A&E Department, which was in a children's hospital. A diagnosis of circulatory overload was made and treatment with oxygen and IV diuretics was given with a good response. The patient was then transferred by ambulance to a general A&E Department and admitted to the CCU for two nights for monitoring due to his significant cardiac history. He was discharged with no further ill effects from the transfusion. The original hospital discovered the incident when a relative of the patient reported the incident to the TSO. The hospital is reviewing its policy on transfusion in the day care setting as a result of this incident and considering restricting the number of units to be transfused in this setting, especially to those patients over 70 years and at greatest risk.

TACO Case 6
This elderly female patient with underlying pneumonia and symptomatic anaemia of unknown cause - Hb 6.0 g/dl - was prescribed three units of red cells over four hours each on three consecutive days. A prophylactic diuretic was not prescribed although there was a positive fluid balance of 724 mls prior to commencing the transfusion. The first unit was transfused over four hours as prescribed and followed by an IV fluid infusion at 125 mls/hr. Three hours later symptoms of dyspnoea, tachycardia, engorged neck veins and falling pO₂ developed. The IV fluids were reduced to 62.5mls/hr but the patient was not reviewed by the medical team. Medical review was sought six hours later due to deteriorating clinical condition. The IV fluid infusion was discontinued, nasal oxygen administered and IV frusemide given with a good diuresis. A chest x-ray was performed the following morning and was suggestive of pulmonary oedema. The patient recovered fully from this episode within two days. Subsequent transfusion of red cells with diuretic pre-medication has been uneventful.
TACO Case 7
This elderly patient presented with a GI bleed (Hb 5.2 g/dl) and was to be transfused with two units of red cells over six hours each on two consecutive days. There was a history of peptic ulcer disease but no known pre-existing cardiac, renal or respiratory disease. The first unit had transfused the previous day uneventfully without a diuretic pre-medication. Although a fluid balance chart was maintained, it was inaccurate. During the 24 hours prior to the transfusion, 1½ litres of crystalloid solution and one unit of red cells had infused, the oral intake and urinary output were not recorded. A diuretic was not prescribed prior to or during transfusion. During this transfusion, symptoms of dyspnoea developed after five hours, when approximately 220 mls had transfused. The transfusion was discontinued completely. Intramuscular (IM) chlorpheniramine and frusemide were given with a diuresis of approximately 300 mls. The chest x-ray showed some pulmonary congestion. This patient has subsequently been transfused uneventfully with prophylactic diuretic medication.

TACO Case 8
This low weight elderly male patient - weight: 60.4 kgs - with pre-existing cardiac disease, presented with gastro-enteritis, dehydration and anaemia of unknown cause - Hb 7.2 g/dl. Two units of red cells were prescribed and transfused consecutively over four hours each. The fluid balance chart was not accurately maintained and diuretic medication was not prescribed prior to or during the transfusion. Towards the end of the transfusion of the second unit, the patient complained of breathlessness and a ‘heavy feeling in the chest’ with associated falling pO2. He was also hypertensive at this time. IV frusemide 40mgs and nasal oxygen were given with relief of symptoms. The patient recovered with no ill effects within 2½ hours.

TACO Case 9
This elderly female patient, with symptomatic anaemia of malignancy – Hb 8.9 g/dl - and pre-existing ischaemic heart disease, was being transfused with one unit of red cells over four hours. There was evidence of first degree heart block on ECG prior to transfusion. She was not routinely on a diuretic, although some of the cardiac medication she was taking had a diuretic effect. Prophylactic diuretic medication was not given pre-transfusion. Twenty minutes after commencing the transfusion symptoms of low grade fever, (37.8°C) tachycardia, dyspnoea, cyanosis and falling pO2 (94% on 100% nasal oxygen) developed. It is not possible to say accurately how much blood had transfused as the fluid balance chart was incomplete. The transfusion was discontinued completely. IV hydrocortisone 200mgs, frusemide 100mgs and cyclomorph 5mgs were given and an infusion of amiodarone 300mgs was commenced. Nebulised atrovent and combivent and sublingual GTN were also administered. The response to frusemide was not documented. Admission to the CCU and ventilation were necessary for 48 hours. The chest x-ray revealed pulmonary oedema with left ventricular failure.

This was initially reported to the NHO as a TRALI due to the fever and respiratory symptoms. However following investigation it was considered that the symptoms could be more accurately ascribed to volume overload in view of the chest x-ray changes. The fever may have been as a result of the underlying malignancy, although this was never confirmed. The only donor involved in the reaction is male and had never been transfused which also made TRALI unlikely.
TACO Case 10
This elderly male patient had a significant history of respiratory and cardiac disease including congestive cardiac failure and chronic obstructive pulmonary disease. On this admission to the ITU the patient was having abdominal investigations, which were complicated by pneumonia and sepsis. Two units of red cells were prescribed, to be transfused consecutively for symptomatic anaemia of chronic disease - Hb 8.8g/dl. Pre-transfusion there was a positive fluid balance of 1475 mls, however the regular diuretic medication was withheld due to persistent hypotension. The first unit was transfused uneventfully over four hours. During transfusion of the second unit, when only 50 mls had transfused, symptoms of dyspnoea, cyanosis, bronchospasm and chest tightness developed with associated falling pO₂, tachycardia, and hypertension. The chest x-ray showed evidence of bilateral interstitial shadowing consistent with pulmonary oedema. The transfusion was discontinued and IV frusemide 60 mgs and hydrocortisone 100 mgs were given. Combivent nebuliser was also administered. There was a good response to the diuretic medication - 1140 mls over six hours and the patient recovered from this incident within four to six hours.
**DELAYED HAEMOLYTIC TRANSFUSION REACTIONS: 2002**

*Definition: Delayed haemolytic transfusion reactions are defined, for the purpose of this report, as those occurring more than 24 hours following the transfusion of a blood component. A haemolytic transfusion reaction occurs when antigen-positive red blood cells are transfused to a patient who develops an alloantibody to that antigen. It results in the lysis, or accelerated clearance, of red blood cells due to immunologic incompatibility between the blood donor and the recipient*36.*

This category accounted for 6% of incidents reported (9 of 155)

Delayed haemolytic transfusion reactions (DHTR), have been estimated to occur in about 1:500 – 850 patients transfused36. DHTR can be difficult to diagnose and may therefore have been underreported in the past. As many of these patients are already very ill, the diagnosis is often overlooked.

Typically the picture is of falling Hb 4-10 days after a transfusion. In some cases it may be associated with jaundice and rarely renal impairment. However, due to the underlying condition in many of these patients, the exact contribution of the DHTR to the renal impairment is difficult to evaluate.

The pre-transfusion antibody screen is usually negative for the antibody responsible, but the red cell antibodies are subsequently detected on post transfusion samples. These reactions are likely to occur where already formed antibodies present due to previous transfusion or pregnancy, fall below the detection limits of the pre-transfusion antibody screen but are rapidly boosted by a transfusion of antigen positive red cells and haemolyse these cells. The antibodies typically are Kidd antibodies (anti-Jka, Jkb) but other antibodies such as Rhesus and Kell may also be involved.

**Findings:**
There were nine cases of DHTR reported during this reporting year. This year we have decided to grade reactions by severity using the SHOT classification system4.

**Group 1**  
Asymptomatic with antibody only detected (with a positive DAT). There were two cases reported (Cases 2 and 9) which were classified as group 1 reactions.

**Group 2**  
Evidence of haemolysis measured by falling Hb and positive DAT. There were five cases reported (Cases 3, 4, 5, 6 and 8) which were classified as group 2 reactions.

**Group 3**  
Falling Hb with jaundice, with or without a positive DAT. There were two cases reported (Cases 1 and 7) which were classified as group 3 reactions.

**Group 4**  
As for group 3, but with renal impairment. No such cases were reported this year.
• This year, there has been an increased number of reports of DHTR detected compared to previous years. This probably reflects greater awareness due to the national haemovigilance scheme rather than any increased incidence.

• One case reported did not progress because it was likely to be a medication associated reaction rather than a DHTR.

• In a further case (Case 7), which we have included, the reaction may have been part of an autoimmune process rather than a DHTR.

• Apart from one case (Case 7), none of the antibodies were detected in the pre-transfusion screen nor on the pre-transfusion sample, even on repeat testing.

• The commonest antibodies implicated were Kidd antibodies with four cases involving anti-Jka. There were two cases involving anti-K one of which was also associated with an anti-E. There was one case each involving anti C+D, anti-c and anti Kp^a + anti Fy^a.

• In Case 5, with anti K + E, the causative antibodies were not detectable until sometime after the transfusion. The patient did not have the expected Hb increment rise following the transfusion of two units of red cells. One of these units was retrospectively found to be positive for the K antigen and it is likely that a haemolytic reaction had occurred. Similar cases have been described in the literature.  

• In Case 7, an anti C + D was associated with evidence of haemolysis and although the transfused red cells were Rh D negative, anti-D was eluted from the red cells. This unusual finding of antibody bound to red cells which lack the corresponding antigen, has been described and is known as the Matuhasi-Ogata phenomenon. This can happen as a non-specific finding when a specific antibody is bound to red cells or in the autoimmune setting when the autoantibody mimics a specific antibody. In this case, association with an autoimmune antibody against factor VIII in the patient would suggest the possibility of an autoimmune process rather than a DHTR.
Recommendations:

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

• Careful history taking in relation to transfusion and pregnancies by the requesting physician is important. However, up to 12% of patients do not realise that they have had a transfusion\textsuperscript{18}, therefore access to and checking of previous transfusion records are essential.

• Use of three cell screening panels, sensitive antibody screening techniques and satisfactory participation in external quality assurance schemes such as the National External Quality Assurance Scheme (NEQAS), should minimise failures to detect weak antibodies.

• As antibodies can develop rapidly, patients being repeatedly transfused, depending on the interval between transfusions, should have a fresh sample submitted within 24–72 hours of a planned transfusion in accordance with BCSH Guidelines\textsuperscript{19}.

• When investigating a DHTR a serum sample should be used for antibody detection as some antibodies, particularly weakly complement binding antibodies not detectable in plasma specimens may be detected in serum samples\textsuperscript{20}.
## Delayed Haemolytic Transfusion Reaction (DHTR) Group 1: Table 32

<table>
<thead>
<tr>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of Component Transfused</th>
<th>Age and gender of patient</th>
<th>Pre-existing condition</th>
<th>Interval between transfusion and onset of symptoms</th>
<th>Treatment</th>
<th>Findings</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHTR Case 2</td>
<td>Group A Rh D positive.</td>
<td>Three units of group A Rh D positive red cells over three weeks.</td>
<td>72 yrs Female</td>
<td>Underlying haematological malignancy with renal impairment.</td>
<td>No symptoms developed.</td>
<td>No treatment prescribed.</td>
<td>During later routine testing, anti-Jk(^a) was discovered and there was a positive DAT.</td>
<td>Subsequent transfusions with antigen negative red cells have been uneventful.</td>
</tr>
<tr>
<td>DHTR Case 9</td>
<td>Group O Rh D positive.</td>
<td>Two units of group O Rh D positive red cells.</td>
<td>69 yrs Female</td>
<td>Undiagnosed symptomatic anaemia – Hb 6.0 g/dl.</td>
<td>No symptoms developed.</td>
<td>No treatment prescribed.</td>
<td>Anti-Jk(^a) and positive DAT identified during pre-transfusion testing 22 days later.</td>
<td>Subsequent transfusions with antigen negative red cells have been uneventful.</td>
</tr>
</tbody>
</table>
## Delayed Haemolytic Transfusion Reaction (DHTR) Group 2: Table 33

*All cases included as full case histories*

<table>
<thead>
<tr>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of Component Transfused</th>
<th>Age and gender of patient</th>
<th>Pre-existing condition</th>
<th>Interval between transfusion and onset of symptoms</th>
<th>Treatment</th>
<th>Findings</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHTR Case 6</td>
<td>Group O Rh D positive.</td>
<td>Nine units of group O Rh D positive red cells and four units of group O Octaplas.</td>
<td>61 yrs Male</td>
<td>Liver disease, renal impairment and sepsisemia with associated bleeding.</td>
<td>Transfusions administered over eight days. Symptoms of falling Hb and rising bilirubin attributed to illness.</td>
<td>Required further transfusion for falling Hb.</td>
<td>Anti Jk&lt;sup&gt;a&lt;/sup&gt; identified during pre-transfusion testing nine days later.</td>
<td>Subsequent transfusion with antigen negative red cells has been uneventful.</td>
</tr>
<tr>
<td>DHTR Case 3</td>
<td>Group A Rh D negative.</td>
<td>Two units of group A Rh D negative red cells.</td>
<td>79 yrs Male</td>
<td>Peripheral vascular disease.</td>
<td>Seven days later a falling Hb was noted which could also be attributed to the underlying illness.</td>
<td>Required further transfusion for falling Hb.</td>
<td>Seven days later antibody screen positive for anti-Kp&lt;sup&gt;a&lt;/sup&gt; and anti Fy&lt;sup&gt;a&lt;/sup&gt;. DAT also positive at this time.</td>
<td>Subsequent transfusion with antigen negative red cells has been uneventful.</td>
</tr>
<tr>
<td>DHTR Case 4</td>
<td>Group A Rh D negative.</td>
<td>20 units of group A Rh D negative red cells over the previous three months.</td>
<td>55 yrs Male</td>
<td>Malignant haematological disorder.</td>
<td>Seven days post transfusion a falling Hb was noted. This could also be attributed to the underlying illness.</td>
<td>Required further transfusion for falling Hb.</td>
<td>Falling Hb and a positive DAT.</td>
<td>Subsequent transfusion with antigen negative red cells has been uneventful.</td>
</tr>
<tr>
<td>DHTR Case 5</td>
<td>Group B Rh D positive.</td>
<td>Two units of group B Rh D positive red cells.</td>
<td>63 yrs Male</td>
<td>Prior to elective orthopaedic surgery.</td>
<td>There was a poor incremental rise post transfusion and three days later the Hb continued to fall.</td>
<td>Required further transfusion for falling Hb.</td>
<td>Antibody screen showed anti-Kell and anti-E two months post transfusion.</td>
<td>Subsequent transfusion with antigen negative red cells has been uneventful.</td>
</tr>
</tbody>
</table>
### Delayed Haemolytic Transfusion Reaction (DHTR) Group 2: Table 33 Continued

<table>
<thead>
<tr>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of Component Transfused</th>
<th>Age and gender of patient</th>
<th>Pre-existing condition</th>
<th>Interval between transfusion and onset of symptoms</th>
<th>Treatment</th>
<th>Findings</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHTR Case 8</td>
<td>Group O Rh D positive.</td>
<td>Two units of group O Rh D positive red cells.</td>
<td>63 yrs Male</td>
<td>Hepatic failure.</td>
<td>Seven days post transfusion a falling Hb was noted.</td>
<td>Required further transfusion for falling Hb.</td>
<td>Antibody screen positive for anti-c. DAT also positive.</td>
<td>Subsequent transfusion with antigen negative red cells has been uneventful.</td>
</tr>
</tbody>
</table>

### Delayed Haemolytic Transfusion Reaction (DHTR) Group 3: Table 34 All cases included as full case histories

<table>
<thead>
<tr>
<th>Case Number</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of Component Transfused</th>
<th>Age and gender of patient</th>
<th>Pre-existing condition</th>
<th>Interval between transfusion and onset of symptoms</th>
<th>Treatment</th>
<th>Findings</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHTR Case 1</td>
<td>Group B Rh D positive.</td>
<td>Three units of group B Rh D positive red cells.</td>
<td>80 yrs Female</td>
<td>Exploratory abdominal surgery. On multiple concurrent medications.</td>
<td>Presented to GP one month post transfusion with malaise, nausea, lower abdominal pain and anorexia which may have been attributed to underlying illness.</td>
<td>No treatment prescribed.</td>
<td>Anti-K and non-specific antibody detected in antibody screen and DAT.</td>
<td>Recovered with no ill-effects. No further transfusions have been necessary.</td>
</tr>
<tr>
<td>DHTR Case 7</td>
<td>Group O Rh D negative.</td>
<td>25 units of group O Rh D negative red cells over one week.</td>
<td>72 yrs Male</td>
<td>GI bleeding. There was also an underlying autoimmune process.</td>
<td>Symptoms of falling Hb, raised bilirubin and LDH developed 25 days following the first unit transfused.</td>
<td>No treatment prescribed.</td>
<td>Transfused with Rh D positive red cells due to failing blood supply three years previously. Raised LDH and serum bilirubin with a falling Hb and positive DAT.</td>
<td>Recovered with no ill-effects. No further transfusions have been necessary.</td>
</tr>
</tbody>
</table>
Delayed Haemolytic Transfusion Reaction

We present the details of seven of the nine cases where there was evidence of haemolysis.

Group 2 Cases

DHTR Case 6
This patient was transfused with nine units of red cells and four units of SD Plasma over eight days for active bleeding. Nine days post transfusion the antibody screen, which had been negative, was positive with anti-Jk\textsuperscript{a} specificity. The DAT, which had also been negative, was also now positive. In view of the patient’s underlying illness, which included liver and renal impairment and sepsis, it was difficult to determine the contribution of the positive red cell antibody to the falling Hb and rising bilirubin. The patient recovered from this episode and subsequently received antigen negative red cells uneventfully.

DHTR Case 3
This elderly patient required a transfusion of two units of red cells for an intra-operative bleed. He grouped as group A Rh D negative, antibody screen negative and was transfused with crossmatch compatible red cells. There was no transfusion history at this hospital and the patient stated that he had never been transfused before. Seven days later due to persistent anaemia a new pre-transfusion sample was processed. This time the antibody screen was positive: specificity of antibody was anti Kp\textsuperscript{a} and anti-Fy\textsuperscript{a}. The post transfusion DAT was positive with anti-Fy\textsuperscript{a} specificity on eluate. Transfusion support was required for three weeks, but this could also be attributed to the underlying illness. Further transfusions with antigen negative red cells have been uneventful.

DHTR Case 4
This patient required ongoing transfusions of red cells for anaemia associated with malignancy. He grouped as group A Rh D negative, antibody screen positive, the antibody specificity was anti-K. Over the previous three months 20 units of K negative red cells had been transfused uneventfully. Before the most recent transfusion the antibody screen was again positive for anti-K and the DAT was positive with a non-specific eluate. Seven days following this last transfusion there was a falling Hb. The antibody screen was positive for anti-K, the DAT was also positive. However the eluate from the red cells now showed anti-Jk\textsuperscript{a}. Further transfusions with antigen negative red cells have been uneventful.

DHTR Case 5
This patient required a red cell transfusion following elective surgery – Hb 8.1g/dl. He grouped as group B Rh D positive, antibody screen negative. Two units of crossmatch compatible red cells were transfused uneventfully. However a poor incremental rise was noted; the post transfusion Hb was 8.7 g/dl. There was no evidence of active or occult bleeding. Three days later, the Hb was 7.9 g/dl. The antibody screen was repeated and remained negative. A further three units were crossmatched and were transfused uneventfully. Following this transfusion, the Hb rose to 11.2 g/dl. Two months later, the patient presented for further surgery and on this occasion the antibody screen was positive for anti-K and anti-E. The DAT was also positive. A possible explanation for these findings is that the patient had been previously alloimmunised but that the antibody level had fallen below detectable levels at the time of the first transfusion. Review of the patient’s transfusion history suggested that this patient may have been transfused eight to ten years previously. This is supported by retrospective information on the phenotype of the donors which has shown that one of the first two units transfused was K positive. The other donor’s K and E phenotype is unknown. The phenotype of two of the three donors transfused
subsequently were K and E negative and the expected Hb increment was achieved following this transfusion. The third donor’s phenotype is unknown.

DHTR Case 8
This patient required an intra-operative emergency transfusion of two units of red cells. He grouped as O Rh D positive, antibody screen negative. The pre-transfusion DAT was positive, with a non-specific eluate. There was a history of transfusion four years previously for a bleeding duodenal ulcer. Seven days post-transfusion the patient developed a falling Hb but was otherwise asymptomatic. Laboratory investigations confirmed the pre-transfusion findings on retrospective testing. Post-transfusion the antibody screen was positive for anti-c and the DAT was positive with anti-c in the eluate. The patient recovered with no ill effects. Subsequent transfusion with antigen negative red cells has been uneventful.

Group 3 Cases

DHTR Case 1
This elderly patient required a transfusion of three units of red cells for post-operative anaemia. She grouped as B Rh D positive, antibody screen negative. Three units of crossmatch compatible red cells were issued and transfused uneventfully. Thirty days later the patient presented to the GP complaining of malaise, lower abdominal pain, nausea, and anorexia. A falling Hb was also noted at this time. Further investigations revealed a raised bilirubin and abnormal liver function tests, which may have been related to previous gall bladder disease. There was also a marginally raised urea and creatinine. There was no haemoglobinuria or urinary urobilinogen. Repeat antibody screen was positive and revealed an anti-K plus a non-specific antibody. The DAT was positive: the specificity of eluate was anti-K and non-specific antibody. Retrospective testing of the pre-transfusion sample was not possible as the specimen, which is only reserved for one month, had been discarded. The patient recovered with no ill effects, and urea and creatinine returned to normal within two days. There were ongoing GI problems, which were not related to the transfusion.

DHTR Case 7
This elderly male group O Rh D negative patient was previously transfused with group O Rh D positive red cells in 1999 due to failing blood supply. On this occasion, as a result of the earlier transfusion, the antibody screen was positive: specificity of the antibody was anti-C+D. He received 25 units of group O Rh D negative red cells over seven days for GI bleeding. A raised LDH and bilirubin developed with a falling Hb and positive DAT 25 days after the first transfusion. No additional antibody could be detected in the serum and the eluate from the red cells, although they were Rh D negative, showed anti-D specificity. This unusual finding of an antibody bound to red cells that lack the corresponding antigen is known as the Matuhasi-Ogata phenomenon\(^37\). As the patient had a autoantibody to Factor VIII, it is likely that the haemolysis was immune mediated rather than a straightforward DHTR.
ACUTE HAEMOLYTIC AND OTHER SEVERE ACUTE TRANSFUSION REACTION: 2002

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

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

This category accounted for 5% of incidents reported (8 of 155). The major concern with these reactions is that they may reflect ABO incompatibility or bacterial infection of the component and both of these possibilities must be excluded. As noted in previous years the direct cause of all these reactions has not been fully established, and in some cases the symptoms were probably related to the patient’s underlying condition.

Findings

• Five of the cases involved the transfusion of red cells (Cases 1, 2, 3, 4 and 5). In two cases (Cases 6 and 7) a platelet transfusion was implicated, and in the final case (Case 8), SD treated plasma was transfused to correct over-anticoagulation. In all cases the patients recovered within 24 hours without sequelae.

• ABO or other red cell incompatibility was excluded in all of the five reactions related to the transfusion of red cells (Cases 1 - 5).

• Five reactions, four of which were associated with the transfusion of red cells (Cases 1 - 3, and 5) involved the development of a fever which required the transfusion to be discontinued. In such cases bacterial contamination of the pack needs to be excluded. This requires cultures from both the patient and the pack as contamination can only be confirmed when at least one component transfused is shown to be contaminated with the same infectious agent as the recipient of that unit. Only one of these cases (Case 5) had blood cultures taken from both the patient and the unit, and in this case bacterial contamination was definitely excluded as the cause of the symptoms.

• Regrettably, in two cases (Cases 2 and 3) blood culture samples from the patient were mislaid. The units in both of these cases had positive cultures. Further investigation has revealed that these positive cultures were likely to have been as a result of contamination during the handling, storage or culturing procedure of the units following transfusion. As a precaution, the supply centre was informed in order to allow the withdrawal of other components from these donations.
In Case 6 where fever was associated with the transfusion of a unit of apherased platelets, the patient was cultured and coagulase negative staphylococcus was isolated which was considered unrelated to the transfusion but the unit was not cultured. This patient also had HLA antibodies which could have been responsible for the transfusion reaction.

In one case (Case 8), the reaction was associated with the transfusion of SD plasma to correct over anticoagulation in a patient with an oozing mouth ulcer rather than using Vitamin K. This patient had a history of previous aortic valve surgery and was considered to be at risk of developing thromboembolism if treated with Vitamin K for warfarin reversal.

Due to the nature of the symptoms described, two incidents (Case 4 and 5) were investigated for the possibility of TRALI, which was subsequently excluded. These reactions had elements that were indicative of either an anaphylactoid transfusion reaction or TACO.

One incident (Case 7) involved a haemolytic reaction in a patient with a rare blood disorder - Paroxysmal Nocturnal Haemoglobinuria (PNH), where the red cells are very susceptible to haemolysis following the transfusion of ABO incompatible HLA matched platelets. The transfusion of ABO incompatible platelets was necessary because HLA matched group specific platelets were not available.

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. Two reactions in this category were observed within the first 50mls of transfusion, (Cases 1 and 2).

Guidelines on oral anticoagulation indicate that the short-term risk of thromboembolism in patients with mechanical heart valves when not anticoagulated is minimal. Such patients with an INR between 6 and 8 with no bleeding or minor bleeding should be managed by stopping warfarin and restarting it when the INR is less than 5.

Rapid reversal of over-anticoagulation using SD treated plasma or Prothrombin Complex Concentrate (PCC) is only considered necessary for patients with serious bleeding or before emergency surgery. An information leaflet relating to the appropriate use of SD treated plasma was issued by the NHO in January 2003 (Apéndice 2).

Platelet transfusions from ABO compatible donors are the component of choice and should be used when available. In the event of a difficulty with the supply of ABO compatible platelets, it may be necessary to administer ABO non-identical platelet transfusions. While this is acceptable practice there may be a poor increment rise or in some rare cases, haemolysis. Advice for the selection of components in such cases is included in Appendix 3.
• 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 or other red cell incompatibility 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

**Take blood samples for:**
  ❖ repeat group, antibody screen and crossmatch to exclude an ABO 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 lactate dehydrogenase (LDH)
  ❖ In the event of fever both the patient and the transfused unit or units should be cultured to exclude bacterial contamination of the unit
  ❖ any other samples eg. urine, sputum deemed necessary to aid in excluding other possible sources of infection.

• A protocol for culturing of the blood component unit 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.
<table>
<thead>
<tr>
<th>Case Number</th>
<th>Component Transfused</th>
<th>Age and Gender</th>
<th>Symptoms</th>
<th>Investigations</th>
<th>Treatment and Outcome</th>
<th>Volume Transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>One unit of red cells</td>
<td>65 yrs Female</td>
<td>Fever (greater than 1ºC), tachycardia and hypotension.</td>
<td>Incompatible transfusion excluded. Patient not cultured. Unit cultured – no organisms isolated. Antibody screen negative pre and post transfusion.</td>
<td>Transfusion discontinued. No medication prescribed. Recovered with no sequelae.</td>
<td>Less than 50 mls</td>
</tr>
<tr>
<td>Case 2</td>
<td>One unit of red cells</td>
<td>73 years Male</td>
<td>Restlessness, tachycardia, hypertension and low grade fever (37.9ºC). Patient became confused and disoriented.</td>
<td>Incompatible transfusion excluded. Blood taken for cultures but samples lost. Unit cultured - contaminant.</td>
<td>Transfusion discontinued. Recovered with no ill effects within 12 hours. No further transfusions necessary.</td>
<td>Less than 50 mls</td>
</tr>
<tr>
<td>Case 3</td>
<td>Two units of red cells</td>
<td>76 years Male</td>
<td>Fever (38.7ºC). Patient became very confused and agitated.</td>
<td>Incompatible transfusion excluded. Blood taken for cultures but samples lost. Unit cultured - contaminant.</td>
<td>Transfusion discontinued. Haloperidol 5 mgs given orally. Symptoms resolved within three hours. Similar symptoms during subsequent transfusion, which was also discontinued. A third attempt to transfuse was successful with pre-medication of haloperidol and paracetamol to alleviate underlying condition.</td>
<td>More than 100 mls of each unit of red cells.</td>
</tr>
</tbody>
</table>
### Acute Haemolytic or Other Severe Acute Transfusion Reaction: Table 35 continued

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Component Transfused</th>
<th>Age and Gender</th>
<th>Symptoms</th>
<th>Investigations</th>
<th>Treatment and Outcome</th>
<th>Volume Transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHOSTR</td>
<td>One unit of red cells</td>
<td>68 years Female</td>
<td>Dyspnoea, hypoxia, falling pO₂ and hypertension. There was a rash on trunk and limbs and reduced cognition. There was no fever.</td>
<td>Incompatible transfusion excluded. DAT positive IgG both pre and post transfusion. Antibody screen negative post transfusion. No HLA antibody detected post transfusion.</td>
<td>Oxygen 100% via assisted ventilation. IV frusemide &amp; hydrocortisone. Bricanyl infusion also required. Recovered with no sequelae.</td>
<td>Less than 100 mls</td>
</tr>
<tr>
<td>AHOSTR</td>
<td>One unit of red cells</td>
<td>77 years Male</td>
<td>Dyspnoea, fever, chills, tachycardia and hypertension.</td>
<td>Incompatible transfusion excluded. Both patient and pack cultured - no organisms isolated. The donor was a previously untransfused male making a diagnosis of TRALI very unlikely.</td>
<td>The complete unit was transfused. IV antihistamine and oxygen were given with relief of symptoms. Recovered with no ill effects.</td>
<td>One complete unit of red cells</td>
</tr>
<tr>
<td>AHOSTR</td>
<td>One unit of apheresed platelet concentrate</td>
<td>80 years Female</td>
<td>Fever (38°C), chills/rgors, nausea and vomiting.</td>
<td>Patient cultured - coagulase negative staphylococcus isolated, unrelated to transfusion. Pack not cultured. Red cell antibody screen negative pre and post transfusion. Leucocyte antibody detected post transfusion - HLA antibody positive.</td>
<td>Paracetomol and IM metoclopramide given. A full recovery was made within 24 hours.</td>
<td>One complete unit</td>
</tr>
<tr>
<td>Case No</td>
<td>Component Transfused</td>
<td>Age and Gender</td>
<td>Symptoms</td>
<td>Investigations</td>
<td>Treatment and Outcome</td>
<td>Volume Transfused</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------</td>
<td>-----------------</td>
<td>---------------------------------------</td>
<td>--------------------------------------------------------</td>
<td>------------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>AHOSTR Case 7</td>
<td>Two units of HLA matched but ABO and Rh D mismatched platelets.</td>
<td>36 years Female</td>
<td>Hypotension and haematuria.</td>
<td>A falling Hb and rising bilirubin was noted the next day.</td>
<td>Transfusion discontinued. Hydration maintained on IV fluids. Urinary output maintained on IV frusemide.</td>
<td>Symptoms developed during the second unit.</td>
</tr>
<tr>
<td>AHOSTR Case 8</td>
<td>Group O SD plasma.</td>
<td>64 years Male</td>
<td>Chest pain, rolling eyes, clammy and perspiring. There was no associated fever.</td>
<td>Patient not cultured. Unit cultured – no organisms isolated. There were no new changes on ECG. Cardiac enzymes within normal range.</td>
<td>Transfusion discontinued completely. Paracetomol administered with effect. Recovered with no sequelae.</td>
<td>More than 100 mls</td>
</tr>
</tbody>
</table>
Reactions associated with the transfusion of Red Cells

AHOSTR Case 1
This patient, with anaemia secondary to an upper GI bleed - Hb 7.4g/dl - required a transfusion of one unit of red cells. The pre-transfusion antibody screen was negative. During the first 15 minutes, when less than 50 mls had transfused, symptoms of fever, tachycardia and hypotension developed. The transfusion was continued at a slower rate initially then discontinued completely following haematology review. No medication was prescribed. The patient was not cultured. The pack was cultured and no organisms were isolated. An ABO and Rh D incompatible transfusion was excluded and the post transfusion antibody screen remained negative. This patient recovered with no sequelae.

AHOSTR Case 2
This elderly patient with symptomatic anaemia of malignancy – Hb 9.6g/dl - was transfused with one unit of red cells. The pre-transfusion antibody screen was negative. When less than 50 mls had been transfused, symptoms of restlessness, tachycardia, hypertension and a low grade fever - 37.9°C – developed. The patient also became confused and disorientated. Concurrent medication included Nu-Seals Aspirin, paracetamol, Aulin and Augmentin. An ABO and Rh D incompatible transfusion was excluded. The post-transfusion antibody screen remained negative. This patient recovered with no ill effects within 12 hours without further treatment. Blood samples were taken from the patient but were lost en route to the laboratory. The unit was cultured and staphlococcus aureus was isolated after seven days. The supplying centre was informed as a precaution so that any other components from the same donor could be withdrawn. Following investigations at the supplying centre, it was felt that this was a contaminant, which occurred after transfusion during the storage, sampling or culturing process. No further transfusion was necessary.

AHOSTR Case 3
This elderly patient with symptomatic anaemia of malignancy – Hb 7.8g/dl – required transfusion with three units of red cells. The pre-transfusion antibody screen was negative. Following approximately 100mls symptoms of fever - 38.7°C - confusion and agitation developed and the patient became uncooperative. The transfusion was discontinued and haloperidol 5 mgs was given orally with relief of symptoms within three hours. Later that same day transfusion was attempted again with a new unit. Similar symptoms developed and again the transfusion was discontinued and haloperidol 5mgs given with effect. Again, a full recovery was made within three hours. The following morning a third attempt to transfuse with a pre-medication of haloperidol 5 mgs and paracetomol 1 gm was made successfully.

An ABO and Rh D incompatible transfusion was excluded. The post-transfusion antibody screen remained negative. Blood samples were taken but were lost en route to the laboratory. The unit was cultured and streptococci were isolated from the contents of the pack after seven days. The supplying centre was informed so that any other components from the same donor could be withdrawn. Following investigation it was felt that the result was likely to be a contaminant. This patient was not transfused again. This reaction most probably relates to the patients underlying condition rather than transfusion.
AHOSTR Case 4
This patient, following myocardial infarction, which was complicated by pneumonia, required a transfusion of two units of red cells for anaemia - Hb 8.5g/dl. The pre-transfusion antibody screen was negative. The patient received the first unit uneventfully. Following transfusion of 50 mls of the second unit symptoms of dyspnoea, hypoxia, falling pO$_2$, - 45% - hypertension (199/100 mm/hg) and reduced cognition developed. There was also a worsening of an existing diffuse rash over trunk and thighs. The transfusion was immediately discontinued and the emergency team called. This patient required intubation and ventilation with 100% oxygen. IV frusemide, hydrocortisone and a bricanyl infusion were administered. The patient recovered from this incident without sequelae.

An ABO and Rh D incompatible transfusion was excluded and the post-transfusion antibody screen was negative. Neither the patient nor the unit was cultured. The sudden fall in pO$_2$ together with hypertension raised the suspicion of volume overload, but there was no documented evidence of overload either on auscultation or on chest x-ray. The donor involved was a previously un-transfused male, and together with the negative chest x-ray, made a diagnosis of TRALI very unlikely. IgA levels were checked three days prior to the reaction and were within normal limits. Tests for HLA leucocyte antibodies were negative. Due to the atypical nature of the symptoms it has been difficult to classify this reaction. However some of the symptoms may be related to the underlying disease process.

AHOSTR Case 5
This elderly patient required a transfusion of one unit of red cells for symptomatic anaemia of malignancy – Hb 7.4g/dl. Following completion of the transfusion symptoms of dyspnoea, fever, chills, tachycardia and hypertension developed. An antihistamine and nasal oxygen therapy were given and the patient experienced relief of symptoms within two hours. An incompatible transfusion was excluded. Both the patient and the unit were cultured and no organisms were isolated. There was no clinical evidence suggestive of volume overload but no chest x-ray was performed. The donor involved was a previously un-transfused male making the possibility of TRALI very unlikely. Due to the absence of cutaneous manifestations and the presence of fever, this reaction was not considered to be an anaphylactoid transfusion reaction.

Reactions associated with the transfusion of platelets

AHOSTR Case 6
This elderly patient, with end stage malignancy, required a transfusion of platelets following a fall resulting in a head injury. One unit of group compatible platelets were transfused. Forty minutes following completion of the transfusion the patient developed symptoms of fever, chills, rigors, nausea and vomiting. Following immediate medical review oral paracetomol and IM metoclopramide were administered. Blood cultures on the patient isolated a coagulase negative staphylococcus, which was not felt to be transfusion related. However the unit was not cultured. Over several previous admissions blood cultures on this patient had isolated E Coli. Recent urinary tract infections also cultured E Coli. HLA antibodies were also detected in this patient. There was a full recovery within twenty-four hours.

This patient developed fever unrelated to transfusion three days later. Investigations revealed a lower respiratory tract infection, which required antibiotic therapy.
AHOSTR Case 7
This patient had a history of PNH, a rare haematological disorder. The patient was also refractory to random donor platelets in the past but had been successfully treated with HLA matched platelets. On this occasion she required a transfusion of HLA matched platelets for a minor elective surgical procedure.

She grouped as B Rh D negative and as there were no HLA matched donors of that specific group, two units of group O HLA matched platelets were issued. The first unit was transfused uneventfully. However there was further bleeding and it was decided to transfuse a further unit of HLA matched platelets. During transfusion of the second unit the patient developed symptoms of hypotension and haemoglobinuria. Following specialist haematology advice, one litre of normal saline was infused over eight hours to maintain hydration. IV frusemide was also administered to maintain urine output. The patient made a full recovery without further intervention.

This acute haemolytic transfusion reaction was induced by the anti-B in the plasma of the group O platelet concentrate. The red cells of PNH patients are sensitive to complement and transfusions of ABO incompatible plasma can precipitate haemolysis. Due to the difficulty in procuring group compatible HLA matched platelets future platelet transfusions for this patient will be with increased doses of group compatible non-HLA matched platelets.

Reaction associated with the transfusion of SD treated plasma

HV No: 0938902 AHOSTR Case 8
This patient was admitted for correction of over-anticoagulation - INR 4.1 - with an oozing mouth ulcer. More than 100 mls of SD treated plasma had been transfused when the patient experienced chest pain, rolling eyes and became sweaty and clammy. There was no associated fever. The transfusion was discontinued completely and paracetamol was administered. The ECG was normal and cardiac enzymes were within normal range. The patient was not cultured. No organisms were isolated from culture of the unit. The patient recovered with no ill effects. No further transfusions of SD plasma were needed and the INR was 2.3 following the transfusion. A clinical decision not to administer Vitamin K was taken as the patient had an aortic valve replaced previously and the physician felt the use of vitamin K in correcting the INR of such patients could easily result in over correction and possible thromboembolism.
PRE-DEPOSIT AUTOLOGOUS DONOR INCIDENTS: 2002

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

This category accounted for 3% of incidents reported (5 of 155). The NHO collected reports in this category for the first time during the 2001 reporting period. All adverse incidents surrounding donation procedures reported were collected and collated within this category.

Pre-deposit autologous donation involves the collection and storage of up to five units of autologous blood during the pre-operative period. This blood is then used to meet some or all of the patient’s transfusion requirements during the peri-operative period. This technique had risen in popularity during the 1980’s as a result of public concern about safety aspects of transfusion. It provides an alternative system of transfusion for patients scheduled for elective surgery where there is a reasonable expectation of requiring blood. One popular area of application for PAD has been in the field of elective orthopedic surgery. Ten years ago, the average estimated blood loss for total hip replacement (THR) averaged between 900 and 1800mls. Today, with current anaesthetic techniques and a standard method of hip arthroplasty, the average blood loss has now been reduced to 500ml. Thus advancements in anaesthesia and surgical technique, in addition to appropriate pre-operative assessment, have reduced the need for transfusion in such patients.

There is a paucity of data available worldwide on actual adverse incidents involving donors participating in PAD programmes.

Incidents that occur during the actual transfusion of autologous blood, continue to be captured under the existing categories for adverse incidents and events during transfusion.

Findings:
- Of the five incidents reported all involved patients undergoing elective pre-deposit autologous donation for orthopaedic procedures. Of these five cases, two were for elective hip arthroplasty, two involved spinal surgery and one was for revision knee arthroplasty.

- The symptoms experienced by four of the donors ranged from immediate light headedness, pallor, sweating, nausea and fainting, which resolved quickly, to symptoms lasting two to three days following donation (Case 3).

- None of five donors received volume replacement.

- Two of these donors were donating for the first time. The other three all had donated previously without adverse sequelae.

- Four donors were female and one was male. There was a wide variation in age ranging from 13 to 77 years.
• None of the adverse events involved hospitalisation of the patient or rescheduling of surgery.

• Four of the five donors recovered without sequelae following a period of further rest.

• No further units were donated by four of the donors.

• Four of the five autologous donors underwent surgery. Of these, only two were transfused perioperatively with autologous blood. No extra allogeneic blood was transfused to any of these donors.

Recommendations:

• Careful pre-operative assessment of the elective surgical patient with detection and correction of underlying anaemia and reversal of sub-clinical iron deficiency with iron supplements may reduce the need for any transfusion21.

• Donor selection criteria for the autologous donor are not as rigid as for the allogeneic donors. As a consequence, such donors already compromised from underlying disease processes, may exhibit complications considered innocuous in healthy individuals which may be of greater significance in this donor population22. Care therefore is required during the pre-donation assessment to elicit any underlying problems and hospitals should have specific criteria for donor acceptability.

• Particular caution must be exercised during the assessment and donation of patients taking betablockers. Volume replacement should be considered for patients on treatment with betablockers and/or ACE inhibitors as their ability to respond to a reduction in blood volume may be compromised by their treatment23.

• The comprehensive pre-donation interview should include confirmation of satisfactory venous access and a definite date for surgery must be set at the time of assessment.

• Promotion of PAD programmes should be carefully targeted to ensure that only patients who are likely to require transfusion are recruited. Regular audit of the usage of blood collected under PAD programmes should be performed. The findings will help to prevent unnecessary collection and over transfusion of autologous donors.

• A recent study42 questions the value of pre-deposit autologous donation in the non-anaemic patient scheduled for THR. The study looked at 96 patients, of whom 42 were autologous donors and 54 non-donors. There was no significant difference in estimated blood volumes, Hb measurements, transfusion rates or the male to female ratio. On admission for surgery, the Hb level was lower in the donor group despite the fact that oral iron had been prescribed for approximately four weeks in this group, and for ten days in the non-donor group. No patient in either treatment group required an allogeneic transfusion. However 69% of the donor group received one autologous unit making autologous donors more likely to receive a transfusion. Finally 41% of all the autologous units collected were discarded. The merit of the pre-donation of one unit of autologous blood in the elective surgical patient, highlighted by this study, requires on going evaluation.
This is particularly the case as autologous transfusion carries the same risk of wrong component transfused and volume overload as allogeneic transfusion. There is also the possibility of bacterial contamination, which although rare, has been reported as somewhat more common in autologous donors than in allogeneic donors. Bacterial contamination may arise through undiagnosed infection in the donor or through contamination during the donation, storage and/or transfusion processes. As the donor selection criteria for autologous donors are less stringent, accidental transfusion of a PAD unit to another patient may have serious implications.

Linden and Kruskall (1997)\textsuperscript{43} reported two cases where PAD blood components were administered to unintended recipients and a third case narrowly avoided. Continued vigilance is therefore necessary to ensure systems are in place to ensure that autologous blood is only transfused to the intended recipient.

It is essential to ensure that the units deposited are available on site for the patient’s surgery and are selected in preference to allogeneic blood. The SANGUIS group study reported that 3 of 55 patients with autologous blood available received allogeneic blood in error\textsuperscript{44}. The NHO Annual Report, 2001\textsuperscript{3}, reported a similar incident.
### Pre deposit Autologous Donor Incidents: Table 36 All cases included as full case histories

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>Weight</th>
<th>Procedure</th>
<th>Current medications</th>
<th>History of donations</th>
<th>Complications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAD Case 1</td>
<td>13 yrs</td>
<td>F</td>
<td>64kgs</td>
<td>Spinal surgery</td>
<td>Ferrograd C</td>
<td>Complained of feeling faint during a previous blood test. Previous autologous donation uneventful.</td>
<td>Symptoms of pallor, light headedness and nausea developed five minutes following donation.</td>
<td>Symptoms resolved after a rest period of 30 minutes, with the end of the bed elevated. Went on to successfully donate a third time.</td>
</tr>
<tr>
<td>PAD Case 2</td>
<td>44 yrs</td>
<td>F</td>
<td>&gt;50kgs</td>
<td>THR</td>
<td>Diclofenac 100mg SR, Solpadeine and Ferrograd C</td>
<td>Previous donor with no previous adverse events.</td>
<td>Light-headed and faint, immediately following donation.</td>
<td>Patient recovered with no sequelae within 30 minutes.</td>
</tr>
<tr>
<td>PAD Case 3</td>
<td>77 yrs</td>
<td>F</td>
<td>&gt;50kgs</td>
<td>THR</td>
<td>Celebrex 100mgs daily, Tenoretic 50 mgs daily and Calcium daily</td>
<td>No previous donation history.</td>
<td>Felt light-headed, nausea, and unsteady for 2-3 days following donation</td>
<td>GP subsequently diagnosed vertigo which was treated with phenothiazine.</td>
</tr>
<tr>
<td>PAD Case 4</td>
<td>57 yrs</td>
<td>M</td>
<td>&gt;50 kgs</td>
<td>Total knee replacement (TKR)</td>
<td>Tylex and Difene gel</td>
<td>Previous donor with no previous adverse events.</td>
<td>Sweating and feeling of panic 10 minutes following donation.</td>
<td>This patient had suffered previous anxiety attacks and recovered fully with no sequelae.</td>
</tr>
<tr>
<td>PAD Case 5</td>
<td>20 yrs</td>
<td>F</td>
<td>&gt;50 kgs</td>
<td>Spinal surgery</td>
<td>Ferrograd C</td>
<td>No previous donation.</td>
<td>Light-headed immediately following donation.</td>
<td>Patient recovered with no sequelae within 15 minutes.</td>
</tr>
</tbody>
</table>
Pre-Deposit Autologous Donor (PAD) Incidents

PAD Case 1
This young girl was scheduled to pre-donate three units of blood prior to elective spinal surgery. The first donation had been uneventful. The patient's Hb was 12.2g/dl prior to the second donation. Five minutes following completion of the second donation, when 475 mls of whole blood had been donated, the donor became light-headed and nauseated with associated pallor. These symptoms resolved after a rest period of 30 minutes and elevation of the end of bed. No volume replacement was given. The patient admitted to a previous episode of feeling faint during a blood test, which she had failed to mention prior to donation. She went on to successfully donate a third unit uneventfully one week later. Two of the three autologous units were transfused, one on the day of surgery and one in the post-operative period. Prior to discharge the Hb was 9.8g/dl.

PAD Case 2
This incident involved the scheduled pre-donation of one unit of whole blood, required for an elective THR. Donor fitness assessment was carried out and the patient's weight and Hb were within acceptable parameters. Medications at the time of donation included analgesics and iron supplements. One unit containing 537 mls of whole blood was collected with no volume replacement. Immediately following donation, the patient developed symptoms of light-headedness and felt faint. Following medical review and a further period of rest of 30 minutes, the patient was discharged. No further attempt at pre-deposit donation was made. Transfusion was not required during the perioperative period. This patient had been a previous blood donor with no history of adverse events.

PAD Case 3
This elderly lady was scheduled to pre-donate one unit of whole blood for an elective THR. Donor fitness assessment was carried out, weight was greater than 50kgs and Hb was 12.3g/dl, both within acceptable parameters. Medications at the time of donation included a cardioselective beta-blocker, analgesics, and calcium supplements. One donation containing 547 mls of whole blood was collected with no volume replacement. The patient left the unit after an uneventful rest period. Twenty-four hours following the donation, symptoms of light-headedness and nausea developed. Following review by the GP vertigo was diagnosed and oral phenothiazine was prescribed. No further attempt at pre-deposit autologous donation was made. A blood transfusion was not required peri-operatively. The Hb on discharge was 9.0g/dl. This patient had been a previous blood donor with no history of adverse events.

PAD Case 4
This incident involved the scheduled pre-donation of one unit of whole blood, required for a TKR. Donor fitness assessment was carried out and the weight and Hb were within acceptable parameters. Medication at the time of donation was an oral analgesic preparation. One donation containing 543 mls of whole blood was collected. No volume replacement was given. Ten to fifteen minutes following this donation the patient began to perspire and felt claustrophobic. Following medical review, and a rest period of twenty minutes the patient recovered with no sequelae. It was subsequently discovered that this patient had a previous history of anxiety attacks. No further attempt at pre-deposit donation was made and the patient subsequently chose not to proceed with surgery. This patient had donated blood uneventfully in the past.
PAD Case 5
This incident involved the scheduled pre-donation of one unit of whole blood, required for elective spinal surgery. Donor fitness assessment was carried out and the weight and Hb were within acceptable parameters. The only medication being taken at the time of donation was an iron supplement. One donation containing 541 mls of whole blood was collected with no volume replacement given. Fifteen minutes following the donation, the patient became light-headed and following medical review and a further rest period of 30 minutes, was discharged. No further attempt at pre-deposit donation was made. This patient had no previous history of blood donation. The autologous unit that had been collected was transfused intraoperatively and no further units were required. The post-operative Hb was 7.6g/dl which was well tolerated and the patient was discharged on oral iron therapy.

This category accounted for 2% of incidents reported (3 of 155). The NHO collects and investigates reports of transfusion-transmitted bacterial and parasitic infections. The NHO also 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, eg 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 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 period.

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. 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:

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

and either

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

or

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

Much concern has been voiced in recent years regarding the risk of transfusion-transmitted infection, and much quality assurance effort has been directed towards appropriate testing and handling of blood after collection. There is very good evidence that with continuous improvements in the donor selection/testing procedures and manufacturing processes used in Ireland, the risk of transfusion-transmitted infection is very small.
The current estimated risk for HIV is less than 1 per 4 million components transfused, and for HCV is less than 1 per 4 million components transfused\(^8\). These residual risk estimates are based on serological testing and nucleic acid amplification testing (NAT) for HCV and HIV.

The risk for HBV has been estimated at approximately 1 per 200,000 since the introduction of testing for antibody to Hepatitis B core in January 2002\(^8\).

The risk of receiving an incorrect blood component is in fact greater than the risk of receiving a transfusion-transmitted infection. Over the 6 year period since the United Kingdom Serious Hazards of Transfusion (SHOT) began reporting, confirmed reports of TTIs accounted for 2.2% of incidents in comparison to reports in the IBCT category, which accounted for almost 63.9\(^%\)\(^4,10,20,41,45,46\).

A total of three incidents, which fit the criteria of suspected transfusion-transmitted infection, were reported to the NHO during this reporting year. Two of the reports were instigated as a result of a positive viral marker found at blood donation and the third was reported by a hospital. In two cases, of HBV and HCV respectively, transfusion has been excluded. In the third case, a case of HBV, investigations are ongoing.

A further two patients who had been transfused with multiple units of FFP and subsequently treated with IV immunoglobulin were found to be HCV positive in 2002. This was reported to the NHO. The investigations by the NHO determined that these patients had been exposed, and most probably infected, by FFP administered before the introduction of mandatory testing for HCV in 1991. They had received no blood components since that date. Therefore these reports fall outside the remit of the NHO scheme which collects and investigates suspected cases of transfusion-transmitted infection occurring since the introduction of mandatory screening for the relevant marker. These reports therefore did not progress and are not included in the figures.

### Suspected Transfusion-Transmitted Infection: Table 37 All cases included as full case histories

<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 investigated</th>
<th>Outcome of the investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTI Case 1</td>
<td>M</td>
<td>2001</td>
<td>Adult</td>
<td>Suspected HBV</td>
<td>1</td>
<td>Possibly transfusion related. Other risk factors exist. Investigations ongoing.</td>
</tr>
<tr>
<td>TTI Case 2</td>
<td>M</td>
<td>2001 and 2002</td>
<td>Adult</td>
<td>Suspected HCV</td>
<td>62</td>
<td>Transfusion excluded as the source of the infection.</td>
</tr>
<tr>
<td>TTI Case 3</td>
<td>M</td>
<td>1998</td>
<td>Adult</td>
<td>Suspected HBV</td>
<td>4</td>
<td>Transfusion excluded as the source of the infection. Other risk factors exist.</td>
</tr>
</tbody>
</table>
We report the details on the three suspected cases.

TTI Case 1
This patient received transfusions following an RTA in 2001 including one unit of red cells from a first time donor who screened negative for all mandatory markers at the time of donation. In 2002, this donor was involved in a look-back as their partner, who subsequently presented as a donor for the first time, tested positive for HBV. The archived sample and follow up samples on the donor showed that the donor was anti-hepatitis B core antibody and surface antibody positive with a pattern consistent with recent cleared infection at the time of the donation. The patient was traced and HBV tested and found to be a chronic HBV carrier. However the patient came from an ethnic background with a high level of endemic HBV infection. This investigation is still ongoing with sequencing of donor and patient to be undertaken to try to determine whether the HBV is likely to be transfusion related.

TTI Case 2
This patient was found to be HCV positive in 2002. He had required multiple transfusions of red cells, platelets and FFP over the previous seven months involving 62 donor exposures in total. All donors were HCV negative by serology and PCR testing at the time of donating. Archived samples or subsequent samples were obtained from all donors; none were found to have markers indicative of possible infectivity at the time of donating the implicated units. It is highly unlikely that the patient’s infection was acquired from transfusion.

TTI Case 3
This donor was found to be HBV positive on first donation during 2002. The past medical history included a transfusion of four units of red cells in 1998 following trauma. However, there were other risk factors. Archived samples or subsequent samples were obtained from all four donors; none were found to have markers indicative of possible infectivity at the time of donating the implicated units and transfusion was excluded as the likely cause.
TRANSFUSION RELATED ACUTE LUNG INJURY: 2002

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

This category accounted for 1% (2 of 155) of incidents reported during this reporting period. One further reaction was reported during 2001, and as investigations were completed during this reporting year, this reaction will be described here. All three cases are described in detail.

TRALI generally manifests itself as an acute respiratory distress, fever and hypotension during or soon after transfusion with associated bilateral pulmonary oedema. There is no evidence of cardiac compromise or acute volume overload. One study found that hypertension was a presenting feature in 15% of cases. Chest x-rays classically demonstrate white-out by interstitial and alveolar infiltrates, but in the first few hours a patchy pattern may be observed. Symptoms typically begin within 1-2 hours of transfusion and are always present by 4-6 hours post transfusion.

The true incidence of TRALI is unknown. In one study carried out prior to the introduction of SAG-M red cell concentrates which contain markedly less plasma, one in 5000 transfusions were associated with TRALI. The SHOT data have found the incidence of TRALI to be significantly less frequent although they recognise that it may be under-diagnosed. In the NHO experience five suspected cases of TRALI were investigated over the first three years. One of these has been excluded. Two cases have been confirmed, one is considered probable and investigations are not yet complete in the remaining one, which is considered a possible case. From this data the estimated incidence of TRALI is 1:186,000 units of red cells issued, 1:40,000 units of platelets issued and 1:56,000 units of FFP issued.

TRALI is thought to result from the presence of anti-HLA and/or anti-granulocyte antibodies mainly in the plasma of multiparous female donors, or less commonly in donors who have received previous transfusions. One or both of these antibody types have been found in 89% of TRALI cases. One study proposed the alternative hypothesis that TRALI is the result of two clinical events: a predisposing clinical condition and the transfusion of biologically active lipids in stored blood. There have been documented cases where there were no associated antibodies.

TRALI has been more frequently described in transfusions containing significant amounts of plasma i.e. FFP and platelets, but it has also been associated with cryoprecipitate, red cell transfusions and intravenous immunoglobulin. SD treated plasma has not been convincingly implicated in TRALI so far, probably because of the dilution of antibodies due to the pooling process during manufacture. However there was one non-confirmed case of TRALI reported following the transfusion of SD treated plasma in the SHOT Report 2001-2002.
Findings:

- There were two cases in this category reported to the NHO during this reporting period, both cases involved the transfusion of pooled platelet concentrates.

- Case 3, involving the transfusion of FFP, was reported during 2001. This report was transferred from the TACO category based on the clinical picture and the results of the donor investigations.

- In Case 1, the respiratory symptoms occurred at least 36 hours after the platelet transfusion. Further review of the clinical details and the chest x-ray were suggestive of pneumonia and therefore a diagnosis of TRALI is highly unlikely.

- Case 2 was initially reported as a transfusion reaction occurring 20 hours after transfusion. On review however, it was noted that while in theatre, the patient developed mild hypotension, which the anaesthetist felt was related to the intra-operative platelet transfusion. Further review revealed some findings that could possibly be attributed to TRALI. Three donors were investigated and found to be negative for anti-HLA and/or anti-granulocyte antibodies. The fourth donor has not yet been tested. Therefore full information on this case is not yet available.

- In case 3 both donors were found to have lymphocyte/granulocyte reactive antibodies. Clinically this case shows features that are suggestive of TRALI. Unfortunately, the patient’s HLA type was not performed, nor have crossmatch studies been undertaken. However, based on the clinical features and the antibody findings, it is felt that this case is likely to be TRALI.

Recommendations:

- Anticoagulant management should be reviewed pre-operatively and guidelines for the use of FFP should be incorporated in the hospital transfusion policy. The importance of avoiding FFP for the reversal of over-anticoagulation before a planned elective surgical procedure is again highlighted (See Appendix 1).

- Any respiratory distress occurring during, or within six hours following transfusion of blood or blood components could potentially be TRALI. Discontinue the transfusion immediately and begin oxygen and supportive therapy. A chest x-ray may help to exclude or support the diagnosis. The differential diagnosis includes TACO, anaphylactic transfusion reaction, bacterial contamination of the transfused blood component and ARDS.
  
  - The symptoms of *transfusion associated circulatory overload* usually begin within several hours of the transfusion of any type of component or product⁹. There may be other symptoms of cardiac insufficiency. Often there is pre-existing cardiovascular or respiratory disease.
  
  - The respiratory distress and cyanosis of *anaphylactic transfusion reactions* is related to bronchospasm and laryngeal oedema, not to pulmonary oedema. Furthermore, cutaneous manifestations are common and typically involve the trunk, face and neck. Fever, generally, is not a manifestation of anaphylactic transfusion reactions⁹.  
  
  - While fever and hypotension are frequent symptoms of *bacterial contamination*, respiratory distress is not as frequently observed. The onset of symptoms is usually immediate, or within 1-2 hours of commencing the transfusion⁹. Although platelets are most frequently implicated due to their ambient storage conditions, red cell transfusions may also be associated with this complication.
• TRALI is clinically indistinguishable from acute respiratory distress syndrome (ARDS). ARDS should be considered if the presentation is more than 12 hours post transfusion, or if the condition fails to resolve within 72-96 hours. This should also be considered in patients with clinical disorders associated with ARDS e.g. pneumonia, sepsis, aspiration of gastric contents and severe trauma.

• During this reporting year efforts have been made to raise awareness regarding TRALI by the NHO. A presentation was given at the annual haemovigilance conference and in addition, a TRALI information leaflet was circulated to all hospitals, (See Appendix 2). Continued careful evaluation of symptoms developing during or after transfusion is necessary to diagnose TRALI appropriately.

• Where there is a case fitting the clinical picture of TRALI the supplying blood centre should be notified of the unit numbers of the components transfused to facilitate the removal of any components from this donation which remain on the shelf, and the temporary deferral of these donors, pending investigation.

• Samples required from the patient for follow-up investigations include: 10mls blood in an EDTA tube for HLA typing and 10mls in a plain tube for HLA antibody testing. Further information may be obtained from the NHO.

• Since November 2002 pooled platelets suspended in male donor plasma and FFP made from male donor plasma has been introduced by the IBTS to help reduce the incidence of this transfusion complication.
### Transfusion Related Acute Lung Injury (TRALI): Table 38 All cases included as full case histories

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age and Gender</th>
<th>Component and number of units transfused</th>
<th>Reason for transfusion</th>
<th>Symptoms</th>
<th>Patient Investigations</th>
<th>Treatment</th>
<th>Donor Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRALI Case 1</td>
<td>79 yrs Male</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Post operative haemorrhage. There was underlying cardiac disease, on aspirin.</td>
<td>Falling pO₂ (74%) and a non-productive cough developed 36 hours following transfusion.</td>
<td>Decreased air entry on auscultation. Chest x-ray suggestive of bibasal pneumonia with small effusions. Sputum cultured – no organisms isolated. Required intubation for deteriorating condition 5 days later.</td>
<td>Admitted to ITU. Oxygen, nebulizers, paracetamol and IV antibiotics administered.</td>
<td>In view of the atypical features of this case, none of the donors involved were recalled for testing.</td>
</tr>
<tr>
<td>TRALI Case 2</td>
<td>77 yrs Male</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Post operative haemorrhage. There was underlying cardiac disease.</td>
<td>Mild hypotension - 105/55 mmHg. Mild crepitations on auscultation.</td>
<td>Chest x-ray revealed bilateral mid-zone infiltrates.</td>
<td>24% - 60% nasal oxygen and IV frusemide given.</td>
<td>Four donors involved and all were temporarily deferred. Three investigated to date and found to be negative for granulocyte antibodies. These three donors have been reinstated. The 4th donor has not been tested as yet.</td>
</tr>
<tr>
<td>TRALI Case 3 Reported during 2001.</td>
<td>44 yrs Male</td>
<td>Two Units of FFP. Anticoagulant therapy not discontinued prior to elective surgery. Coagulation studies not performed.</td>
<td>Mild hypertension - 140/100 mmHg, fever - 38.7°C - and falling pO₂ – 88% - at completion of transfusion.</td>
<td>No chest x-ray performed.</td>
<td>Oxygen therapy. Chlorpheniramine 10mg and hydrocortisone 100mg given IV.</td>
<td>Two donors involved and temporarily deferred. Both were found to have lymphocyte reactive antibodies. One donor also had granulocyte specific antibodies. Both donors have been permanently deferred.</td>
<td></td>
</tr>
</tbody>
</table>
Transfusion Related Acute Lung Injury

TRALI Case 1
This elderly patient had a complex medical history including significant cardiac disease and was on long-term aspirin therapy which was not discontinued prior to this elective surgical procedure. Post-operatively a pooled platelet concentrate was transfused. Approximately 36 hours following this transfusion the patient developed a non-productive cough and his pO_2 fell to 74%. He did not complain of shortness of breath or chest pain. Medical review revealed decreased air entry into the left lung base and coarse crepitations over the right lung field. Chest x-ray changes were suggestive of bibasal pneumonia with small effusions. The patient was admitted to ITU and was treated with oxygen, nebulizers, paracetamol and IV antibiotics. There was little resolution of symptoms and five days later the patient required intubation for deteriorating condition and impending respiratory failure. Renal function was also compromised and a dopamine infusion was required to maintain renal perfusion. Six days later the patient was discharged from ITU. In view of the clinical findings together with the delay in presentation, TRALI was considered to be highly unlikely, therefore none of the donors were recalled for testing.

TRALI Case 2
This elderly male patient with a post operative haemorrhage required further surgery and transfusion of eight units of red cells, four units of SD plasma and one unit of pooled platelet concentrate. Interoperatively, following the platelet transfusion, the patient developed mild hypotension, which the clinicians felt was directly related to the transfusion. During anaesthetic review, bilateral crepitations over the lung fields were heard. The chest x-ray showed bilateral mid-zone infiltrates. The patient was treated with oxygen therapy and frusemid. A subsequent cardiology review revealed moderate to severe aortic stenosis. Approximately 20 hours after the first episode the patient developed severe hypotension (78/43 mmHg) with falling pO_2 to less than 90% on 60% nasal oxygen. No further diuretics were given. The patient recovered within the next 24 hours on supportive management.

Three of the four donors of this unit of pooled platelet concentrate were female. The single male donor and two of the female donors have been investigated to date. Granulocyte-specific and anti-lymphocyte antibodies were not detected in the serum of these donors. These donors have been reinstated on the donor panel. The 4th donor has not yet been tested.

TRALI Case 3
This 44-year-old man, with a history of deep venous thrombosis (DVT), was on oral anticoagulant therapy and was admitted for an elective surgical procedure. The anticoagulant therapy was not discontinued prior to admission. Coagulation studies were not performed pre-operatively, instead two units of FFP were administered prior to surgery. At the end of the 2nd unit the patient developed symptoms of fever, mild hypertension and the pO_2 fell to 88% in room air. Following review nasal oxygen was commenced and IV chlorpheniramine 10mg and hydrocortisone 100mg were given. A chest x-ray was not performed. There was a full recovery without further intervention.

There were two female donors involved. Both donors were found to have white cell antibodies. The reaction in one donor was thought to be weak and non-specific. The results from the second donor however suggested the presence of both granulocyte specific IgM antibodies and granulocyte/lymphocyte reactive IgG antibodies. Both donors have been permanently deferred.
PAEDIATRIC INCIDENTS: 2002

As paediatric patients form an important sub-group of transfusion patients we have summarised the findings of the 12 paediatric cases. For the purpose of this report the term paediatric refers to the age range from new-born up to and including 15 years. All 12 cases are represented here in table format and can be referred to in detail throughout the text as per associated case numbers.

Of the 12 cases mentioned, eight are errors from the IBCT category, three are reactions from the AA category and one reaction from the PAD category. The primary causes of error identified in the IBCT category were supply in three cases, request in two and hospital transfusion laboratory related in two. Neonatal patients require specialised support in terms of transfusion, which may indicate the cause of such supply errors.
## Paediatric incidents (Incorrect Blood Component Transfused): Table 39 *Included as a full case history*

<table>
<thead>
<tr>
<th>Level</th>
<th>Case Number</th>
<th>Age</th>
<th>Gender</th>
<th>ABO and Rh D Group of Patient</th>
<th>ABO and Rh D Group of IBCT</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</td>
<td>16 days</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One unit of pooled platelet concentrate.</td>
<td>No sequelae.</td>
<td>Incorrect component issued from supplying centre, correct component issued to another hospital. Error not identified in hospital laboratory prior to issue or at bedside checking prior to transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT</td>
<td>15 yrs</td>
<td>M</td>
<td>Group A Rh D positive</td>
<td>Group A Rh D negative</td>
<td>One unit of irradiated pooled platelets.</td>
<td>CMV status of patient not known.</td>
<td>Component issued by supplying centre was irradiated but not CMV antibody negative as requested. Error not detected despite multiple checking procedures pre-transfusion.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT</td>
<td>15 yrs</td>
<td>F</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>Less than 100mls of red cells.</td>
<td>Apprehension chills, rigors, itching and urticaria. Recovered within hours. Both patient and unit cultured – no organisms isolated.</td>
<td>Failure to request CMV antibody negative and irradiated component for this patient with a newly diagnosed malignant haematological disorder.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT</td>
<td>1 month</td>
<td>M</td>
<td>Group AB Rh D negative</td>
<td>Group O Rh D negative</td>
<td>One unit of platelet concentrate apheresis.</td>
<td>No symptoms No sequelae.</td>
<td>Supply centre issued group O Rh D negative standard platelets. This baby should have received washed group O Rh D negative platelets only if group A Rh D negative platelets were not available. The hospital transfusion laboratory assumed that the correct product had been issued. The error was identified when checking on-call work the following morning.</td>
</tr>
<tr>
<td>Level</td>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>ABO and Rh D Group of Patient</td>
<td>ABO and Rh D Group of IBCT</td>
<td>Volume of Incorrect Blood Component or Product Transfused</td>
<td>Symptoms and Outcome</td>
<td>Cause of Error</td>
</tr>
<tr>
<td>-------</td>
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<td>----------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 55*</td>
<td>23 days</td>
<td>M</td>
<td>Mother Group A Rh D positive</td>
<td>Group O Rh D negative</td>
<td>10 mls of one aliquot of a paedipack - red cells for neonatal use.</td>
<td>No symptoms No sequelae.</td>
<td>Neonatal pack of partially packed red cells in CPDA, CMV antibody negative, kept in stock for neonatal resuscitation was inappropriately made available for this non-emergency transfusion. The error was discovered six days later when a further transfusion was requested. The infant had one unnecessary donor exposure.</td>
</tr>
<tr>
<td>2</td>
<td>IBCT Case 56*</td>
<td>1 day</td>
<td>M</td>
<td>Group O Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of a paedipack - red cells for neonatal use.</td>
<td>No sequelae.</td>
<td>Crossmatch for this infant carried out on a paedipack allocated for another infant.</td>
</tr>
<tr>
<td>3</td>
<td>IBCT Case 67</td>
<td>2 weeks</td>
<td>M</td>
<td>Group A Rh D positive</td>
<td>Group O Rh D positive</td>
<td>One aliquot of paedipack - red cells for neonatal use.</td>
<td>No symptoms No sequelae.</td>
<td>Issue hospital number transcribed onto issue label on unit. Error identified during pre-transfusion checking procedure of second aliquot.</td>
</tr>
<tr>
<td>1</td>
<td>IBCT Case 72*</td>
<td>12 yrs</td>
<td>M</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>3000 units (one vial) of Benefix (Factor IX) given instead of Refacto (Factor VIII).</td>
<td>No sequelae.</td>
<td>Benefix (Factor IX) requested instead of Refacto (Factor VIII). A series of multiple errors allowed the error to progress along the chain to administration, including computer system warning overridden and no formal checking procedure being carried out. The error was identified when further factor concentrate was requested some days later.</td>
</tr>
</tbody>
</table>
### Paediatric incidents (Severe Acute Anaphylactoid/Anaphylactic Transfusion Reaction): Table 40 *Included as a full case history*

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Age</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>Sequelea/Recommendations for future transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA Case 10*</td>
<td>6 yrs</td>
<td>F</td>
<td>One unit of apheresis platelet concentrate.</td>
<td>Thrombocytopenia secondary to haematological disorder and underlying sepsis - Platelet count $18 \times 10^9$/l.</td>
<td>Urticaria, dyspnoea, restlessness, anxiety and facial and tongue swelling. Falling $pO_2$ – 84% in room air.</td>
<td>Neither patient nor unit cultured. IgA levels were not checked.</td>
<td>Transfusion was almost complete.</td>
<td>Transfusion discontinued. IV hydrocortisone &amp; chlorpheniramine given. Nasal oxygen given with relief of symptoms.</td>
<td>Patient recovered from this event with no sequelae. IgA levels may need to be checked if future transfusions are required.</td>
</tr>
<tr>
<td>AA Case 24*</td>
<td>15 yrs</td>
<td>F</td>
<td>One unit of red cells.</td>
<td>Post operative anaemia - Hb 5.9g/dl.</td>
<td>Urticaria and periorbital oedema.</td>
<td>Both patient and pack cultured, no organisms isolated. IgA levels within normal limits. ABO incompatible transfusion excluded.</td>
<td>During the first 15 minutes of transfusion, when less than 100 mls had transfused.</td>
<td>Transfusion discontinued. Chlorpheniramine given orally.</td>
<td>Patient recovered from this event with no sequelae. No further transfusions required.</td>
</tr>
<tr>
<td>AA Case 27</td>
<td>8 yrs</td>
<td>F</td>
<td>One unit of pooled platelet concentrate.</td>
<td>Thrombocytopenia secondary to malignancy - platelet count $9 \times 10^9$/dl.</td>
<td>Urticaria, pyrexia $(38.5^\circ C)$, rigors, and tachycardia.</td>
<td>Central line cultured – no organisms isolated. Pack not cultured. IgA levels not checked. No red cell or HLA antibodies detected.</td>
<td>Following completion of transfusion.</td>
<td>IV hydrocortisone and chlorpheniramine.</td>
<td>Recovered with no ill effects within one day. Subsequent transfusions have been uneventful.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Age</td>
<td>Gender</td>
<td>Weight</td>
<td>Procedure</td>
<td>Current medications</td>
<td>History of donations</td>
<td>Complication</td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td>------------</td>
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<td>--------</td>
<td>-----------------</td>
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<td>--------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>PAD Case 1*</td>
<td>13 yrs</td>
<td>F</td>
<td>64 kgs</td>
<td>Spinal fusion.</td>
<td>Ferrograd C.</td>
<td>Complained of feeling faint during previous blood test. Previous donation uneventful.</td>
<td>Symptoms of pallor, light headedness and nausea developed five minutes following donation.</td>
<td>Symptoms resolved after a rest period of 30 minutes, with the end of the bed elevated. Went on to successfully donate a third time.</td>
<td></td>
</tr>
</tbody>
</table>
ACKNOWLEDGEMENTS

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.

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Mr Geoff O’Conell and Staff at the Virus Reference Laboratory, University College Dublin.
References


APPENDIX 1
Solvent Detergent (SD) Plasma

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

Points to note

- In 2001, the National Haemovigilance Office (NHO) received 16 (11%) reports of Transfusion Associated Circulatory Overload (TACO). Six (37.5%) of these were associated with Fresh Frozen Plasma (FFP).
- Occasional severe anaphylactoid reactions have been reported in association with FFP, especially with rapid infusion rates. During 2001 the NHO received 35 reports of severe acute anaphylactoid reactions, 11 (30.5%) of which were associated with FFP. Anaphylactic or anaphylactoid reactions due to hypersensitivity to infused plasma proteins or anti-IgA following the transfusion of Solvent Detergent Plasma (SDP) are rare (<1: 1000), and are likely to be of the same order as for FFP.
- The dosage of SDP depends upon the clinical situation and underlying disorder, but 12-15 mls/Kg is a generally accepted starting dose. It is important to monitor the response both clinically and with measurement of prothrombin time (PT), partial thromboplastin time (PTT) or specific factor assays.
- The statement on both the label and the product insert recommends that ‘the thawed product should be used immediately’. This must be interpreted in such a way as to minimise the risk of volume overload. The infusion of SDP should begin as soon as clinical circumstances permit after thawing. British guidelines recommend that each unit of plasma be transfused to an uncompromised adult over 30 minutes. Generally, the thawed product should be transfused within four hours of thawing. Coagulation factor replacement in the massively haemorrhaging patient may require faster infusion rates.
- The patient who is elderly, very small and/or cardiac or respiratory compromised deserves special mention. There is a significant risk of volume overload leading to respiratory distress with severe morbidity/mortality especially using rapid infusion rates. In the non-bleeding situation, transfusion rates for this group of patients should not exceed 2-4 mls/kg per hour.
- Each unit of SDP contains a standard volume of 200mls, in contrast to a unit of FFP, which contains 220-300mls. This smaller volume may need to be considered when calculating doses.

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

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

<table>
<thead>
<tr>
<th>Patient Weight</th>
<th>Units Required</th>
<th>Rate of Transfusion per hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 kg</td>
<td>1 unit</td>
<td>40 mls – 80 mls</td>
</tr>
<tr>
<td>30 kg</td>
<td>2 units</td>
<td>60 mls – 120 mls</td>
</tr>
<tr>
<td>40 kg</td>
<td>3 units</td>
<td>80 mls – 160 mls</td>
</tr>
<tr>
<td>50 kg</td>
<td>3 units</td>
<td>100mls – 200 mls</td>
</tr>
<tr>
<td>60 kg</td>
<td>4 units</td>
<td>120mls – 240 mls</td>
</tr>
</tbody>
</table>

Firm indications for giving plasma:

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

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

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

Table 2. Recommendations for management of bleeding and excessive anticoagulation

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

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

Managing Anticoagulation in the Perioperative Period

Elective invasive procedure: Stop anticoagulant for three days prior to surgery
Emergency invasive procedure: Where surgery cannot be postponed, reverse anticoagulant with low dose Vitamin K as above.

In emergency situations, Vitamin K should be given IV, which will reduce the INR within 4 hours, with complete reversal to the therapeutic range within 24 hours. In less urgent situations, it can be given orally. As Vitamin K tablets are only available as 10 mgs, the intravenous solution of Vitamin K can be given orally and is effective. Only 1mg is required to reduce the INR from >4.5 to a target of 2.0-3.0 within 24 hrs.

SD Plasma is not indicated in treatment of:
• Hypovolaemic shock
• Selected nutritional deficiencies
• Correction of immunodeficiency
• Replacement fluid in plasmapheresis with the exception of TTP

References


For further information contact:
National Haemovigilance Office at the NBC,  
James’s St, Dublin 8.
APPENDIX 2
Transfusion-Related Acute Lung Injury (TRALI)

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

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

Implicated Products
TRALI has been more frequently described in transfusions containing significant amounts of plasma i.e. fresh frozen plasma (FFP) and platelets, but it has also been associated with cryoprecipitate, red cell transfusions and intravenous immunoglobulin. Solvent detergent plasma (SD plasma) has not been implicated in TRALI probably because of the pooling process involved during manufacture.

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

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

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

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

**Recommendations**

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

**Differential Diagnosis**

<table>
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<th>TRALI</th>
<th>↑</th>
<th>↓↑</th>
<th>↑</th>
<th>Bilateral Pulmonary Oedema</th>
<th>During / up to 1-6 hours after</th>
<th>Granulocyte serology</th>
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<td>↑</td>
<td>↑</td>
<td>Cardiac Failure Pulmonary Oedema Positive Fluid Balance</td>
<td>During/after</td>
<td>ECG, cardiac enzymes, ECHO</td>
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<td>↑</td>
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<td>IgA Levels</td>
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<tr>
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<td>↓↓</td>
<td>↑</td>
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<td>Blood cultures of patient and blood component</td>
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<td>↓↑</td>
<td>↑</td>
<td>Bilateral Pulmonary Oedema</td>
<td>Consider if onset later than 6 hours</td>
<td>Investigations for underlying conditions</td>
</tr>
</tbody>
</table>

**Bibliography**

6. For further information contact:
   National Haemovigilance Office at the NBC, James’s St, Dublin 8.
APPENDIX 3

Irish Blood Transfusion Service
Guidelines for the Provision of Platelets where Platelets of the Patient’s own ABO/Rh D Group are not available

Introduction

Platelet concentrates of identical ABO group to that of the patient and which are Rh D compatible are the component of choice for patients requiring platelet transfusion. However, it is not always possible to have such platelets available for issue and it is occasionally necessary to issue platelets of an alternate group. This guideline will review the importance of ABO/Rh D compatibility in relation to platelet transfusion and will provide recommendations on the selection of platelets in situations where the platelets of the patient's own group is not available.

Background

ABO incompatibility

ABO antigens are expressed on platelet surfaces but the expression is variable both between patients and in the same individual. The antigen density is much weaker than that on red cells (about 5%).

Major ABO Incompatibility

There is insufficient red cell contamination (<0.03ml) to incur a risk of haemolytic reaction however major ABO incompatibility where the patient is exposed to an ABH antigen not present on his/her red cells is associated with reduced platelet recovery. This varies from 20% to 70% depending on the study. Factors influencing the variable recoveries reported include the number of ABO incompatible platelet transfusions, timing of the post platelet count and the quality of the product used (platelet rich plasma, buffy coat derived or apheresis). In one study it was shown that although initial recovery is reduced, the survival thereafter does not appear to be affected. The cumulative effect of provision of incompatible platelets was reported by Heal et al whereby three or more ABO incompatible platelet transfusions showed a significantly lower corrected count increment compared with those transfused with identical ABO platelets.

Minor ABO Incompatibility

Haemolytic reactions are a potential complication of transfusing plasma-containing antibodies to AB antigens present in the recipient. This typically occurs with donations containing high titre ABO antibodies and can also occur with infusion of large amounts of incompatible plasma as can happen with multiple incompatible transfusions or transfusion in small children. Group O individuals have higher anti-A /anti-B titres than Group B or A individuals.

Review of the published cases of severe haemolytic reactions shows that the majority relate to apheresis donations and that they all involve transfusion of Group O donor plasma to group A, B or AB recipients. Where anti-A or Anti-B titres are reported they range from 128 in saline, 1024 by indirect antiglobulin titre to 16384 in saline. All blood donations collected by the IBTS and the UK blood transfusion services are screened for the presence of high titre anti-A and Anti-B titres and plasma rich components are labelled as containing high titre isohaemagglutinins.

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where identified. However there is no generally agreed discriminatory test for high titre antibodies and there are no precise guidelines. Haemovigilance reports from Ireland and the UK suggest that haemolysis can occur with lower titres where large volumes are transfused. These reports and the BCSH guidelines recommend that hospital blood banks and clinical users should be aware of possible haemolysis associated with the transfusion of group O platelets to non group O recipients.

Shortened platelet survival (18% reduction) has also been shown to occur in minor ABO incompatibility, which may be due to the formation of immune complexes between the patient’s soluble ABH antigens and the alloantibodies in the donor plasma.

Rh D incompatibility
Rh antigens are not expressed on platelets and therefore Rh D incompatibility has no effect on platelet survival. However, residual red cell contamination of platelet concentrates is sufficient to induce Rh D sensitisation even in immunosuppressed recipients. Early studies where the red cell contamination of platelet concentrates was relatively high (>1 ml red cells) suggested an immunisation rate of up to 20%. However, current platelet concentrates have much lower levels of residual red cells (platelet pools containing up to 0.3-0.6ml and apheresis concentrates <0.005ml). The risk is also lower in immunosuppressed recipients than in immunocompetent patients. A more recent study on paediatric oncology patients demonstrated no Rh D alloimmunizations following incompatible transfusions to 42 patients. Only leukodepleted apheresis platelets were transfused with a red cell contamination estimated as not greater than 7.3 x 10⁶ red cells/unit. The conclusion reached by the authors of this study was that anti-D immunoprophylaxis was not required when administering RhD incompatible leukodepleted apheresis platelets to Rh D negative paediatric oncology patients. A study in adult patients with a variety of haematological malignancies also demonstrated a lower risk of Rh D alloimmunization using platelets prepared by modern technology. However platelets produced from pooled buffy coats have a higher level of red cell contamination in the region of 0.6ml. The consequence of Anti-D production needs to be considered. It is clear that a female of childbearing potential should not be put at risk of primary Rh D immunisation due to the risk of Haemolytic Disease of the Newborn in future pregnancies and if Rh D positive platelets are transfused then anti-D prophylaxis is also given. The other consequences for both males and females: increased serological investigations to exclude presence of red cell antibodies and consequent delays in crossmatching, inability to use RhD positive cells for future transfusions, red cell reduction of Rh D positive bone marrow though not insurmountable may also be taken into consideration when the need for anti-D prophylaxis is being evaluated. UK guidelines for anti-D prophylaxis recommend that anti-D prophylaxis be given to females of childbearing potential and that it is unnecessary to give prophylaxis to males/females of non-childbearing potential with haematological malignancy. The Council of Europe guidelines similarly recommend that anti-D prophylaxis should be considered in female recipients of childhood age or younger. In Ireland where there are recurrent shortages of O Rh D negative blood there may be a case for recommending anti-D prophylaxis where Rh D incompatible platelets are administered to patients with recurrent haemorrhage requiring large volume transfusion of Rh D negative blood.

Ideally anti-D should be given intravenously in thrombocytopenic patients where a licensed preparation is available. Intramuscular preparations can be used instead if administered subcutaneously.
Summary Guidance on Selection of Platelet Components where platelets of the patient's own group are not available.

1. Platelet components of patient's own ABO/Rh D group should be selected as far as possible.

2. If CMV seronegative platelets are requested check if patient requires CMV negative or if leukodepleted platelets will suffice according to published guidelines. If not then provide non-CMV seronegative ABO identical platelets if available.

3. The hospital transfusion laboratory should inform the clinician looking after the patient that platelets of a different ABO group to the patient are being issued.

4. It is preferable to select group A platelets for Group B recipients and vice versa where ABO identical platelets are not available. Group O donors in general have stronger anti-A/anti-B activities than group A or B donors. The platelets must not be labelled as high titre anti-A/B positive.

5. If Group O platelets are used for non-group O neonates and infants <1 year they must not be labelled as positive for high titre anti-A/anti-B. In addition the supernatant plasma should be removed and the volume restored with saline or platelet additive solution to further reduce the risk of haemolysis.

6. Group O platelets should only be selected for non-Group O adults and children if they have been shown to be negative for high titre anti-A/anti-B (are not labelled as high titre positive). However, a negative test for high titre anti-A/anti-B does not exclude a risk of haemolysis and the number of incompatible platelet transfusions should be limited to the equivalent of one dose at a time especially in children and patients with small blood volumes.

7. Major ABO incompatible platelet transfusions (e.g. group A for O or B) are associated with reduced platelet count increment but subsequent survival and haemostatic effect are satisfactory. It is therefore acceptable to select ABO incompatible when ABO identical platelets are in short supply. This should be limited to one or two transfusions at a time.

8. Rh D negative platelets should be given where possible to Rh D negative patients but especially to females of childbearing potential (i.e. age <50 years).

9. If Rh D positive platelets are to be issued to Rh D negative recipients then apheresis derived products (lower red cell contamination) should be used where possible.

10. Anti-D immunoglobulin should be administered to any female of childbearing potential in receipt of Rh D incompatible platelets. A dose of 250iu should be sufficient to cover up to 5 incompatible transfusions over a 4-week period. The current intravenous preparation is presented in vials of 1500iu, which should cover up to 12 platelet transfusions. If a licensed intravenous anti-D product is unavailable the intramuscular preparation may be used but it should be administered subcutaneously in thrombocytopenic patients. The current intramuscular preparation is available in doses of 1,250iu.
11. Anti-D immunoglobulin is not routinely recommended for male recipients or female recipients beyond childbearing potential due to the low risk of anti-D production. It may be considered where Rh D incompatible platelets are given to patients who are immunocompetent and likely to require large volume blood transfusion in an emergency (e.g. patients with oesophageal varices) necessitating the use of Rh D positive blood.

References


APPENDIX 4

Management of an Acute Transfusion Reaction

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

**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 (500 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.

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

**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.

**Persists or patient becomes unwell**

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

**Other severe reaction-non respiratory?**

**Normal CVP/JVP**

**Raised CVP/JVP**

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

**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.
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