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## List of Abbreviations

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<tr>
<th>Abbreviation</th>
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<tr>
<td>AA</td>
<td>Severe Acute Allergic/Anaphylactic Reaction</td>
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<td>A&amp;E</td>
<td>Accident and Emergency</td>
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<td>ANSARE</td>
<td>Annual Notification of Serious Adverse Reactions and Events</td>
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<tr>
<td>AHTR</td>
<td>Acute Haemolytic Transfusion Reaction</td>
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<tr>
<td>APPT</td>
<td>Activated Partial Thromboplastin Time</td>
</tr>
<tr>
<td>ATR</td>
<td>Acute Transfusion Reaction</td>
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<tr>
<td>BBTN</td>
<td>Better Blood Transfusion Network</td>
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<tr>
<td>BCSH</td>
<td>British Committee for Standards in Haematology</td>
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<tr>
<td>BNP</td>
<td>Brain–type Natriuretic Peptide</td>
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<tr>
<td>CIS</td>
<td>Clinical Indemnity Scheme</td>
</tr>
<tr>
<td>CMV</td>
<td>Cytomegalovirus</td>
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<tr>
<td>CPAP</td>
<td>Continuous Positive Pressure Ventilation</td>
</tr>
<tr>
<td>DAT</td>
<td>Direct Antiglobulin Test</td>
</tr>
<tr>
<td>DCU</td>
<td>Dublin City University</td>
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<tr>
<td>DHTR</td>
<td>Delayed Haemolytic Transfusion Reaction</td>
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<tr>
<td>DNP</td>
<td>Did Not Progress</td>
</tr>
<tr>
<td>DOHC</td>
<td>Department of Health and Children</td>
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<tr>
<td>EC</td>
<td>European Community (Commission)</td>
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<td>EHN</td>
<td>European Haemovigilance Network</td>
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<tr>
<td>ESTM</td>
<td>European School of Transfusion Medicine</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>F</td>
<td>Female</td>
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<tr>
<td>FFP</td>
<td>Fresh Frozen Plasma</td>
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<tr>
<td>FNHTR</td>
<td>Febrile Non-Haemolytic Transfusion Reaction</td>
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<tr>
<td>Hb</td>
<td>Haemoglobin</td>
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<tr>
<td>HBsAg</td>
<td>Hepatitis B surface antigen</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B Virus</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C Virus</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>HLA</td>
<td>Human Leucocyte Antigen</td>
</tr>
<tr>
<td>HSE</td>
<td>Health Service Executive</td>
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<td>HTC</td>
<td>Hospital Transfusion Committee</td>
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<td>HVO</td>
<td>Haemovigilance Officer</td>
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<tr>
<td>IBCT</td>
<td>Incorrect Blood Component Transfused</td>
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<td>IBTS</td>
<td>Irish Blood Transfusion Service</td>
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<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
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<tr>
<td>IgA</td>
<td>Immunoglobulin A</td>
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<td>IMB</td>
<td>Irish Medicines Board</td>
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<td>INAB</td>
<td>Irish National Accreditation Board</td>
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<td>INR</td>
<td>International Normalised Ratio</td>
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<tr>
<td>ISBT</td>
<td>International Society of Blood Transfusion</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>ISO</td>
<td>International Standards Organisation</td>
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<tr>
<td>IT</td>
<td>Information Technology</td>
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<tr>
<td>ITP</td>
<td>Idiopathic thrombocytopenia</td>
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<tr>
<td>IV</td>
<td>Intravenous</td>
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<tr>
<td>KIU</td>
<td>Kilo International Units</td>
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<tr>
<td>LDH</td>
<td>Lactic dehydrogenase</td>
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<tr>
<td>LIS</td>
<td>Laboratory Information Systems</td>
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<tr>
<td>M</td>
<td>Male</td>
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<tr>
<td>MERS-TM</td>
<td>Medical Event Reporting System for Transfusion Medicine</td>
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<tr>
<td>MRTC</td>
<td>Munster Regional Transfusion Centre</td>
</tr>
<tr>
<td>NAT</td>
<td>Nucleic Acid Amplification Testing</td>
</tr>
<tr>
<td>NBC</td>
<td>National Blood Centre</td>
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<tr>
<td>NBS</td>
<td>National Blood Service</td>
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<tr>
<td>NCHD</td>
<td>Non Consultant Hospital Doctors</td>
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<td>NHO</td>
<td>National Haemovigilance Office</td>
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<tr>
<td>NTproBNP</td>
<td>N terminal pro hormone brain-type natriuretic peptide</td>
</tr>
<tr>
<td>O₂</td>
<td>Oxygen</td>
</tr>
<tr>
<td>ORAS gold™</td>
<td>Online Recording and Assessment System</td>
</tr>
<tr>
<td>PAD</td>
<td>Pre-deposit Autologous Donation</td>
</tr>
<tr>
<td>PCC</td>
<td>Prothrombin Complex Concentrate</td>
</tr>
<tr>
<td>PTP</td>
<td>Post Transfusion Purpura</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>RCC</td>
<td>Red Cell Concentrate</td>
</tr>
<tr>
<td>Rh</td>
<td>Rhesus</td>
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<tr>
<td>RhD</td>
<td>Rhesus D</td>
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<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
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<td>SAR</td>
<td>Serious Adverse Reaction</td>
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<tr>
<td>SNBTS</td>
<td>Scottish National Blood Transfusion Service</td>
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<tr>
<td>SD</td>
<td>Solvent Detergent</td>
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<tr>
<td>SHOT</td>
<td>Serious Hazards of Transfusion, (United Kingdom)</td>
</tr>
<tr>
<td>SI</td>
<td>Statutory Instrument</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>STTI</td>
<td>Suspected Transfusion Transmitted Infection</td>
</tr>
<tr>
<td>TACO</td>
<td>Transfusion Associated Circulatory Overload</td>
</tr>
<tr>
<td>TAD</td>
<td>Transfusion Associated Dyspnnea</td>
</tr>
<tr>
<td>TA-GvHD</td>
<td>Transfusion Associated Graft-versus-Host Disease</td>
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<tr>
<td>TRALI</td>
<td>Transfusion Related Acute Lung Injury</td>
</tr>
<tr>
<td>TTI</td>
<td>Transfusion Transmitted Infection</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>vCJD</td>
<td>variant Creutzfeldt Jakob Disease</td>
</tr>
<tr>
<td>VRL</td>
<td>Virus Reference Laboratory</td>
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<tr>
<td>WNV</td>
<td>West Nile Virus</td>
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Introduction

The publication of the 2007 National Haemovigilance Office (NHO) Annual Report marks the eighth complete year of reporting of transfusion associated severe adverse events and reactions in Ireland. In 2007, for the first time since the NHO was set up, the number of reports in the serious adverse events/incorrect blood component transfused (IBCT) category has reduced, with an overall slight reduction in the total number of reports. The decreased number may, in part, be due to the fact that level 3 incidents (minor events) are no longer accepted by the NHO.

The reduced number of inappropriate transfusions reported suggests, however, that hospital haemovigilance efforts have been focused on implementation of the European Union (EU) Directive 2002/98/EC, particularly on the requirements to ensure full traceability and to achieve Irish National Accreditation Board (INAB) accreditation in the hospital transfusion laboratories by November 2008 rather than on the clinical areas.

Ensuring safe clinical transfusion practice remains a critical part of haemovigilance. While the rigorous screening measures currently in place have lowered the risk of transmission through blood transfusion of the known viruses Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV), the emergence of other infectious diseases as new transfusion risks, such as variant Creutzfeldt Jakob Disease (vCJD), West Nile Virus (WNV) and Dengue Fever emphasises the need to avoid unnecessary transfusions.

The key learning points highlighted in this report should be discussed and adopted by the Hospital Transfusion Committee (HTC) in each hospital.

The Haemovigilance Handbook to aid consistent reporting following the implementation of the EU Directive 2002/98/EC and Commission Directive 2005/61/EC is now available on the Irish Blood Transfusion Service (IBTS) website – www.giveblood.ie. This document was developed by the NHO and the Irish Medicines Board (IMB) and will be updated and improved in the coming months to take account of clarifications from the European Communities/Commission (EC) Working Group on Serious Adverse Events and Reactions – Blood and Blood Components.

Dr. Paul Strengers, past-president of the European Haemovigilance Network (EHN), presented his review of Haemovigilance in Ireland in 2006 to the Department of Health and Children (DOHC) in early January 2007. Whilst some areas were recommended for improvement, notably Information Technology (IT) systems and Haemovigilance Officer (HVO) working structures, he felt that compared to other EU Member States, the Irish Haemovigilance system was well developed and had become one of the best in Europe.

The NHO/IBTS hosted the 9th European Haemovigilance Seminar in Dublin Castle early in 2007. This was the first Seminar following full implementation of EU Directives
2002/98/EC and 2005/61/EC. Topics relating to the implementation of Directive requirements in different European countries and how haemovigilance was developing internationally were presented to the audience of over 250 delegates from 30 countries. The conference was both a scientific and social success and I would like to thank again all those involved in the organisation and in ensuring that it ran so smoothly.

The NHO/IBTS partnership continues with the Nursing Studies Department at Dublin City University (DCU) in the provision of modules in haemovigilance practice. We appreciate the support received from DCU staff, NHO staff, lecturers from the IBTS and the hospitals. The modules continue to be well evaluated and well subscribed. We continue to work with DCU in an effort to expand and develop the courses to address the changing needs of the students.

The results of the NHO Near Miss Project (2003-2005) were published in 2007. The results of this project can be used to support improvements in the delivery of transfusion to Irish patients and I would like again to thank the hospitals who took part. The experience gained also suggested changes to the NHO database allowing more detailed error causal analysis as presented in this report.

The NHO would like to take this opportunity to show our appreciation to a number of Health Service disciplines who support its daily operations, in particular, HVOs, Medical Laboratory Scientists, Consultant Haematologists/Pathologists and others for their continued efforts. The advice of the Director of Human Medicines and staff of the IMB – the Competent Authority, is acknowledged as is the expertise of the staff of the IMB’s Compliance and Pharmacovigilance Departments.

The continued efforts of the IBTS Chief Executive, Mr. Andrew Kelly, National Medical Director, Dr. William Murphy and the staff of the IBTS in recruiting voluntary blood donors and developing increasingly higher standards in blood processing and distribution are the backbone of the national haemovigilance scheme.

We hope that you find the NHO Annual Report 2007 useful in your practice. In compliance with the Official Languages Act 2003 copies of this report are also available in Irish.

As always, feedback and comments are welcome.

Dr. Emer Lawlor,
Director NHO
The NHO was set up in the IBTS in 1999 to collect confidential anonymised reports of transfusion associated severe adverse reactions and events from healthcare professionals. The duty to report these reactions and events was based on professional responsibility.

EU Directive 2002/98/EC was transposed into Irish law by European Communities (Quality and Safety of Blood and Blood Components) Regulations 2005 Statutory Instrument (SI) 360/2005 from 8th November 2005. Reporting of serious adverse reactions (SAR) which may be attributed to the quality and safety of blood components has become mandatory as have serious adverse events (SAE) relating to the collection, testing, processing, storage and distribution of blood and blood components. Reporting of non mandatory SAE IBCT to the NHO remains part of professional responsibility.

The remit of the NHO is to:

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

The NHO is located at the National Blood Centre, (NBC) James’s St., Dublin 8 and functions under the directorship of a Consultant Haematologist with four and a half whole time equivalent HVOs, a Programme Administrator and Assistant Administrator.

**Definition of Terms used in Haemovigilance**

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

**Serious Adverse Reaction:** An unintended response in the patient associated with the collection or transfusion of blood and blood component that is
- Fatal
- Life-threatening, disabling or incapacitating or
- Which results in, or prolongs hospitalisation or morbidity (SI 360/2005)

The type of reactions and events which are reportable are set out in 2005/61/EC SI 547/2006. Further information on the reactions and events which are reportable and how to report is available in the Haemovigilance Handbook on the IBTS website – www.giveblood.ie
Irish Medicines Board (IMB)
The IMB is the Competent Authority for implementation of all aspects of the EU Blood Directive. The IMB held regular case review meetings with NHO representatives during 2007 to discuss reported incidents.

Education, promotion and developments
The NHO continues to support the development of hospital in-service training programmes and transfusion education for nursing and medical laboratory science students by working closely with hospital based HVO.

All newly appointed HVOs are invited to the NHO Open day where the workings of the NHO are explained, particularly reactions and event reporting. Two open days were arranged in 2007 with 32 people attending. Nationwide networking among HVOs is also promoted through regular telephone/email communication and personal visits.

The NHO partnership with DCU continued, providing two professional development modules “Understanding and Management of Blood Transfusions in a Haemovigilance Context” and “Haemovigilance: Blood Transfusion Practice”. Support for this project continued from the IBTS and the hospital network. We are grateful to all visiting lecturers from the IBTS and from hospitals who have generously invested their time and experience in this initiative.

Audit of Haemovigilance in Ireland
Dr. Paul Strengers, past-president of the EHN, presented his report on haemovigilance in Ireland to the DOHC in 2007 following a three day review in 2006. His remit was to assess the compliance of the Irish system with the EU Directives. Whilst recommending some improvements for IT systems, quality issues and HVO working structures, Dr. Strengers found that compared to other EU Member States, the Haemovigilance system in Ireland was well developed and one of the best in Europe although he noted that a national blood tracking system would improve compliance with the traceability aspect of the Directive. He recommended that the NHO remain within the IBTS and that the current reporting relationships be maintained between the IMB and the NHO.

Scientific Meetings
European Haemovigilance Seminar – Dublin February 2007
In February 2007, the 9th European Haemovigilance Seminar was held in Dublin hosted by the NHO/IBTS. This was the first such event following full implementation of EU Directives 2002/98/EC and 2005/61/EC. Over 250 international delegates gathered to discuss issues ranging from appropriate blood usage, education initiatives and the implementation of the EU Directives on blood quality and safety with presentations by Irish and international speakers. A full list of speakers and topics are included on the IBTS website – www.giveblood.ie.

In addition to the plenary sessions, there were four workshops covering Implementation of the EU Directive – how it is interpreted in practice?, Donor Haemovigilance, a training session on the use of EHN Website including Rapid Alert System and a very well attended workshop on Appropriate Blood Utilisation which examined the role of audit and alternatives to blood transfusion. There was also a poster exhibition.

The Seminar venue was the historic Dublin Castle Conference Centre and the social programme offered an opportunity to visit the 17th century Royal Hospital, Kilmainham for the gala dinner whilst the welcome reception was held in Dublin’s City Hall.

Presentations at Scientific Meetings
A number of presentations were made by NHO staff during the year:

Presentations at the European Haemovigilance Seminar February 2007
Haemovigilance in Ireland 1999-2007 - Dr. Emer Lawlor
Addressing Learning Needs, the Development of Haemovigilance Modules in Dublin City University - Ms. Marcia Kirwan
Sources of knowledge and perceptions of barriers to evidence-based transfusion practice - Ms. Marina Cronin
Dr Lawlor was an invited speaker at the Haematology Association of Ireland Meeting in Sligo in October, 2007. The title of her talk was *Haemovigilance 2000–2007/EU Directive: Where to from here?*

Ms. Kirwan represented the NHO at the European School of Transfusion Medicine (ESTM) Residential Course on Optimal Use of Blood and Blood Components in San Sebastian in November 2007. She presented two papers during the course, *The Role of the Haemovigilance Nurse in Hospital Transfusion Practice* and *Addressing the needs of Specialist Haemovigilance Nurses in Dublin City University.*

The NHO Annual Conference was not held in 2007 due to the hosting of the European Haemovigilance Seminar. The Annual Report 2006 was presented at the IBTS Hospital Liaison Workshop 7th November 2007 at The National College of Ireland Dublin by Ms Marina Cronin. Other NHO presentations included *Annual Notification Form of EU Directive* - Ms. Jackie Sweeney and *Jehovah’s Witness – Medical and Legal Issues* - Dr. E. Lawlor.

**Publications from NHO**

The results of the Near Miss Project based on the Medical Event Reporting System for Transfusion Medicine (MERS-TM) (Kaplan et al 2002) undertaken in ten hospital sites between 2003–2005 were published by Vox Sanguinis in 2007 (Lundy et al 2007).

A total of 759 near-miss events from these sites were analysed and root cause analysis used to identify error cause. It was shown that near misses occur 18 times more frequently than adverse events causing harm. Sample collection - site of first error in 468 (62%) events - was found to be the highest risk step in the work process. Medical personnel were frequently involved and general wards/emergency departments identified as high-risk areas. Seventy eight (10%) further events occurred within the transfusion laboratory. The data obtained through this research has provided Irish hospitals with new and clear evidence that seemingly low risk, recurring errors are in fact signals of more serious underlying latent defects existing in the transfusion process.

The NHO is grateful to the hospital staff in the ten sites and the consultant haematologists who participated in the research, namely Dr. Emer Lawlor and Dr. Stefan Laspa, IBTS, Dr. Eibhlin Conneally, St. James Hospital, Dublin, Dr. Joan Fitzgerald, St. Vincent’s University and St. Vincent’s Private Hospitals Dublin, Dr. Gerard Crotty Midland Regional Hospitals at Portlaoise, Mullingar and Tullamore, Dr. Maeve Leahey and Dr. Mary Cahill of Limerick Regional Hospitals, (including St. John’s, St. Munchin’s Maternity and Croom Orthopaedic Hospitals). The efforts of HVOs and laboratory medical scientists in coordinating the collection and reporting of data is also acknowledged.

Dr. Laspa and Dr. Lawlor also contributed to the Vox Sanguinis International Forum *Measures to prevent TRALI* (2007) 92 258-277

The *NHO News*, an information newsletter circulated to all HVOs, provides an informal forum for the reporting of work carried out within the NHO and individual hospitals, and includes local education and training initiatives and social events which may be of interest to other HVOs. Details of events of national and international interest are also reported. During 2007, one edition of this newsletter was issued to HVOs.

**E Learning Programme**

Preparation and training for the ORAS Gold™ (Online Recording and Assessment System) Transfusion E Learning Pilot Project began in early 2007 and Ms. Ann O’Connor, NHO HVO was appointed as project leader.

An E Learning Training day was held in May, 2007 for HVOs, clinicians, representatives of hospital management and IT staff from five hospital pilot sites taking part in this project. Ms Sandra Gray and Ms Sarah Crooks (Effective Use of Blood Group and the Better Blood Continuing Education Programme of the SNBTS) provided a background to E Learning and the Scottish ORAS experience to date and practical ORAS training was given for pilot site HVOs and IT staff. In July 2007, Ms. O’Connor attended an SNBTS training session for Health Services Administrators which incorporated an overview of new and existing ORAS functions and related scenario based activities. Further training
was then provided for pilot sites in August 2007 as part of the initiation phase of the Pilot Implementation Framework.

The Pilot Execute phase began with the assignment of administrative rights to HVOs at the five pilot sites, who each identified key stakeholders to act as systems sponsors. A Pilot Agreement between the NHO and individual sites was set out, outlining learning targets, communication and promotion strategies, with weekly progress reports and end user evaluations being returned to the NHO. Pilot site implementation began in September 2007 with the closing date being extended to February 2008. Pilot results will be available in 2008.

**Working Parties**

**EC Working Group:** The NHO and the IMB participated in a working group to develop a common approach for definition of reportable serious adverse events and reactions as laid down in the Blood Directive 2002/98/EC and Commission Directive 2005/61/EC. This Working Group convened by the European Commission of Competent Authorities and other experts from a number of other European member states, met in Brussels in December 2007 to discuss definitions of reportable SAR and SAE as set out in Article 8 of Directive 2005/61/EC to be reported by the Competent Authorities through the Annual Notification of Serious Adverse Reactions and Events format (Part D of Annex II and Part C of Annex III of Directive 2005/61).

**The Better Blood Transfusion Network (BBTN)** met in Dublin in February 2007 in conjunction with the European Haemovigilance Seminar. This is a working group of UK and Irish haematologists and transfusion medicine specialists, hospital clinicians and transfusion nurse specialists set up to share information on best practice in the clinical aspects of blood transfusion. Drs. Emer Lawlor, Joan O’Riordan and Joan FitzGerald, Ms. Marcia Kirwan and Ms. Marina Cronin represented the NHO and IBTS during 2007.

Information on Haemovigilance can be directly accessed on the IBTS website at www.giveblood.ie (Clinical Services - Haemovigilance)
SAE Key Recommendations

Haemovigilance

- All facilities which transfuse patients should have a Haemovigilance Officer (HVO) in post.
- While participation in the haemovigilance reporting scheme for SAR and SAE affecting the quality and safety of blood components is mandatory, reporting of non-mandatory adverse events should be encouraged among all facilities which transfuse blood. The NHO is concerned about a reduction in reporting of adverse clinical events in 2007. Management and reporting of these events has an important role in improving patient safety not only in transfusion but also in areas not confined to transfusion such as patient identification, record keeping etc.
- The important role played by HVOs in discovery and analysis of adverse events is yet again highlighted this year. It is imperative that HVOs are supported in developing a root cause analysis approach in investigating IBCT/SAE and develop action plans to address adverse events. It is recommended that hospital HVOs receive appropriate training and develop good working relationships with local organisational or regional risk managers or clinical risk advisors from the Clinical Indemnity Scheme (CIS). To address this demand, the NHO in partnership with CIS will provide increased training in root cause analysis at programmes in Dublin City University.
- HVOs should present feedback on the analysis of IBCT/SAE both to the Hospital Transfusion Committee and to staff involved in the error or working in the area where the error occurred.
- The majority of errors found by HVOs were discovered during post transfusion surveillance activity. This indicates that potentially many errors could have been detected by other staff in the transfusion process prior to completion of transfusion. This highlights the need for hospitals to provide continuing education for clinical and laboratory staff involved in the transfusion process.

Clinical transfusion practice

- An analysis of all adverse transfusion events since 2000 shows that prescription/request has consistently been reported as the most common site of first error each reporting year. It is the responsibility of the prescribing doctor to ensure that the most recent laboratory results are checked prior to prescribing. This check should include verification of the patient’s details and the date the sample was drawn. Particular care should be taken when reading results from the computer screen to ensure the correct result is read.
- All hospitals should have systems in place to ensure that protected time is made available for medical staff to attend haemovigilance training so that doctors involved in the prescription of blood/blood components are aware of current guidelines in relation to prescription and appropriate use of blood/blood components.
- Sampling errors by doctors led to five unnecessary transfusions in 2007. The Near Miss Project also found that the majority of pretransfusion sample collection errors involved doctors whereas phlebotomists were only involved in a small number (Lundy et al, 2007). While provision of training and competence assessment of phlebotomy techniques for medical and all other staff involved in sample collection should be provided, extension of phlebotomy services would help reduce the errors by doctors who
already have a heavy clinical workload, particularly out of hours.

- Electronic systems which enforce compliance in pretransfusion sampling and administration should be introduced, where possible, to reduce the risk of human error. Where this is currently not feasible, it is imperative that correct procedure be strictly followed for patient identification both at pretransfusion sampling and at the final bedside checking procedure prior to administration.

- In 2007, a number of unnecessary transfusions occurred when patients were receiving shared care between treating centres or between hospital teams. Where there is shared care or locum cover this should be covered by comprehensive protocols/handover from the primary carer.

- Paediatric patients have specialised blood requirements and errors can be associated with serious sequelae. Medical staff require specific education and ongoing training in relation to the prescribing needs of neonates and infants.

**Laboratory practice**

- Good communications systems between laboratories in different transfusion facilities are critical to ensure optimal patient care. Findings from 2007 report highlight some of the challenges which still exist. A national patient antibody register for patients with significant red cell antibodies merits serious evaluation. The introduction of a unique health identifier would be crucial to this initiative.

- Training for all hospital blood bank staff is now mandatory under the provisions of EU Directive 2002/98/EC and formal ongoing training programmes for medical scientists of all grades including those providing cross-call cover in transfusion should be provided in every hospital transfusing blood. These systems should include regular evaluation and competency assessment of staff (Irish National Accreditation Board, 2006).

- Laboratories should have systems to ensure that units intended for disposal are labelled/marketed appropriately. Units for disposal should be stored in a designated, quarantined area with controlled access by laboratory staff. Units returned for disposal should be disposed of as soon as possible to reduce the risk of re-issue/collection in error.

- The laboratory is responsible for controlling access to laboratory blood fridges. The increasing numbers of reports relating to storage of components probably reflects increased awareness and reporting of these incidents since the implementation of the EU Blood Directive. A comprehensive quality management system should cover storage and collection of blood components in the blood transfusion laboratory. There should also be parallel clinical policies covering storage and collection from satellite fridges. Automated systems that provide controlled access/audit trails of movement of units in and out of laboratory blood fridges would help to reduce error and a national tendering process for such a system has commenced.

- It is recommended that wherever possible group O apheresis platelets are reserved for group O patients and should not be used for patients whose blood group is A, B and AB. Transfusion of group O apheresis platelets to patients whose blood group is A, B or AB has potential to cause haemolysis as group O platelets may have high-titre anti-A and anti-B in spite of a negative test for haemolysins.
SAR Key Recommendations

General Recommendations for Acute Transfusion Reactions

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

- Each hospital must have a policy in place for the identification and management of an acute transfusion reaction. This should include the medical and nursing management of the patient’s symptoms and the investigations necessary to complete the transfusion reaction analysis. Following a severe transfusion reaction, the transfusion should be discontinued completely and no further units from this crossmatch should be transfused until an ABO incompatible transfusion has been excluded and the blood has been recrossmatched. The National Blood Users Group (NBUG) has produced recommendations for the Management of an Acute Transfusion Reaction (NBUG 2004)

- Wherever possible, as a minimum, blood cultures and investigation for haemolysis should be taken on patients suffering a Febrile Non Haemolytic Transfusion Reaction (FNHTR) to exclude red cell incompatibility or bacterial contamination.

- Patients who have experienced a severe allergic/anaphylactic reaction during a blood component transfusion should have an alert on their record to draw attention to clinical staff that the patient has a history of transfusion reactions to ensure appropriate component selection and pre-medication prior to future transfusions.

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

Delayed Haemolytic Transfusion Reaction (DHTR)

- It is likely that DHTR is underdiagnosed. It is essential that any patient presenting with unexplained anaemia some days after a transfusion should be investigated for immunological haemolysis (bilirubin, LDH, DAT and antibody screen) to exclude DHTR.

- In a number of the reports of DHTR in 2007 the investigation was incomplete. The successful diagnosis also depends on accurate history taking and the eliciting of a history of recent transfusion.

- A national patient antibody register merits serious evaluation, as noted on page 11 in the SAE recommendations.

Transfusion Associated Circulatory Overload (TACO)

- All patients, especially those at risk, should be assessed pre-transfusion to assess their risk of developing TACO. At risk patients are those of older age, low body weight, or may be physiologically compromised, e.g. history of cardiac, respiratory or renal insufficiency or chronic anaemia. These patients should be transfused slowly at a rate of 1 ml/kg/hour (Popovsky, 2001). Transfusion should be on a unit–by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component.
• Single unit transfusions can result in TACO and therefore should be monitored as closely as multiple unit transfusions. In very low weight/at risk patients, it may be advisable to transfuse units with an interval of 24 hours between each unit, in combination with pretransfusion diuretics.

• Clinical evaluation of pre and post transfusion fluid balance and pre and post transfusion N terminal pro hormone brain-type natriuretic peptide (NTproBNP) or Brain-type Natriuretic Peptide (BNP) BNP levels may be helpful in differentiating TACO from TRALI (Zhou et al 2005).

• In the massive transfusion setting, sudden dyspnoea and falling O₂ saturations are often taken as a sign of TRALI but should also prompt evaluation for evidence of circulatory overload particularly in young females.

**Transfusion Transmitted Bacterial/Viral Infection**

• Investigations into STTI of viral origin are difficult. They can involve considerable upset to donors who often have to be recalled and offered testing and they are resource intensive.

• Patients such as haematology patients undergoing chemotherapy who will require ongoing transfusion should be offered testing before therapy and at regular intervals with storage of samples wherever possible for further testing if necessary. In these patients, virology screening for HBV should include anti-hepatitis B core and surface antibodies in addition to HBsAG as reactivation of HBV may occur as a result of chemotherapy.
Serious Adverse Reactions and Events 2007

Annual Notification of Serious Adverse Reaction and Events’ (ANSARE)

This year, hospitals transfusing blood were required to fill in the ANSARE form in compliance with Commission Directive 2005/61/EC Annex II D and III C and return the form to the NHO by Friday 14th March 2008.

In January 2008, 84 reporting centres (82 hospitals and two supply centres) were issued with the ANSARE form, for the reporting year 2007. Reporters were offered the option of reporting electronically and the majority chose this format. All 84 forms were returned and then imported into a database at the NHO for analysis. Twenty-five (30%) sites reported one or more SAR and nine (11%) reported one or more SAE. Eleven (13%) reported both SAR and SAE and a further 39 (46%) indicated that they had not reported any SAR or SAE in 2007. The ANSARE form, however, does not collect non mandatory clinical IBCT incidents. These accounted for 37% of the total number of reports analysed by the NHO in 2007, therefore ANSARE returns underestimate the overall rate of reporting from hospitals to the NHO.

Reporting Trends in 2007

The NHO has examined reporting trends throughout 2007. There were 86 reporting establishments; 84 hospitals and two supply centres which also act as a transfusion laboratory for a number of smaller hospitals. Up to 36% (31) hospitals did not submit any mandatory or non mandatory reports to the NHO. These were smaller organisations with less than 1000 units transfused per annum.

The NHO received 297 reports of IBCT/SAE and SAR. While 54 reporting establishments submitted reports, 75 reports did not progress as they did not meet reporting criteria. The subsequent analysis of IBCT/SAE and SAR is based on 222 reports from 51 reporting establishments.

Denominator Data

During 2007 a total of 187,845 (including Solvent Detergent (SD) plasma) components were issued by the IBTS (Table 1).

Table 1 Blood and Blood Components issued by IBTS 2007

<table>
<thead>
<tr>
<th>Component</th>
<th>Number issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Cells and Whole Blood</td>
<td>140,089</td>
</tr>
<tr>
<td>Platelets – Therapeutic Doses</td>
<td>22,123</td>
</tr>
<tr>
<td>Fresh Frozen Plasma</td>
<td>639</td>
</tr>
<tr>
<td>SD Plasma (Octaplas)</td>
<td>22,478</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>2,429</td>
</tr>
<tr>
<td>Granulocytes</td>
<td>87</td>
</tr>
<tr>
<td>Total components issued</td>
<td>187,845</td>
</tr>
</tbody>
</table>

Serious Adverse Reactions (SAR) and Incorrect Blood Component Transfused (IBCT)/Serious Adverse Event (SAE) Reports

In total 222 incidents were accepted for this Report down by 82 (30%) on 2006 figures. These reports were categorised as follows: 115 were IBCT/SAE and the remaining 107 were SAR. (Figure 1). The highest number of reports was, as in previous years, in the SAE/IBCT category followed by Allergic/Anaphylactic (AA) and then Febrile Non-Haemolytic Transfusion Reactions (FNHTR).

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1 The minor discrepancy in the figures between ANSARE and the NHO reports is due to the fact that some subsidiary hospital sites report ANSARE through their supplying hospital, whereas they reported during the year individually. Some smaller sites on the NHO database no longer transfuse and were not contacted for ANSARE.
An analysis of confirmed SAR and IBCT per components issued from IBTS is presented in Table 2.

### Table 2 - Incidence of IBCT/SAE and SAR per unit issued for IBTS – 2007

<table>
<thead>
<tr>
<th>Category</th>
<th>No. of Reports</th>
<th>Red Cells (140,089 units issued from IBTS)</th>
<th>Platelets (22,123 units issued from IBTS)</th>
<th>Plasma (23,117 units issued from IBTS)</th>
<th>Granulocyte (87 units issued from IBTS)</th>
<th>Total Components (187,845 units issued from IBTS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBCT/SAE</td>
<td>(95)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 per 1,977</td>
</tr>
<tr>
<td>FNHTR</td>
<td>(30)(^2)</td>
<td>1 per 5,388</td>
<td>1 per 7,374</td>
<td>1 per 87</td>
<td></td>
<td>1 per 6,262</td>
</tr>
<tr>
<td>Immunological Haemolysis due to ABO incompatibility</td>
<td>(1)</td>
<td>1 per 140,089</td>
<td></td>
<td></td>
<td></td>
<td>1 per 187,845</td>
</tr>
<tr>
<td>Immunological haemolysis due to other allo-antibody (Acute &lt; 24 hrs)</td>
<td>(3)</td>
<td>1 per 46,696</td>
<td></td>
<td></td>
<td></td>
<td>1 per 62,615</td>
</tr>
<tr>
<td>Immunological Haemolysis due to other allo-antibody (Delayed)</td>
<td>(6)</td>
<td>1 per 23,348</td>
<td></td>
<td></td>
<td></td>
<td>1 per 31,308</td>
</tr>
<tr>
<td>TACO (18)(^3)</td>
<td></td>
<td>1 per 8,240</td>
<td>1 per 23,117</td>
<td></td>
<td></td>
<td>1 per 10,436</td>
</tr>
<tr>
<td>Anaphylaxis/hypersensitivity (AA)</td>
<td>(40)(^4)</td>
<td>1 per 7,373</td>
<td>1 per 1,053</td>
<td></td>
<td></td>
<td>1 per 4,696</td>
</tr>
<tr>
<td>OSR - Unclassified SAR</td>
<td>(5)</td>
<td>1 per 28,018</td>
<td></td>
<td></td>
<td></td>
<td>1 per 37,569</td>
</tr>
<tr>
<td>Confirmed Transfusion Transmitted Viral Infection</td>
<td>(0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible Transfusion Transmitted Bacterial Infection</td>
<td>(1)</td>
<td>1 per 140,089</td>
<td></td>
<td></td>
<td></td>
<td>1 per 187,845</td>
</tr>
</tbody>
</table>

\(^1\)This includes cryoprecipitate. No reported IBCT/SAE and SAR to these components.

\(^2\)FNHTR: RCC - 26 Pooled Platelets - 3 Granulocytes - 1

\(^3\)TACO: RCC-17, SD Plasma -1

\(^4\)AA: RCC-19, Platelets-21
Incorrect Blood Component Transfused (IBCT)/Serious Adverse Events (SAE)

Reporting Definitions

The NHO collects both SAE which are mandatory under legislation (EU Blood Directive 2002/98/EC) and IBCT which are not mandatory but reportable under professional responsibility.

The difference between the two definitions is that the IBCT category covers errors occurring in the clinical areas of the transfusion chain such as sampling of the patient and administration of the component whereas SAE covers the quality and safety of the blood components and does not cover errors associated with blood products or cover errors in the clinical areas.

An IBCT is defined as;
‘the transfusion of a blood component/product which did not meet appropriate requirements and/or was intended for another patient’ (SHOT 1996)

A SAE is defined as;
‘any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs hospitalisation or morbidity’. (2002/98/EC)

Findings

In 2007, 115 IBCT/SAE reports related to blood components and products were reported to the NHO. This represents almost 52% of the total reports which were progressed.

Reports of IBCT/SAE were submitted from 47% (40) of all reporting facilities.

While there is no change in reported mandatory adverse events, reporting on errors in the clinical area has decreased by 25% in 2007.

Twenty of the 115 reports were associated with blood products (Factor concentrates and Anti D) and these are separately assessed on pages 39 - 43.

Table 3 illustrates how reports were categorised.

Table 3: SAE Reports progressed by NHO n=115

<table>
<thead>
<tr>
<th>Reportable under the EU Directive</th>
<th>Yes (SAE)</th>
<th>No (IBCT)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td>32</td>
<td>63</td>
<td>95</td>
</tr>
<tr>
<td>Products</td>
<td>0</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

IBCT/SAE with blood components

This section of the report covers 95 IBCT/SAE i.e. both mandatory and non-mandatory adverse events/errors relating to blood components and SD plasma received by the NHO in 2007.

Thirty two (34%) of the reports considered in this section, met the criteria of an SAE reportable under the Directive 2005/61/EC. The remaining 63 reports were IBCT concerned with errors in the clinical area. The findings and causal analysis of both IBCT and SAE reports are amalgamated in this section. A further more detailed analysis of the mandatory SAE reports is provided on page 35.

Adverse events relating to paediatric patients are covered on pages 37-38.
While there was no change in reported mandatory adverse events, reporting on errors occurring in the clinical area has decreased by 25% in 2007. (see Figure 2)

**KEY POINTS**

- While participation in the haemovigilance reporting scheme for SAR and SAE affecting the quality and safety of blood components is mandatory, reporting of non-mandatory adverse events and reactions should be encouraged among all facilities which transfuse blood.

- The NHO is concerned about a reduction in reporting of adverse clinical events in 2007.

- Management and reporting of these events has an important role in improving patient safety not only in transfusion but also in areas not confined to transfusion such as patient identification, record keeping etc.
Categorisation of IBCT/SAE reports received

All reports received are categorised by the nature of the event. Figure 3 outlines reports received in 2007 and classifies each report category into mandatory (SAE) and non-mandatory (IBCT). There were 32 mandatory reports and 63 non-mandatory reports.

Figure 3- IBCT/SAE classification by nature of event, n = 95

- Unnecessary transfusion represent 27% of adverse events (26 events)
- There were three reports of the transfusion of components of the incorrect ABO group. As platelets and plasma were implicated in all of these reports, none of the patients suffered an adverse reaction as result of these errors. It should, however, also be noted that one ABO incompatible red cell transfusion was reported in 2007 but as it was associated with a reaction it is captured in the SAR category (SAR Case History 15). There was one report of transfusion of platelets of an incorrect RhD group and two reports where antigen incompatible/antigen positive red cells were transfused to patients. These errors account for 6% of errors reported in the IBCT/SAE category.
- Fifteen (15%) adverse events were reported as transfusion of an incorrectly stored component. Medical scientists, nurses and portering staff were involved in these adverse events. The occurrence of transfusion of incorrectly stored units of red cells has almost doubled since last year, with reporting increased from 8% to 15% of overall reports received.
- Reports of the wrong component transfused accounted for 12% (11) reports. These incidents involved errors across the transfusion chain at prescription, request, blood transfusion processing, in collection and at administration, and involved both red cells (6) and SD plasma (6).
- Nine (9) adverse events were reported as a failure to transfuse the patient with
Cytomegalovirus (CMV) negative and irradiated blood where required. These included incidents where one or other requirement was not met; failure to transfuse CMV negative blood (2 cases), failure to transfuse irradiated blood (3 cases) and a failure to meet both requirements (4 cases). Reports in this category have not significantly altered since 2006.

- The remaining 27, (28%) adverse events were reported in the “Other category”. This category included;
  - Administration Errors- 16
  - Laboratory processing errors - 10
  - Miscellaneous – 1
- There was one report of transfusion of an expired red cell component.

**Unnecessary transfusions n=26**

This category captures adverse events where a patient is transfused with a blood component* which was not required by the patient.

In line with the decreased reporting of non-mandatory reports, there has been an overall decrease (6%) in these reports. However it remains the largest single category of adverse transfusion events, accounting for 26% of reports received in the SAE/IBCT category.

Twenty five unnecessary transfusions were assessed as being “high risk” patient events. Female patients were predominantly implicated in 68% (17) of the unnecessary transfusions. Elderly patients were more likely to receive unnecessary transfusions, with approximately 42% (11) of unnecessary transfusions being administered to patients over 70 years. However, 12% (3) of unnecessary transfusions were administered to infant patients (1-4 years). A breakdown of components involved in unnecessary transfusion is presented in Figure 4:

**Case History 1**

This young female patient was prescribed four units of red cells for known iron deficiency anaemia- Hb 6.7 g/dl. The patient had previously been transfused and was very reluctant to receive blood on this occasion. She was persuaded to proceed and two units were transfused uneventfully. The error was discovered during routine post-transfusion surveillance. On investigation it was found that a locum consultant had ordered the transfusion when the patient’s primary consultant would have ordered an intravenous infusion of iron. The remaining two units were not given. There were no complications as a result of this.

* includes SD plasma
transfusion but the patient, who did not want to be transfused, was unnecessarily exposed to a blood component.

- In a further case, a patient required an emergency transfusion following collapse. She received four red cells, four SD plasma and a unit of platelets. Her post transfusion Hb was 14.7g/l, suggesting that one or more of the red cell units were unnecessary.

- There were three reports of unnecessary red cell transfusion, occurring following sampling errors caused by poor phlebotomy techniques by doctors. (see Case History 2)

**Case History 2**

This patient was admitted with a bleed post insertion of a PEG tube. He was transfused in an emergency setting with two units of red cells based on an incorrect Hb result which was reported as 6g/dl. The error occurred at sampling, when a Non Consultant Hospital Doctor (NCHD) took a sample from the patient’s arm where intravenous fluids were infusing. The NCHD had not received phlebotomy training. The error was discovered in the haematology laboratory following analysis of a second sample which showed a Hb of 13.2 g/dl.

- The haematology laboratory led to one unnecessary transfusion. In this case, a patient received a transfusion of red cells when an incorrect Hb result was reported back to the clinical area. A review of this incident suggested that a small clot may not have been noted or was undetectable at time of the initial examination, contributing to the erroneous result.

- One unnecessary transfusion occurred when a nurse administered a unit of red cells following review of the patient’s medical notes (see Case History 3).

**Unnecessary SD Plasma transfusions**

- There were seven unnecessary SD plasma transfusions.

- Four unnecessary transfusions associated with SD Plasma occurred as result of errors at prescription/request and involved medical staff. In one case, SD plasma was administered where the indication was the insertion of a central line. No baseline coagulation screen had been taken to check that it was required.

- In the second case a female patient with a fractured femur was transfused one unit of SD plasma. Although she has a slightly prolonged International Normalised Ratio (INR) of 1.6, there was no documented clinical indication for the transfusion. In both cases, the SD plasma was prescribed by a NCHD.

- In the third case, an obstetric patient received one unit of SD plasma after three units of red cells. This patient had no baseline coagulation screen taken. In this instance, all blood components were ordered by the patient’s obstetric team, and not by the anaesthetic team as was usual practice in the hospital. This transfusion was considered unnecessary by the hospital transfusion committee.

**Case History 3**

This patient was transferred from Accident and Emergency (A&E) to a ward area in the early hours of the morning. The nurse accepting the patient was told there were two units of red cell remaining in the fridge for the patient. Only one unit was prescribed. The nurse looking after the patient requested and administered the two units of red cells. While the nurse had received confusing information, this error could have been prevented if the requirement for transfusion had been verified against the prescription. This did not occur.
In the final case SD plasma was ordered and administered for reversal of low molecular weight heparin. This occurred as the patient was transferred between hospitals and the SD plasma was ordered and administered in the receiving hospital. Where reversal is required it is usually sufficient to withdraw heparin but if rapid reversal is required, protamine sulphate is a specific antidote (but only partially reverses the effects of low molecular weight heparins) (British National Formulary, 2008).

Sampling errors contributed to two unnecessary SD plasma transfusions. In both cases where SD plasma was transfused, samples were drawn from heparinised lines.

An error occurring in the coagulation laboratory contributed to one unnecessary transfusion of SD plasma. This error occurred when an automated screen read a falsely high result. The medical scientist failed to recheck this result by a manual method, where this false reading would have been picked up. Further high readings were not verified as it was assumed that verification had previously occurred.

Unnecessary platelet transfusions

There were three cases of unnecessary platelet transfusion. In one case, a patient with underlying haematological malignancy received an unnecessary platelet transfusion in a peripheral hospital. There was confusion around the decision to transfuse the platelets. On review, the consultant haematologist deemed the transfusion to have been unnecessary. In two cases, platelets were administered to patients with idiopathic thrombocytopenia (ITP) where platelets are rarely indicated. In both cases, the patient’s primary team were not caring for

The patient. One of these cases is described below (Case History 4).

Case History 4

A patient with ITP was admitted via A&E under the care of the medical team within the hospital. Platelets were prescribed and administered. The error was discovered by the Consultant Haematologist, on reviewing the patient’s care, the following day. The team admitting the patient did not have experience in specialist haematology. While there was a policy in the hospital on management of patients with ITP, this was not followed. The organisation does not provide full time haematology cover outside routine hours, and this was also identified as a cause of this error.

KEY POINTS

- Errors occurring at prescription/request step of the blood transfusion process accounted for almost 68% (17) of all reports of unnecessary transfusions in 2007, while errors occurring at the sampling stage of the process contributed to 20% (5) and those occurring in the laboratory contributed to 8% (2) unnecessary transfusions.

- In 2007, a number of unnecessary transfusions occurred when patients were not cared for by their primary care team or were cared for in a different centre.
Incorrect ABO, RhD group, antigen and component transfused n=17

This section reviews cases where incorrect ABO group (3), incorrect RhD group (1), antigen incompatible (2) and incorrect component (11) were transfused. In all of these events, patients did not experience any reaction.

Incorrect ABO group transfused n=3

These events involved patients receiving incorrect ABO group platelets (2) and SD plasma (1). Errors occurring in the hospital blood transfusion laboratory (2) and the supply centre (1) contributed to these adverse transfusion events.

In both cases, involving platelets (apheresis in one case and pooled in another) patients with blood group A received group O platelets. In one case, the medical scientist in the supply centre offered a hospital blood bank a choice of platelets, although where there was a clear policy outlining what should be issued. In the second case, during an emergency, a second medical scientist issued group O platelets to a patient whose blood group was A. (Case History 5)

Case History 5

In this case, an infant required a transfusion of platelets for low platelet count associated with an underlying malignant condition. Her ABO blood group was group A but she received a unit of group O platelets in error. The error occurred in the laboratory which, at the time, was extremely busy. Two units of apheresis platelets (group A and group O) were ordered from the supply centre for two different patients. Both units arrived at the hospital blood bank separately and the group O platelets arrived first while the laboratory was extremely busy issuing blood for an emergency transfusion. Another medical scientist, who was training for on-call work, offered to assist his colleague and issued the group O platelets to the patient whose blood group was A. This medical scientist understood the group O platelets being issued did not match the patient’s record, and assumed this had been authorised by the senior scientist. In fact, the group O platelets were intended for another patient. The nurse collecting the unit noticed the platelet unit was a different ABO group from the patient and queried it at the time of collection and again on the ward but she was reassured the unit was compatible and no action was taken. The error was discovered by the medical scientist when the group A platelets were received from the supply centre a few hours later. The laboratory contacted the ward but the transfusion had already commenced and the haematology team advised to continue the transfusion as the patient had been already exposed to that donor. The patient suffered no sequelae but the Direct Antiglobulin Test (DAT) remained positive for a number of days.

These cases highlight errors occurring in both clinical and laboratory areas. Both clinical and laboratory policies should incorporate guidance on platelet selection and training must be provided for both clinical and laboratory staff.

Where uncertainty remains on issuing, expert advice should be sought from the haematologist either in the transfusing hospital or at the IBTS.

KEY POINT

It is recommended that group O apheresis platelets are reserved for group O patients and should not be used for patients whose blood group is A, B or AB. Transfusion of group O apheresis platelets to patients whose blood group is A, B or AB has potential to cause haemolysis as group O platelets may have high titre anti-A and anti-B in spite of testing for haemolsins (BCSH, 2003).
There was one case where a group B patient was transfused with group A SD Plasma.

**Case History 6**

This error occurred in the blood transfusion laboratory, when a medical scientist was processing three requests for patients who were bleeding. A quick group was carried out for a patient requiring SD Plasma. While the patient was correctly grouped as B, the medical scientist entered the patient’s blood group as A in error. Following on from this, group A SD Plasma was issued and transfused. This error was not picked up during the pre-transfusion checking procedure. This error occurred outside routine working hours and the single medical scientist on call did not normally work in the blood transfusion laboratory.

**Incorrect RhD group transfused n =1**

This case involved a transposition of labels between two units which were being issued for different patients and this resulted in a patient receiving an incorrect RhD group platelets. The error was discovered by nurses crosschecking the second unit of platelets prior to transfusion. The error occurred in the blood transfusion laboratory, when the medical scientist did not adhere to laboratory policies.

**Transfusion of antigen incompatible red cells n=2**

There were two cases where patients received incompatible red cells, where lack of, or poor communication, between laboratories was identified as a cause of both errors.

**Case History 7**

This patient required transfusion for anaemia secondary to a malignant haematological disorder (Hb 7.8g/dl). The patient was grouped and crossmatched in his local hospital and cold auto agglutinins and an anti-Jk\(^b\) antibody were identified. The sample was referred onto a reference laboratory for further testing where the presence of anti-Jk\(^b\) antibody was confirmed. Antigen negative red cells were transfused uneventfully in this site. The patient was then transferred to another hospital for further treatment. The laboratory and the patient’s medical team did not inform the receiving hospital about the patient’s previous positive antibody history either verbally, or in writing, prior to transfer. A group and crossmatch was carried out in the receiving hospital and on this occasion the Jk\(^b\) antibody was not detectable. The patient was transfused with two units units of red cells which were subsequently found to be Jk\(^b\) positive. The error was discovered the following day when a repeat sample was processed and the anti-Jk\(^b\) antibody was detected on this occasion. The patient suffered no reaction. System and human communication failures were identified as causes of this error. There is no system in place for laboratories to communicate or make available significant transfusion histories between referring centres. In practice, laboratories may not be aware that patients have been transferred.

**Case History 8**

In the second case, a patient who needed a transfusion was admitted to a hospital where he had not previously been a patient. The laboratory crossmatching blood for the patient telephoned the laboratory which had previously carried out a crossmatch on the patient. The medical scientist checked the blood group on the LIS but failed to check if the patient had any significant antibody history. This involved accessing further screens on the LIS. This error was discovered on receipt of the written confirmation of the previous transfusion history by the cross-matching hospital. The original laboratory has amended its procedures to ensure patients results are now faxed to requesting hospitals and where a fax number is unavailable, results are only provided from a
These adverse events highlight the challenges in the provision of optimal patient care where patients have a significant antibody history. Where a patient is transferred from one hospital to another, it is difficult to identify a secure method of communicating the information to the primary care centre. Very often, the transfusion laboratory in the hospital is unaware the patient is to be transferred or has been admitted from another hospital.

**KEY POINT**

Good communications systems between laboratories are critical to ensure optimal patient care. However, these case studies highlight some of the challenges. A national patient antibody register for patients with significant red cell antibodies merits serious evaluation (Lariat and Fisher, 2005; O’Brien, 2008, personal communication)

**Incorrect component/product transfused n=11**

The NHO has captured reports of blood components/products transfused instead of another component in this category.

<table>
<thead>
<tr>
<th>Age category</th>
<th>No of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant (1 - 12 months)</td>
<td>3</td>
</tr>
<tr>
<td>Adult (18-30 years)</td>
<td>1</td>
</tr>
<tr>
<td>Adult (31-50 years)</td>
<td>1</td>
</tr>
<tr>
<td>Adult (51 - 70 years)</td>
<td>2</td>
</tr>
<tr>
<td>Elderly (70+)</td>
<td>4</td>
</tr>
</tbody>
</table>

- Three red cell transfusions involving the incorrect component were administered to infants and are described in greater detail in the Paediatric section on page 38 - 39

- Red cells were also implicated in three further cases involving adults.

  - One of these cases involved an error occurring at request, when a nurse ordered red cells instead of SD plasma for a patient. A failure to verify the order against the prescription at time of pre-transfusion checking was the cause of this error.

  - Two errors occurred at collection, resulting in patients receiving inappropriate red cell components. In one case, a nurse collected uncross-matched O Rh negative red cells, instead of the designated emergency units which were available. (Case History 9) In the second case, a patient received uncross-matched O RhD negative red cells, instead of designated emergency O RhD negative red cells. (Case History 10)

**Case History 9**

This patient was admitted with severe trauma and required an emergency transfusion. Due to an error in collection the patient was transfused with uncross-matched non emergency blood O
Rh negative, instead of the designated emergency stock. The causes of this error were multiple; the error occurred out of hours, and there was no laboratory cover. Designated emergency group O Rh D negative blood was not clearly marked or labelled in the fridge. The nurse collecting the blood had not been trained in collection procedures. Following this error, designated emergency stock is now clearly marked and labelled in the issue fridge, and a training programme in collection procedures has been implemented for all staff.

**Case History 10**

Medical staff were implicated in this error. This incident occurred in a post-anaesthetic care unit when a patient required blood immediately. When the blood was removed from the fridge, the unit numbers did not match the units on the accompanying compatibility report. The doctor involved correctly decided not to transfuse the units. However, as blood was required immediately, a clinical decision was made to administer two group O Rh D negative units which had been cross-matched for another patient. This hospital does not maintain a stock of emergency O negative blood in a local satellite fridge which, if available, would have been suitable for transfusion in this emergency situation.

**Incorrect/Unnecessary Transfusions involving SD Plasma n=5**

There were five cases where SD plasma was administered and it was not the most appropriate product. All of these cases involved errors made at prescription/request where SD plasma was ordered for patients who required reversal of anti-coagulation. All of these cases involved reversal of warfarin and unless there are contraindications to its use, Prothrombin Complex Concentrate (PCC) is the product of choice for reversal of warfarin anticoagulation where the patient has serious bleeding or is going for an emergency procedure. None of the patients were actively bleeding but were going for procedures. While this indicates poor awareness of best practice guidelines for reversal of anticoagulation, a closer examination of these cases illustrates how the complex nature of hospital care contributed to these errors. Miscommunication contributed to three of these events.

- In one case, a poorly written prescription led nurses to order SD plasma - (Octaplas) with a similar name, instead of the correct product PCC (Octaplex).
- In another case, a patient received two separate treatments for reversal of warfarin under the care of two teams within one hospital prior to surgery, following communication failures. The patient was administered Vitamin K and PCC by the A&E team, and SD plasma by the anaesthetic team. The anaesthetic team failed to check the most recent INR result and prescribed SD plasma – as they were unaware that the patient had already received treatment. The doctor concerned was also unaware of best practice guidance on use of PCC for reversal of warfarin.
- In the third case, a doctor ordered SD plasma to correct an abnormal INR as he had been incorrectly told the patient was not on warfarin.

**Incorrectly stored components n=15**

- There were 15 reports of transfusion of incorrectly stored units in 2007.
- Twelve reports related to incorrect storage of red cells, two to platelets, and one to SD plasma.
- Twelve reports were considered as SAE, and these reports all related to red cells.
### Table 5: Description of storage SAE n =12

<table>
<thead>
<tr>
<th>Type of error</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion of red cells, removed from controlled storage and transfused over four hours later</td>
<td>5</td>
</tr>
<tr>
<td>Red cells were stored in uncontrolled / domestic fridges</td>
<td>3</td>
</tr>
<tr>
<td>Failure of monitoring systems* or power in hospital</td>
<td>2</td>
</tr>
<tr>
<td>Red cells were stored and transported in an incorrect box</td>
<td>1</td>
</tr>
<tr>
<td>Red cells transported in an un-validated storage box</td>
<td>1</td>
</tr>
</tbody>
</table>

* In this incident, a lookback of 97 components was carried out at hospital level. This involved a complete chart review of all patients transfused.

- Three reports were considered as IBCT, two of which related to platelets. In both cases, platelets were stored in a satellite fridge by nursing staff prior to transfusion. In the third case, a nurse stored SD plasma in an uncontrolled fridge in a clinical area, while a cannulae was re-sited.
- Adverse events resulting in transfusion of incorrectly stored units resulted from errors occurring across all stages of the transfusion process including prescription /request, collection, storage in the blood transfusion laboratory and at administration.

### Key Points

- The increasing numbers of reports relating to storage of components most likely reflects increased awareness and reporting of these incidents since the implementation of the EU Blood Directive. However, as laboratories continue to improve and develop quality management systems, a reduction in these reports is likely to occur. A comprehensive quality management system should cover storage and collection of blood components in the blood transfusion laboratory. There should also be parallel clinical policies covering storage and collection from satellite fridges.
- The development by the EC working party (see page 9) of common definitions to reporting SAE and SAR has meant that definitions of mandatory reports continued to change through out 2007. At the beginning of 2007, all adverse events around incorrect storage were mandatory reports even if they occurred in the clinical area. Currently, this has been narrowed to cover laboratory adverse events where the transfusion time exceeds four hours after the red cells were initially removed from controlled storage, and the red cells were re-issued by staff from the Blood Transfusion Laboratory or where red cells were subsequently taken back into stock, and reissued for another patient (NHO Handbook 2007)

### Transfusion of incorrectly labelled units n=10

- These reports were captured in the “Other” category.
- Red cells were implicated in nine adverse events, and platelets in one event.
- All reports were classified as mandatory SAE.
- All these reports were unit labelling errors.
  - In nine cases, there was a transposition of cross-match labels within a single cross-match of red cells, and transposition of labels during labelling of platelets.
  - The final case involved an error where a temporary patient identifier was not removed from the LIS, and this number was applied to the compatibility report and hospital unit labels. This temporary number
was not a unique patient identifier allocated by the hospital information system.

- All adverse events were assessed as medium risk to patients.
- A breakdown of these reports revealed the first site of error as the blood transfusion laboratory. These errors were not picked up at either collection or during pre-transfusion checks at time of administration.

Risk assessment of reports received to NHO
All events were categorised as high or moderate using an assessment of their potential to cause harm.

Table 6: Potential to cause harm n=95

<table>
<thead>
<tr>
<th>Potential to cause harm</th>
<th>No. of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>44</td>
</tr>
<tr>
<td>Moderate</td>
<td>51</td>
</tr>
</tbody>
</table>

An analysis of risk assessment of individual categories of reports received is presented in Figure 5.

Figure 5: Risk Assessment by category of report received n =95
When the risk assessment of events is compared to that of 2006, it is notable that there has been a 27% increase in the number of errors with a moderate risk rating reported, while errors with a high risk rating remained broadly similar.

**Error discovery - Where, Who What, Why?**
This highlights areas of the blood transfusion process where errors are discovered, and who is discovering those errors.

**Figure 6: Step in work process where error was discovered n= 95**

- A large majority of adverse transfusion events (72%) were discovered at the step in the work process identified as “Other”. This is generally post transfusion and error discovery occurred at both ward level and in the laboratory. Errors at this stage of the process were discovered by HVO (43), medical scientist (18) nurses (6) and doctors (2).

- Twelve (12%) of adverse events were discovered in both the blood transfusion or other laboratory. Errors were discovered during routine rechecking of on-call work, at a subsequent crossmatch or following issue to clinical area. While the majority of these errors were discovered by medical scientists (10), two errors were discovered by HVO.

- Ten (10%) were discovered during the administration step of the process. Nurses discovered seven of these errors, and the HVO discovered three errors.

- Adverse events were discovered at the prescription/request stage of the process in two instances. These errors were discovered by the HVO.

**Who discovered errors?**
- The HVO discovered 53% (51) of adverse events across all stages of the transfusion process.

- Medical scientists discovered 29% (28) of adverse events following transfusion.

- Nurses discovered 14% (14) adverse events either during administration (following commencement of a transfusion) or post transfusion.

- Only two adverse transfusion events were discovered by doctors. One involved an unnecessary transfusion, and the second was where an incorrect component had been transfused.

**Figure 7: Who discovered the error? n=95**
**Findings**
Examination of data around error discovery identified that all staff in the transfusion chain play an important role in monitoring the process for deviations.

**KEY POINTS**

**Haemovigilance**
- All facilities which transfuse patients should have a HVO in post.
- While participation in the haemovigilance reporting scheme for SAR and SAE affecting the quality and safety of blood components is mandatory, reporting of non-mandatory adverse events should be encouraged. The NHO is concerned about a reduction in reporting of adverse clinical events in 2007 as management and reporting of these events has an important role in improving patient safety not only related to transfusion but also in other areas such as patient identification, record keeping etc.
- The important role played by HVOs in discovery and analysis of adverse events is yet again highlighted this year. It is imperative that HVOs are supported in developing an analytical approach in analysing and developing action plans to address adverse events. Hospital HVOs should receive training in root cause analysis and develop good working relationships with their organisational risk managers. The NHO, in partnership with the Clinical Indemnity Scheme (CIS) will provide increased training in root cause analysis at the haemovigilance programmes.
- The majority of errors found by HVOs were discovered during post transfusion surveillance activity. This indicates that potentially many errors could have been detected by other staff in the transfusion process prior to completion of transfusion. This highlights the need for hospitals to provide continuing education for clinical and laboratory staff involved in the transfusion process.

**Error occurrence**
This section outlines the details surrounding event occurrence, looking at where and at what part of the transfusion process and who was involved.

**Figure 8: Site in transfusion process where first error occurred, n = 95**

- Similar to the findings of the 2006 Annual Report, the findings clearly illustrate that prescription request, administration and laboratory processing were the most frequently identified first site of error. While all adverse events cause risk to patients, 49% (21) of all adverse events rated as high risk, occurred at prescription/request stage of the process.
- Collection was identified as site of first error in 7% (7) cases. Nurses, laboratory
In the following section, adverse events where the first site of error was prescription/request (n=32), administration (n=21), and blood transfusion laboratory processing (n=19) will be reviewed in greater detail.

Analysis of adverse events with first site of error at prescription/request, administration and blood transfusion laboratory processing.

First site of error; prescription/request n =32

As only doctors can prescribe blood, the majority of prescription/request errors involved medical staff.

Table 7: Staff involved in prescription/request errors n =32

<table>
<thead>
<tr>
<th>Staff group</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical staff</td>
<td>25 (78%)</td>
</tr>
<tr>
<td>Nursing staff</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>Multiple staff groups</td>
<td>4 (13%)</td>
</tr>
</tbody>
</table>

Prescription request errors involving medical staff resulted in the following outcomes for patients.

Table 9 Outcomes for patients following prescription/request errors involving medical staff, n =25

<table>
<thead>
<tr>
<th>Patient outcomes as result of errors</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unnecessary transfusions</td>
<td>15</td>
</tr>
<tr>
<td>Failure to receive CMV negative and/or irradiated components</td>
<td>5</td>
</tr>
<tr>
<td>Incorrect component/product transfused</td>
<td>5</td>
</tr>
</tbody>
</table>

- Errors at prescription request were caused by both system and human failures. While individual human failures such as lack of knowledge, failing to check patient results or to adhere to policy or communication between individuals were responsible, broader system failures were reported in many of these cases. These included lack of clear transfusion policies, failure of hospital management to prioritise transfusion safety and general...
organisational culture (See Error Causes page 33).

**KEY POINTS**

- An analysis of all adverse transfusion events since 2000 shows that prescription/request has consistently been reported as the most common step where errors first occur and accounts for 38% of all errors.

- It is the responsibility of the prescribing doctor to ensure that the most recent laboratory results are checked prior to prescribing.

- This check should include verification of the patient’s details and the date the sample was drawn. Particular care should be taken when reading results from the computer screen to ensure the correct results are read.

- All hospitals should have systems in place to ensure that protected time is made available for medical staff to attend Haemovigilance training so that doctors involved in the prescription of blood/blood components are aware of current guidelines in relation to prescription and appropriate use of blood/blood components.

Administration of the transfusion was identified as first site of error in 21 reports. Nineteen of these involved nursing staff reflecting the fact that the majority of transfusions in Irish hospitals are administered by nurses.

**Table 10: Patient outcomes following administration errors made by nursing staff n= 18**

<table>
<thead>
<tr>
<th>Patient outcomes as result of errors</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unnecessary transfusion</td>
<td>1</td>
</tr>
<tr>
<td>Transfusion of incorrectly stored unit</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
</tr>
</tbody>
</table>

- One patient received an unnecessary transfusion when the nurse requested and transfused RCC following review of the medical notes (Case History 3)

- There were four errors related to incorrect storage, where the first site of error was deemed to have occurred at time of administration. In all cases, units were returned to fridges following transfer to the clinical areas.

- Thirteen reports of adverse events at administration were categorised as “Other”. Up to 85% (11) of these involved transfusions of RCC over six hours. One report related to the concurrent transfusion of dextrose with RCC and the final report related to the use of an incorrect administration set. The patients suffered no sequelae.

- Medical staff alone were solely implicated in one error, where the first site of error was at administration (Case History 10).

**First site of error: administration n =21**

**Table 9: Staff involved in Administration errors n =21**

<table>
<thead>
<tr>
<th>Staff Group</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing staff</td>
<td>18 (86%)</td>
</tr>
<tr>
<td>Medical Staff</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Both</td>
<td>2 (9%)</td>
</tr>
</tbody>
</table>

**KEY POINT**

The final checking procedures at the bedside need to be strictly followed. The final bedside check is complex, involving multiple documentation/patient checks which, if not done correctly by trained staff, can lead to error.
Automated systems for bedside checking should be introduced where possible to reduce the risk of human error.

First site of error: laboratory processing – Blood Transfusion n= 19

- The blood transfusion laboratory was identified as first site of error in 19 reports to NHO in 2007. While the laboratory was identified as site of first error in these incidents, this section does not include all errors occurring in the blood transfusion laboratory.

- All of these errors involved medical scientists working in the blood transfusion laboratory.

- These errors resulted in the following outcomes for transfused patients.

Table 11: Patient outcomes following errors in the blood transfusion laboratory n=19

<table>
<thead>
<tr>
<th>Patient outcomes as result of errors</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect ABO and/or RhD group transfused</td>
<td>3</td>
</tr>
<tr>
<td>Failure to transfuse CMV negative and/or irradiated components</td>
<td>2</td>
</tr>
<tr>
<td>Incorrect component/product transfused</td>
<td>1</td>
</tr>
<tr>
<td>Transfusion of an incorrectly stored component</td>
<td>1</td>
</tr>
<tr>
<td>Transfusion of an expired stored component</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
</tr>
</tbody>
</table>

- The majority of cases fell into the ‘Other’ category and involved transfusion of incorrectly labelled units but there were three events where components of the wrong ABO or Rh group were transfused. Two occurred during emergencies (Case Histories 5 and 6)

KEY POINT

Training for all hospital blood bank staff is now mandatory under the provisions of EU Directive 2002/98/EC and formal ongoing training programmes for medical scientists of all grades including those providing cross-call cover in transfusion should be provided in every hospitals transfusing blood. These systems should include regular evaluation and competency assessment of staff to comply with ISO 15189.

Some of the errors reported occurred out of hours when only one or two staff were on duty and were under considerable pressure. Hospitals should ensure that out of hours work is confined to emergency requests and that routine requests e.g. routine preoperative group and crossmatching are not undertaken out of hours.

Error Cause n =95

When an adverse event occurs, there are usually a number of factors causing and contributing to it. There are two main explanations cited as to why adverse events occur, and these are latent (system) and active (human) factors (MERS-TM). Latent errors are those that occur due to underlying system failures, ultimately leading to adverse events. These include technical causes e.g. design of equipment or defects in materials and organisational causes e.g. errors arising due to inadequate or absent policies or a culture focussed not on patient safety. Active/Human failures result from human failure. This approach focuses on error caused by failures in knowledge, to follow polices, of skills and other factors (Kaplan et al, 1998).

Building on the experience gained from the Near Miss Project (2003-2006), the NHO adopted the categorisations of human and system failures from the Mers-TM. In many of
the cases reported to the NHO in 2007, the findings clearly illustrate that both system and human causes contribute to these adverse events and an event may have more than one cause.

Table 12: Causes of errors reported n= 95

<table>
<thead>
<tr>
<th>Type of Failures</th>
<th>No of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Failures</td>
<td>39</td>
</tr>
<tr>
<td>Human Failures</td>
<td>91</td>
</tr>
</tbody>
</table>

Table 12 outlines that system failures were reported in 39 cases and human failures in 91 cases. An analysis of reports received showed all reports had root causes identified, and in many cases, there were several factors contributing to the adverse events. Table 13 outlines the most frequently reported system failures in 39 cases.

Table 13: System failures identified in adverse transfusion events received by NHO

<table>
<thead>
<tr>
<th>Type of system failure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policies/Procedures</td>
<td>15</td>
</tr>
<tr>
<td>Errors occurring due to unclear/outdated or absent Standard Operating Procedures (SOPs).</td>
<td></td>
</tr>
<tr>
<td>Management Priorities</td>
<td>13</td>
</tr>
<tr>
<td>Errors occurring as a result of organisational management prioritisation of other issues over safety</td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td>6</td>
</tr>
<tr>
<td>Errors arising from a collective approach to safety and risk e.g. where groups may establish their own modes of function as opposed to following prescribed methods.</td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>6</td>
</tr>
<tr>
<td>Errors arising due to inadequate design of equipment, software or materials.</td>
<td></td>
</tr>
<tr>
<td>Materials</td>
<td>2</td>
</tr>
<tr>
<td>Errors arising due to deficits in materials.</td>
<td></td>
</tr>
</tbody>
</table>

Lack of clearly defined policies on transfusion practice and an absence of management priorities on transfusion practice (such as failure to invest in staff, staff training, and systems) were the most frequently reported system failure contributing to the adverse events reported in 2007. Two system failures were identified in three cases. In all three cases, an absent or inadequate policy covering work practices aligned with poor system design in two cases, and failure of management to prioritise safety in one case were identified as contributing to these adverse events.
Human Failures

Table 14 outlines most frequently reported human failures in 91 reports received by the NHO in 2007. In 34 cases, several human failures caused the adverse event.

Table 14: Human failures identified in IBCT/SAE Reports

<table>
<thead>
<tr>
<th>Type of human failure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to adhere to policies and procedures</td>
<td>42</td>
</tr>
<tr>
<td>Knowledge</td>
<td>36</td>
</tr>
<tr>
<td>Verification</td>
<td>21</td>
</tr>
<tr>
<td>Co-ordination/Communication</td>
<td>19</td>
</tr>
<tr>
<td>Monitoring</td>
<td>4</td>
</tr>
<tr>
<td>Slip</td>
<td>4</td>
</tr>
<tr>
<td>Patient Related</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
</tr>
</tbody>
</table>

- Poor adherence to policies and failure to employ knowledge by all staff involved in the transfusion process were the most frequently reported human failures, contributing to errors.
- There are many cross-checking procedures in the entire blood transfusion process and verification failures were identified as significant causes of human error reported.
- Co-ordination/Communication failures between and within disciplines contributed to the adverse events.

Error researchers have identified the importance of jointly examining both human and system failures contributing to error, with less focus on human factors and greater emphasis on system or organisational factors (Vincent and Taylor-Adams, 2001; Reason, 1990). In 35 reports, both system and human failures were identified as causing these errors.

Changes to practice

Interestingly, no changes to practice were reported in almost 50% (47) of cases. No information was provided in 13 cases. Changes to practice were reported in 37% (35) cases.

Practice changes were introduced following 20 of 51 events which were assessed as moderate risk and in 15 of 44 high risk events. Changes to transfusion practice were introduced where system (n=1), human (n=17) and both system and human (n=17) causes contributed to error. Where changes were introduced, it was to prevent re-occurrence. These included changes to policies and procedures, introduction of further verification steps and extension of training to staff.

However in 20 cases where system causes were identified as causing error, no practice changes were introduced.
KEY POINTS

- Reporting in 2007 identified that there is some level of analysis of adverse transfusion events ongoing in Irish Hospitals. A review of human causes of error showed that the most frequently identified causes were errors around verification and poor compliance to blood transfusion policies, while the most frequently reported changes to practice included the introduction of further verification steps and policy changes.

- Analysis of clinical events is a powerful methodology for improving overall practice. Critical incident analysis of individual cases very often reveals the complexity of the chain of events leading to an adverse event (Vincent and Taylor-Adams, 2001). However, a measured approach is recommended to minimise the chance of simplistic explanations for event occurrence and guarantee the most effective patient care solutions are put in place (Kaplan et al, 1998).

- Where changes are introduced following an adverse event, there will be a need to inform staff, potential for retraining, and evaluation of the impact of the change.

- It is recommended that hospital HVOs receive appropriate training in analysing adverse events and develop good working relationships with local organisational, regional risk managers or clinical risk advisors from the CIS.


There were 32 reports received in 2007 which were mandatory under Commission Directive 2005/61/EC.

Table 15 identifies how these reports were categorised and the components implicated in these reports.

Table 15: Mandatory reports received in 2007 n = 32

<table>
<thead>
<tr>
<th>Category of report</th>
<th>Components implicated</th>
<th>Total</th>
<th>RCC</th>
<th>Platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion of a incorrectly stored component</td>
<td>12</td>
<td>12</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
<td>9</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Failure to transfuse CMV negative and irradiated components</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Incorrect component transfused</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Incorrect ABO group transfused (no patient reaction)</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Incorrect RhD group transfused (no patient reaction)</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Transfusion of other antigen incompatible RCC (no patient reaction)</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
Table 16: Annual notification of SAE n=32

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Total number</th>
<th>Product defect</th>
<th>Equipment failure</th>
<th>Human error</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing of Donations*</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Storage</td>
<td>12</td>
<td>0</td>
<td>2</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>19</td>
<td>0</td>
<td>0</td>
<td>17</td>
<td>2</td>
</tr>
</tbody>
</table>

Risk Assessment of mandatory reports
All reports were individually assessed in terms of potential to cause harm to patients.

- Eleven (34%) reports were assessed as “high potential to cause harm” to patients. These included all reports relating to transfusion of incorrect component and ABO RhD and antigen incompatible components to patients. A risk assessment of SAE classified as storage incidents revealed that 50% (6) errors were assessed as having high potential to cause harm to patients.

- Twenty two (66%) of reports had “moderate potential to cause harm” to patients. These included reports of errors categorised as “Other” and those relating to storage. Fifty percent (6) of storage SAE were classified as moderate risk to patients.

Causes of errors in mandatory reports
Under Commission Directive 2005/61/EC, an analysis of all SAE should be instigated to identify root causes of events. Analysis of reports received 2007 identified the following system and human failures contributing these SAE.

Table 17: System failures identified in mandatory reports n= 18

<table>
<thead>
<tr>
<th>Type of system failure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management priorities</td>
<td>10</td>
</tr>
<tr>
<td>Policies/Procedures</td>
<td>4</td>
</tr>
<tr>
<td>Design</td>
<td>3</td>
</tr>
<tr>
<td>Materials</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 18: Human failures identified in mandatory reports n=43

<table>
<thead>
<tr>
<th>Type of human failure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to adhere to policies</td>
<td>14</td>
</tr>
<tr>
<td>Verification</td>
<td>9</td>
</tr>
<tr>
<td>Knowledge</td>
<td>9</td>
</tr>
<tr>
<td>Carrying out task incorrectly</td>
<td>4</td>
</tr>
<tr>
<td>Slip</td>
<td>3</td>
</tr>
<tr>
<td>Co-ordination /Communication</td>
<td>2</td>
</tr>
<tr>
<td>Patient related</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
</tbody>
</table>

Changes to practice
Commission Directive 2005/61/EC seeks information on corrective measures taken to address these errors. However in 53% (17) cases, changes were not reported. Where corrective measures were implemented, these primarily included re-training and on-going training of both laboratory and clinical staff.

Some organisations implemented specific changes to address particular failures in their work processes e.g. to address a verification failure which resulted in a transposition of labels in a cross-match, a specific check was introduced to minimise reoccurrence. In another case to address a communication failure where incomplete information was shared between blood transfusion laboratories resulting in transfusion of antigen incompatible RCC, the transfusion laboratory will now crossmatch only on receipt of written information.

* This refers to Case History 9 where the presence of an antibody was not reported to the requesting hospital.
Errors Involving Paediatric Patients 0-18 years (n=14)

Findings
There were fourteen cases within the SAE/IBCT category involving paediatric patients. This represents almost 15% of the total number of SAE/IBCT events reported (excluding Anti-D and factor concentrates). Eleven involved red cells, two involved platelets and one involved SD plasma. Six reports involved neonates and infants, five involved children aged 1-11 years and three occurred in adolescents (12-18 years).

Figure 9: Breakdown of Paediatric Events n = 14

Transfusion completed >6hrs following removal from controlled storage, 1, 8%
Administration error, 1, 8%
Antibiotic given based on incorrect information from supply centre, 1, 8%
Failure to give irradiated component, 2, 15%
Unnecessary transfusion, 5, 38%
Unnecessary exposure to another donor, 3, 29%

- The most common adverse events relating to paediatric patients were wrong component transfused/overtransfusion/unnecessary transfusions occurring in five (36%) cases. Three involved young children and two occurred in adolescents.

- Two cases involved transfusions prescribed based on incorrect blood results. In the first of these cases, the prescription was based on an incorrect Hb result from the previous day and staff did not wait for the results of the repeat Hb, (Case History 11) before commencing the transfusion. In the second case, where the patient was treated unnecessarily with SD plasma, the sample was collected from a heparinised line resulting in a prolonged Activated Partial Prothromboplastin Time (APTT).

- The third unnecessary transfusion involved the transfusion of platelets in a patient with ITP where due to a lack of communication, no haematology advice was sought.

- In the fourth case, three units of blood were transfused for severe iron deficiency anaemia which was asymptomatic.

- The final case involved a young child being over transfused and requiring venesection to reduce the Hb. (Case History 12).

- Two (13%) events involved failure to give irradiated components. In one case, non-irradiated red cells were issued as the scientist involved did not check the status of the component. In the second case, the special requirements were not requested.

- Three (21%) of the paediatric cases involved infants where there was unnecessary exposure to a further donor and all involved red cell transfusions. Two of these errors occurred in the blood transfusion laboratory, when new paedipacks were issued to infants although remaining aliquots of the paedipacks which had been assigned to them were available. These errors were caused by verification errors (failure to cross-check if any remaining aliquots were available in the laboratory) and patient-related and knowledge factors. In one of these cases, a new paedipack was issued to a patient following a name change and the already designated paedipack was not re-crossmatched for the child.

- The third unnecessary exposure concerned the transfusion of a unit of red cells issued to cover a surgical procedure but where surgery had been cancelled and the unit was collected in error from the satellite fridge although there were aliquots remaining from a designated paedipack in the blood transfusion laboratory.
• One event involved the transfusion of ABO incompatible platelets to a young child. (Case History 5 page 22).

• In one case, the transfusion of a unit of red cells was completed more than six hours from removal from controlled storage.

• One case involved the transfusion of red cells through a non-filtered giving set when the incorrect administration set was selected in error. The nurse involved was very busy at the time of the incident and selected the wrong administration set as giving sets for both intravenous fluids and blood components were stored on the same shelf.

• The final case involved a neonatal patient who received antibiotic treatment based on incorrect information from the supply centre. (Case History 13).

• One further event involving a paediatric patient is described in the IBCT/SAE Factor Concentrate section (Page 39).

Case Histories Involving Paediatric Patients

Case History 11

This young child was prescribed one unit of red cells. The day prior to the transfusion the patient’s Hb was reported as 7.5g/dl. The following day a repeat blood sample was collected and a transfusion of red cells commenced. When 90mls had been transfused the results of the repeat Hb were reported to the ward as Hb 11.5g/dl. Both samples were then re checked and the Hb result from the sample of the previous day was incorrect possibly due to a small clot in the sample that had not been detected on initial testing. As a result of this incident all results are to be checked if Hb reported is < 9g/dl.

Case History 12

This critically ill young child with respiratory distress and an underlying inherited red cell disorder was prescribed an emergency transfusion of three units of O RhD negative red cells for severe anaemia Hb 1.7 g/dl. The three units were rapidly transfused without reassessment of the patient or a repeat Hb check. The post-transfusion Hb was 18.4.g/dl. The patient then required a venesection to correct the Hb to 14.g/dl. Post-transfusion the patient required ventilation, but is unclear if this is related to the transfusion or the patient’s clinical condition. On investigation it was discovered the volume prescribed and given was 60mls/kg when the correct dose should have been 20mls/kg. The error was made by a NCHD and neither the consultant paediatrician nor registrar was aware that all three units had been transfused. A contributory factor was the urgency of the situation where several clinicians were managing the patient simultaneously but not communicating the patient’s treatment to each other. There was also a change of staff during this time. The patient subsequently made a complete recovery.

Case History 13

This seriously ill neonate required a transfusion of platelets for platelet count of 71 x 10^9/L. The transfusion was uneventful. Approximately one hour following completion of the transfusion the hospital was contacted by the supply centre and informed that the unit of platelets had tested positive for possible bacterial contamination on BactAlert screening. The consultant paediatrician was informed, a decision was made to commence the baby on an additional antibiotic and the first dose was given. Further investigation of the implicated platelet unit showed no evidence of contamination. However, the supply centre discovered that the unit number had in fact been issued to another hospital and the baby had received an unnecessary dose of antibiotic. There were no sequelae from this incident.

Recommendations

KEY POINTS

• Paediatric patients are a distinct patient group and their requirements can differ greatly from those of adults. Particular consideration should be given to reducing donor exposure to decrease the possible long-term side effects of transfusion for paediatric patients many
of whom are long-term survivors and expected to have a normal life-span (New, 2006).

- One case involved an over transfusion of red cells in an emergency setting. Good communication is important where patients are under the care of more than one specialty. Close coordination between specialist teams caring for the patient is vital.

- Paediatric patients have specialised blood requirements and errors can be associated with serious sequelae. Medical staff require specific education and ongoing training in relation to the prescribing needs of neonates and infants.

- The patient's Hb should be monitored regularly to avoid overtransfusion.

**IBCT/SAE Involving Factor Concentrates/Blood Products**

The NHO collects errors involving factor concentrates (reactions are reportable to the Pharmacovigilance section of the IMB). There were four IBCT involving factor concentrates/blood products in this reporting year, one (25%) of which involved a paediatric patient (<18 years).

**Findings**

**Wrong dose given (n=2)**

Two (50%) errors involved the wrong dose of product being given resulting in overdosage of the product. In one event, the patient received an overdosage of the product as the nurses involved did not follow the procedure for reconstitution and administration of the product. A contributory factor was that one of the nurses was called away during checking of the product and the second nurse was familiar with the patient's condition and treatment and did not adhere to recommended protocols. The second case, is described in Case History 14.

**Case History 14**

One case involved a six year old male with a diagnosis of a mild Factor VII deficiency. The child required out of hours treatment of a fracture and Factor VIIa was prescribed by a non-specialist doctor. The hospital policy was to prescribe the product in micrograms or milligrams but in this instance the doctor wrote the prescription for the correct dose but used the incorrect unit of measurement. The product stated the dose in milligrams and Kilo International Units (KIU) and the hospital laboratory issued the product in KIU. The confusion resulted in the patient receiving an over dosage of the product in excess of twenty times the prescribed amount. This occurred on two occasions. The error was discovered by the consultant haematologist when the case was reviewed. No adverse reaction occurred as a result of this incident. Since this event the hospital policy has been changed so this product can only be prescribed in milligrams or micrograms and the transfusion laboratory will only issue the product in milligrams or micrograms.

**Wrong Product Given (n=2)**

Two (50%) events involved the wrong product being given. One was due to a failure to check the patient's chart and second was due to an error in requesting the product. The first event involved a patient with a severe Factor VIII deficiency receiving plasma derived Von Willebrand Factor instead of recombinant Factor VIII. The error occurred as the computer system was not operational at the time of the incident and staff did not check the hard copy of the patient's file. A contributory factor was that this event occurred out of hours.
In the second case a patient with severe bleeding was prescribed Factor VIIa. However, Factor VIII was requested and issued. The prescription was checked by two nurses but the error was unnoticed.

**Recommendations**

- The risk of errors when administering factor concentrate therapy 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 in St. James’ Hospital, Dublin 8.

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

- All staff involved in the prescription, issue and administration of factor concentrates should receive appropriate training.

- It is important that even when staff are familiar with patients and their conditions that hospital policies and protocols are followed.
Adverse Events associated with Anti-D immunoglobulin

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

Serious Adverse Events related to Anti-D immunoglobulin are not reportable to IMB under the Blood Directive.

There were 16 reports of serious adverse events associated with Anti-D administration.

Table 19: Errors Associated with Anti-D Immunoglobulin (n=16)

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omission/Delay of Anti-D Ig</td>
<td>12</td>
</tr>
<tr>
<td>Omission</td>
<td>5</td>
</tr>
<tr>
<td>Delay</td>
<td>7</td>
</tr>
<tr>
<td>Unnecessary Treatment with Anti-D</td>
<td>4</td>
</tr>
<tr>
<td>Anti D given to mother of D neg infant</td>
<td>1</td>
</tr>
<tr>
<td>Anti-D given to RhD positive mother (human error)</td>
<td>2</td>
</tr>
<tr>
<td>Unnecessary Dose of Anti-D given (human error)</td>
<td>1</td>
</tr>
<tr>
<td>Total Cases</td>
<td>16</td>
</tr>
</tbody>
</table>

**Omission of Anti-D (n=5)**

Findings

In five (5) cases, Anti-D should have been given but was omitted. All cases were associated with human error in the clinical setting.

In two cases no obvious factor contributed to the omission other than an oversight.

In a further incident, an assumption was made that the patient did not require Anti-D following a sensitising event. This decision was based on the fact that Anti-D had been previously given nine days earlier. (Case History 15)

In a further event due to human error and patient related factors, Anti-D was omitted. The patient presented with a bleed at just over 12 weeks. A sample was collected from the patient, however, it was incorrectly labelled and was discarded. The patient was contacted and advised to return, but she had left the country and did not return to the hospital for a number of weeks.

In the final case, again both human error and patient related factors were involved. The patient presented with an antepartum haemorrhage. She was sent home in error before receiving Anti-D and despite a number of attempts to contact her.

**Case History 15**

Omission of Anti-D due to an error in clinical judgement.

This Rh D negative mother presented with a vaginal bleed at 11 weeks gestation. Anti-D was administered at this time. Nine days later the patient miscarried and required surgical intervention. Based on the presence of detectable antibody in the serum at the time of the procedure Anti-D was not administered as the doctor incorrectly assumed that the previous dose of Anti-D was sufficient.

**Delay in administering Anti-D (n=7)**

Findings

In a further seven (7) cases, Anti-D administration was delayed beyond the recommended outer limit of 72 hours post exposure.

In five (5) cases failure to adhere to policies and procedures was the main cause of error.

In one of these cases, the delay was due to the incorrect assumption that following delivery of a Rh
D positive baby, the patient did not require Anti-D as she had received a dose of Anti-D 10 days prior to delivery for a sensitising event.

In a further case a patient in early pregnancy presented with a vaginal bleed. She was reviewed and discharged without receiving Anti-D. No blood was taken to check the patient’s blood group and a historical record of the patient which was available was not checked. The error was detected when the patient presented at an antenatal review 18 days later.

In a further two cases due to errors in the delivery suite, no cord blood samples were sent for testing and in the second of these cases a delay in prescribing the Anti-D also contributed to the late administration of the product.

In a further case due to a co-existing medical condition which required frequent anti-coagulation monitoring, the need for Anti-D was overlooked.

Failure in communication was the main contributing factor in a further case where the patient’s blood group was incorrectly recorded in ward documentation. It was not detected until discharge that the patient was in fact Rh D negative and Anti-D was required.

In one further case where a patient was under the care of a community midwife, the Anti-D was issued by the laboratory but due to human error the midwife omitted to collect the Anti D from the laboratory issue fridge. The Anti-D was not administered until five days post delivery. A contributory factor in this case was the fact that community midwives do not have patient’s charts and there was no record of the patient’s blood group on the home visit sheet. Since this incident, changes in practice have occurred and the mother’s blood group is now documented on the home visit record sheet which is completed prior to the visit.

### Unnecessary Treatment with Anti-D (n = 4)

There were two cases of unnecessary Anti-D administration to Rh D positive mothers and a further two cases of unnecessary Anti D administration to Rh D negative mothers

#### Unnecessary treatment with Anti-D Immunoglobulin to Rh D positive mothers

Findings (n=2)

In both cases Anti D was given in error due to failure to adhere to policies and procedures and failure to confirm positive patient identification at the bed side prior to administration.

In the first case, the error was discovered when staff were updating the patient’s chart. The staff involved had gone to the wrong patient’s bedside, they checked the product and the prescription but failed to follow correct patient identification procedures and did not check the patient’s identity bracelet prior to administration.

In the second case, the error was again detected after administration of the product. The Anti-D was checked at a remote site by two staff members, correct identification procedures were not followed, the patient was not asked to verify her name and her identity bracelet was not checked. Following administration, while in conversation with the patient, the midwife realised that the product was given to the wrong patient.

#### Unnecessary treatment with Anti-D Immunoglobulin to Rh D negative mothers

Findings (n=2)

#### Unnecessary Dose of Anti-D given (n=1)

A number of contributory factors were involved in this error. The patient presented at 33 weeks with urinary retention. Incorrect patient clinical details were transcribed on the Anti-D request form. Anti-D was issued on the basis of these details. The patient presented the following day in the emergency room. A doctor was asked to prescribe the Anti-D and it was administered by the midwife. The patient’s notes were not consulted.
Anti D given to mother of Rh D neg infant (n=1)
In this case, cord bloods were taken, processed and reported on the day following delivery. The baby’s blood group was Rh D negative and the ward was informed. The mother was transferred to another ward but due to an error in communication, the staff were unaware of the cord blood result. A repeat group and screen were sent to the laboratory and Anti-D was issued from the laboratory and administered unnecessarily. As a result of this error, a change in practice has occurred and all staff both clinical and laboratory must ensure that the current clinical details are given before Anti-D is issued or administered.

Key Points and Recommendations
It is evident that a number of hospitals still lack guidelines for Anti-D administration. Each hospital should have clear written protocols in place for when and how to administer Anti-D.

Failure in communication and poor documentation were notable factors in the delays and omissions of Anti-D prophylaxis in this year’s report. In most of the cases there was a failure in the maternity discharge checklist procedure.

There is also evidence of failure to adhere to or understand the guidelines for Anti-D prophylaxis. There is a lack of understanding by clinical staff of the need to give further Anti-D for sensitising events following previous antenatal administration. There is a real need for targeted education around Anti-D prophylaxis in these situations particularly when routine antenatal Anti-D prophylaxis (RAADP) is introduced (NICE, 2002; BCSH, 2006a).

Recommendations
- The requirement for Anti-D prophylaxis must be included in the discharge checklist procedure for Rh D negative women.
- Clear procedures for communication of the requirement for Anti-D prophylaxis should be implemented.
- The patient should be advised of her Rh D negative status and situations requiring Anti-D prophylaxis.
- There should be clear identification of the patient’s RhD negative status in both hospital and shared care files.
- Hospitals should consider issuing an RhD negative card (BCSH, 2006b) with listed indications for prophylaxis to the patient.

- Hospital guidelines need to state clearly that Anti-D prophylaxis should be administered in response to sensitising events regardless of recent or planned administration of prophylactic Anti-D.
- Omissions and delays in Anti-D administration should be reported to the NHO in addition to reporting internally within the hospital risk management procedures. There should be clinical follow-up and retesting in 6 months of patients in whom Anti-D administration has been delayed or omitted. Any sensitisations arising should be reported to the NHO as well as internally.
- There are currently no mechanisms in place to ascertain the residual risk or causes of Anti-D immunisations occurring in RhD negative pregnancies in this country. The collation of such data is necessary in the assessment of the efficacy of the current system and following the proposed introduction of a national programme for routine Anti-D prophylaxis in the reduction of the level of Anti-D immunisations.
- The NHO proposes to examine the feasibility of a pilot programme of actively seeking notifications of all new cases of Anti-D sensitisation.
There were 150 SAR reports during the reporting year 2007. After review 107 SAR reports were accepted by the NHO. As in previous years, there were no reports of Transfusion Associated Graft versus Host Disease (TAvGHD) or Post Transfusion Purpura (PTP). There were two initial reports received as TRALI. Following review, one case was recategorised as being due to the patient’s underlying condition and not due to transfusion. The second was originally submitted as TRALI but was later reclassified as TACO. In addition there were no reports of donor adverse reactions related to predeposit autologous transfusion (PAD).

Acute Transfusion Reactions (ATR)

ATR are defined as those occurring within 24 hours of transfusion. During the reporting year 2007, 79 reports of ATR were reported.

Acute reactions include:
- Acute Haemolytic Transfusion Reactions,*
- Febrile Non-Haemolytic Transfusion Reactions,*
- Acute Allergic and Anaphylactic Transfusion Reactions.
- Unclassified

* Acute Haemolytic Transfusion Reactions (AHTR) (n=4)

AHTR is defined as a reaction occurring within 24 hours of a transfusion where clinical and/or laboratory features of haemolysis are present (International Society of Blood Transfusion (ISBT) Working Party, Capetown, 2006). Acute haemolysis may be caused by ABO incompatibility, other antigen incompatibility e.g. RhD, Kell or to non-immunological factors such as hypertonic/hypotonic solutions or medicinal products mixed with the blood component.

EU Notification Category

These AHTR are reportable to the EU as

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other alloantibody - Acute
- Non-immunological haemolysis.

There were four acute haemolytic transfusion reactions reported in 2007. One of these involved an ABO incompatible red cell transfusion. Two of the four reactions were associated with errors in the hospital laboratory.

Case History 16

Immunological haemolysis due to ABO incompatibility

This patient with anaemia who was grouped as group A Rh D negative and crossmatched for three units of blood on call and was commenced on a unit of group A Rh D negative red cells in the late evening. Within five minutes, the patient developed symptoms of dyspnoea, chills, generalised pains and a feeling of doom. The unit was stopped and the on call doctor was contacted. The checks on the patient’s identity and the crossmatched units were correct. The doctor recommended that the unit be sent back to the laboratory for investigation and the second unit from the crossmatch be put up. Fortunately the laboratory was contacted to return the first unit and the medical scientist on duty insisted that all the units be returned to the laboratory for investigation. It was decided not to transfuse the patient further that night. The samples for investigation were not returned to the laboratory until the next morning by which time the laboratory staff rechecking the on call work had discovered that a sample error had happened.

The patient was in fact group O Rh D positive when regrouped. The patient who also had haemoglobinuria required ventilation and analgesia but made a complete recovery within 24 hours.
Error Cause: A medical scientist who worked in the transfusion laboratory but who was working out of hours received two samples at one time in the laboratory, one of which was urgent. The wrong sample was processed without rechecking patient identifiers as per protocol.

Comment. This story illustrates a number of important points. While the original error occurred in the laboratory, it was compounded by the doctor’s failure to realise that no further units from that crossmatch should be used until an investigation had been carried out. Disaster was only averted because the laboratory was contacted and the medical scientist on call at the time, who did not normally work in the transfusion laboratory, but who had recently undergone on call training insisted that all the units be returned to the laboratory and investigation undertaken before any further blood was transfused. In spite of this, the samples were not taken until the next morning by which time the error had been detected.

Immunological haemolysis due to other allo-antibody (Acute < 24 hrs) n = 3

- One of the cases was associated with an error in the blood transfusion laboratory (Case history 17).
- The second patient had a rare antibody (anti-Vel) and needed repeat transfusions. Antigen negative blood, due to its rarity, had to be imported from a number of blood centres in different countries. On one occasion, the patient had a mild reaction characterised by pyrexia and a raised Lactate dehydrogenase (LDH). On retesting of the unit, the unit tested weakly positive for the Vel antigen. The patient made a complete recovery.
- In the third case, a patient who had anti-Fya antibodies had massive bleeding during surgery and the Fya antigen crossmatched blood for the patient had all been transfused, so the emergency O RhD negative blood which was not Fya negative had to be used. This was appropriate as failure to transfuse while waiting to get compatible blood in an emergency is more of a risk than the risk of delayed haemolysis. The patient had a mild rise in bilirubin post transfusion and evidence of transient renal impairment, but no clinical evidence of a transfusion reaction.

Case History 17

Immunological haemolysis due to other allo-antibody

A patient with anti-E antibodies was transfused with a unit of red cells which were E antigen positive. There were no symptoms, but post transfusion the patient’s bilirubin and LDH levels were elevated.

Error Cause: The laboratory was short staffed. Two lots of screened blood had arrived from the supply centre. One lot was E antigen positive, the other E antigen negative. The medical scientist selected and issued E antigen positive blood in error failed to adhere to the policies and procedures. A system error was also involved as the computer system does not provide a check to determine whether the selected blood is compatible when the patient has antibodies. The patient required no treatment.

Febrile Non-Haemolytic Transfusion Reactions (FNHTR) (n=30)

Definition: FNHTR is defined as a rise in temperature of >1.5°C above the patient’s (pre-transfusion) baseline value together with rigors or chills, occurring during or within four hours
following transfusion without any other cause, such as haemolytic transfusion reaction, bacterial contamination or the patient’s primary diagnosis. Although traditionally counted as unpleasant but not serious, as patients usually recover quickly, FNHTR can be upsetting for the patient and may recur on further transfusions. These are reportable to the NHO where symptoms lead to increased morbidity.

FNHTR may present as chills or rigors without fever (ISBT, 2006; NHO Handbook, 2007)

The major concern in evaluating these reactions is to exclude bacterial contamination of the unit or haemolysis due to incompatible red cells. (Heddle & Kelton, 2001)

EU Notification Category: FNHTR is incorporated in the following EU category: Other - Febrile Non Haemolytic Transfusion Reaction.

Findings
There were 30 reports which fulfilled the criteria for a reportable FNHTR reaction. The number reported show a decrease of eight reports on 2006.

Twenty eight of the patients experiencing FNHTR reactions were adults, the majority of these being elderly (>70 years). Two FNHTR reactions occurred in adolescent patients. Twenty one cases (70%) were considered as likely/probable associated with the transfusion and nine (30%) cases were considered possibly due to transfusion.

Twenty six reports involved red cells only, three involved pooled platelets, and in one case the implicated component was buffy coat derived granulocytes.

Blood cultures from the patient were undertaken in 20 out of the 30 cases and from the unit in 20 cases. However cultures of both unit and patient were performed in only 14 cases (47%)

In one case, an initial culture from the patient showed bacterial growth but repeat culturing was negative and there was no growth from the unit. In two cases, growth was found in the unit but in both these cases, the patient’s blood cultures showed no growth and the cultures from the unit were considered by the microbiologist in the reporting hospital to be a contaminant.

While in many of the cases the patient was acutely unwell, 28 patients fully recovered, one patient died unrelated to the transfusion and the outcome for the last patient was not given. In the 20 cases where time to recovery information was provided, 15 recovered fully within 12 hours. Three further patients recovered within 24 hours, but two patients took over 24 hours to recover. Review of these two cases suggested that the delay in recovery may have been due to the patients underlying condition.
KEY POINTS

Wherever possible, as a minimum, blood cultures and investigation for haemolysis should be taken on patients suffering a FNHTR to exclude red cell incompatibility or bacterial contamination.

Acute Allergic and Anaphylactic Transfusion Reactions (AA) (n=40)

Anaphylaxis/Hypersensitivity occurs when a patient who is pre-sensitised to an allergen is re-exposed to the particular antigen. A few patients with severe IgA deficiency develop antibodies to IgA. Some of these patients may have severe anaphylaxis if exposed to IgA through transfusion (McClelland, 2001).

Clinical Signs & Symptoms and Laboratory Findings

Allergic and anaphylactic transfusion reactions span a range of symptoms of varying severity.

- The symptoms encompass mild allergic-type reactions such as urticaria/pruritis associated with or without gastrointestinal discomfort, to major reactions with stridor, wheeze, angioedema, bronchospasm and hypotension occurring during or within four hours of transfusion (ISBT, 2006).

- An anaphylactic reaction or anaphylaxis is characterized by severe hypotension and collapse which may be accompanied by laryngeal oedema and respiratory obstruction (Povosky, 2001).

- Tryptase levels if available prior to the transfusion and within 2-3 hours of the reaction taking place, may help to confirm diagnosis.

- Allergic type reactions apart from pruritis, mild rashes or urticaria associated with transfusion should be submitted to the NHO.

EU Notification Category

- AA reactions are reportable to the EU as Anaphylaxis/Hypersensitivity.

Figure 11: Components implicated in Acute Allergic and Anaphylactic Type Reactions 2007 (n=40)

Findings

- There were 40 AA reactions reported in 2007 which fulfilled the reporting criteria, an increase of eleven cases (38%) from 2006. 19 reactions were associated with red cells and 21 with platelets, see Figure 11 above. During 2007, pooled platelets in additive solution (PAS) were issued from the Dublin centre from the end of July onwards and replaced pooled platelets in plasma. Eight of the reactions reported occurred with platelets in plasma.

- Thirty one of the patients were adults and nine were paediatric/adolescents patients.

- No cases of AA due to IgA deficiency with antibodies were reported, but Immunoglobulin IgA levels were reported in only 17 cases.
Allergic reactions may present without mucocutaneous signs and symptoms. In two cases received this year it was unclear initially if the reactions were anaphylactic/hypersensitivity type reactions as both patients had fevers and no skin manifestations.

The first patient developed temperature rise with hypotension and in the second case overload was initially suspected as the patient developed temperature rise with tachycardia, cyanosis, falling O₂ saturation, stridor/wheeze, chills/rigors, gastrointestinal (GI) symptoms and tachypnoea 3.5 hours into the transfusion. Following further review of both these cases they were captured as anaphylactic/hypersensitivity type reactions.

**Recommendations for management of Acute Transfusion Reactions including Acute Severe Allergic and Anaphylactic Reactions.**

- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly and the patient observed closely for the first 15 minutes/50mls as severe reactions are most likely to occur within this time. (BCSH, 1999; NBUG, 2004)

- Each hospital must have a policy in place for the identification and management of an acute transfusion reaction. This should include the medical and nursing...
management of the patient’s symptoms and the investigations necessary to complete the transfusion reaction analysis. Following a severe transfusion reaction, the transfusion should be discontinued completely and no further units from this crossmatch should be transfused until an ABO incompatible transfusion has been excluded and the blood has been re-crossmatched. The NBUG has produced recommendations for the Management of an Acute Transfusion Reaction (NBUG 2004) (Appendix 1).

**Delayed Haemolytic Transfusion Reactions (DHTR)**

**Definition**

Delayed haemolytic transfusion reactions (DHTR) are defined as evidence of clinical or laboratory features of haemolysis occurring more than 24 hours and up to 28 days following the transfusion of a blood component and associated with serological evidence of antibodies. (ISBT, 2006)

**EU Notification Category**

DHTR are reportable to the EU as Immunological haemolysis due to other allo-antibody - Delayed.

**Clinical Symptoms and Laboratory Findings**

Clinical signs of delayed haemolysis can be similar to those described for acute haemolytic transfusion reactions, but are usually less severe and the diagnosis may be missed if not suspected. Clinical symptoms may be absent and the only sign may be falling haemoglobin. For the purpose of analysis, the NHO grades such reactions by severity using the Serious Hazards of Transfusion criteria (SHOT, 1999).

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Asymptomatic with ‘antibody only’ detected, with or without a positive DAT level.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 2</td>
<td>Demonstrates evidence of haemolysis measured by falling haemoglobin levels and a positive DAT level.</td>
</tr>
<tr>
<td>Group 3</td>
<td>Evidence of a falling Haemoglobin level associated with jaundice, with or without a positive DAT level.</td>
</tr>
<tr>
<td>Group 4</td>
<td>Graded as for Group 3, but with associated renal impairment.</td>
</tr>
</tbody>
</table>

There were six reactions in this category accounting for 5.6% of all SAR and 2.7% of all reports. None of these reactions were associated with an error in the laboratory. Five of the six cases were assessed as likely/probably associated with transfusion, but in many of the cases, investigations for haemolysis were incomplete. In one case (DHTR Case 3) associated with anaemia, detected six weeks after transfusion, the anaemia may have been due to the patient’s underlying condition not haemolysis and no tests for haemolysis were done.

Many of the patients also had serious underlying medical conditions and the relative contribution of the haemolytic process to the signs can be difficult to assess particularly in patients with evidence of pre-existing liver and renal disease. In DHTR Case 1 after the reaction, the patient when questioned about any previous reactions produced an antibody card from 1992 which indicated presence of an anti-Jk\(^b\).

In DHTR Case 5, the patient had underlying liver disease and in DHTR Case 6, the patient who was extremely ill, had evidence of underlying renal disease, but there was evidence in both cases that the haemolysis transiently exacerbated the underlying condition. All patients recovered.
without long term sequelae. The antibodies identified were those commonly associated with delayed haemolytic reactions i.e. anti-Kidd, anti-Rh, anti-Duffy and anti K antibodies.

**Recommendations**

- It is likely that DHTR is underdiagnosed. It is essential that any patient presenting with unexplained anaemia some days after a transfusion should be investigated for immunological haemolysis (bilirubin, LDH, DAT and antibody screen) to exclude DHTR. In a number of the reports of DHTR in 2007 the investigation was incomplete. The successful diagnosis also depends on accurate history taking and the eliciting of a history of recent transfusion.

- As already recommended in the IBCT/SAE section, consideration should be given to issuing antibody cards to patients with clinically significant antibodies (NBUG 2004) and the possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated (Lariat and Fisher 2005; O’Brien, 2008, personal communication).
<table>
<thead>
<tr>
<th>Case No</th>
<th>Serious Adverse Reaction</th>
<th>Age</th>
<th>Gender</th>
<th>Imputability</th>
<th>Findings</th>
<th>Antibody</th>
<th>Category</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Immunological haemolysis due to other allo-antibody (Delayed &gt; 24 hrs)</td>
<td>Elderly (70+)</td>
<td>Female</td>
<td>Certain</td>
<td>Fall in Hb, jaundice, haemoglobinuria, DAT negative</td>
<td>Anti-JK&lt;sup&gt;b&lt;/sup&gt; Anti-K Anti-E</td>
<td>Group 3</td>
<td>Complete Recovery</td>
</tr>
<tr>
<td>2</td>
<td>Immunological haemolysis due to other allo-antibody (Delayed &gt; 24 hrs)</td>
<td>Elderly (70+)</td>
<td>Male</td>
<td>Possible</td>
<td>No Hb level, DAT positive</td>
<td>Anti-e Anti-C</td>
<td>Group 2</td>
<td>Complete Recovery</td>
</tr>
<tr>
<td>3</td>
<td>Immunological haemolysis due to other allo-antibody (Delayed &gt; 24 hrs)</td>
<td>Adult (51-70 years)</td>
<td>Female</td>
<td>Possible</td>
<td>Fall in Hb, DAT negative</td>
<td>Anti-K, Anti-Jk&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Group 2</td>
<td>Complete Recovery</td>
</tr>
<tr>
<td>4</td>
<td>Immunological haemolysis due to other allo-antibody (Delayed &gt; 24 hrs)</td>
<td>Elderly (70+)</td>
<td>Female</td>
<td>Probable</td>
<td>Fall in Hb jaundice, renal impairment</td>
<td>Anti-Jk&lt;sup&gt;b&lt;/sup&gt; Anti-Fy&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Group 4</td>
<td>Recovery</td>
</tr>
<tr>
<td>5</td>
<td>Immunological haemolysis due to other allo-antibody (Delayed &gt; 24 hrs)</td>
<td>Elderly (70+)</td>
<td>Female</td>
<td>Probable</td>
<td>Fall in Hb</td>
<td>Anti-JK&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Group 2</td>
<td>Complete Recovery</td>
</tr>
<tr>
<td>6</td>
<td>Immunological haemolysis due to other allo-antibody (Delayed &gt; 24 hrs)</td>
<td>Adult (18-30 years)</td>
<td>Female</td>
<td>Probable</td>
<td>DAT positive, jaundice, renal impairment on background of pre existing renal impairment</td>
<td>Anti-Jk&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Group 4</td>
<td>Recovery</td>
</tr>
</tbody>
</table>
Transfusion Related Acute Lung Injury (TRALI)

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

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

TRALI is characterised by the following
- Acute onset of symptoms
- Hypoxemia SpO₂ <90% on room air or other evidence of hypoxemia
- Bilateral infiltrates on frontal chest X-ray
- No evidence of circulatory overload
- No pre-existing acute lung injury (ALI) before transfusion or during or within six hours of transfusion
- No alternative risk factors for ALI present

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

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

EU Notification Category: TRALI

Donor Investigations

Although not part of the definition of TRALI which is a clinical one, the majority of cases of TRALI have been shown to be associated with components from donors who have developed Human Leucocyte Antigen (HLA) Class I or II or granulocyte antibodies as a result of pregnancies or transfusion which react with antigens present on the patient’s white cells. (Kopko and Popovsky 2007) HLA and granulocyte antibody testing is undertaken on female donors and male donors with a history of transfusion implicated in TRALI. Where the antibody in the donor has a specificity which reacts with an antigen present on the patient’s cells, this is consistent with a diagnosis of TRALI. Donors involved in a TRALI investigation who are found to have HLA or granulocyte antibodies are permanently deferred.

There were two initial reports received as TRALI. Following review, one case was recategorised as being due to the patients underlying condition and not due to transfusion. The second case was originally submitted as TRALI but was later re-classified as TACO (TACO Case History 18)

Transfusion Associated Circulatory Overload (TACO)

NHO Definition

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

EU Notification Category: Other TACO

FINDINGS (n=18)

There were 18 cases of TACO reported in 2007, accounting for 16% of reports of serious adverse reactions accepted by the NHO. Seventeen (17) cases were associated with components and reported as SAR under EU Directive 2005/61/EC. The majority of cases reported (72%) were attributed as “likely–probable” (imputability level 2) due to the transfusion.

The majority of cases were associated with red cell transfusion. One case was associated with SD plasma given to correct a mildly elevated INR pre procedure.
The age and gender of the patients implicated in these reports were as follows

**Table 23: Age/Gender of patients implicated in TACO reports 2007 n=18**

<table>
<thead>
<tr>
<th></th>
<th>Adolescent (12-17 years)</th>
<th>Adult (51-70 years)</th>
<th>Elderly (70+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>0</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>2</td>
<td>9</td>
</tr>
</tbody>
</table>

**Symptoms and underlying condition**
Symptoms of overload developed 15 minutes to 24 hours after transfusion with a median onset of 2.25 hours.

The most commonly reported symptoms are outlined in Table 24.

**Table 24: Most frequently occurring symptoms in TACO n=18**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>7</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>8</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>11</td>
</tr>
<tr>
<td>Falling O₂ Saturation</td>
<td>10</td>
</tr>
</tbody>
</table>

While dyspnoea was reported in 11 cases, a number of reports described patients experiencing a "choking sensation". Hypotension was reported in one case associated with massive haemorrhage. (Case History 18).

The draft ISBT definition of TACO is more restrictive than that accepted by the NHO. The ISBT definition requires any four of the following occurring within six hours of completion of transfusion:

- Acute or worsening pulmonary edema on frontal chest radiograph
- Evidence of positive fluid balance

It is interesting that only two reported cases met the necessary four out of the five ISBT criteria. Both cases had three of the four clinical criteria (tachycardia, hypertension and dyspnoea), and a chest x ray was reported in both cases. The failure to meet the ISBT criteria appears in part due to the fact that only 13 patients had a chest x-ray and only four had a completed fluid balance chart.

While symptoms developed under six hours in 16 (88%) cases there were two reports where symptoms developed at 10 and 24 hours respectively. Both were reassessed but considered to represent TACO rather than the alternative diagnosis of Transfusion Associated Dyspnoea (TAD)\(^1\).

**Underlying Condition**
Sixteen (88%) of the patients had complex underlying medical problems.

**Table 25: Underlying condition of patients who developed TACO n=16**

<table>
<thead>
<tr>
<th>Underlying condition</th>
<th>No of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>13</td>
</tr>
<tr>
<td>Respiratory</td>
<td>5</td>
</tr>
<tr>
<td>Renal</td>
<td>7</td>
</tr>
</tbody>
</table>

In seven cases, patients were reported as having more than one underlying condition and in four cases, patients were reported as having underlying cardiac, respiratory and renal conditions.

In two cases, blood was transfused too quickly with both patients receiving up to 300mls within 30-60 minutes contributing to the development of TACO. Neither were in the

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\(^1\) TAD a new ISBT reaction category is characterised by respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient’s underlying condition or any other known cause.
setting of massive transfusion; one of the cases involved a single red cell unit transfusion. The patients involved in these reactions were both elderly and both had significant underlying co-morbidities. One transfusion was administered in a clinical area, outside routine working hours and the second in theatre.

Another elderly female patient with underlying cardiac disease who weighed less than 40kgs developed symptoms of TACO following a transfusion of a single unit of red cells over four hours.

**KEY POINT**

Certain patients will always remain at risk of TACO. These include patients with underlying medical conditions or of low weight. These cases highlight the challenges of transfusing these patients. Careful medical assessment prior to the transfusion along with consideration for pre-transfusion diuretics and monitoring of at-risk patients is recommended.

**TACO in bleeding patients**

One case occurred in an adolescent female in a massive transfusion setting which had originally been submitted as a TRALI. Although TACO in young, previously healthy adults and adolescents is unusual, there have been four similar cases, all in females under age 30 years associated with massive transfusion reported to the NHO between 2000 and 2007.

**Case History 18 (TACO)**

The patient, an adolescent girl, who suffered a miscarriage had severe vaginal bleeding for two hours prior to admission to hospital. Her Hb shortly after admission was 10.6 g/dl. She received 3.7L of Hartmanns and 1L Gelofusion in the seven hours after admission prior to being brought to theatre for evacuation of retained products of conception. She was given four units of red cells (approx 1000-1100 mls) in theatre as her Hb was 5.4gms. Red cells were given over about 1-1.5 hours along with 500mls of Gelofusion.

On extubation, her O₂ saturations fell to 62% and she had bilateral infiltrates on chest X-ray. She was treated with frusemide 60mg, with a good diuresis of 3000mls within two hours. She was also put on Continuous Positive Pressure Ventilation (CPAP) and O₂ saturations recovered rapidly. CPAP was discontinued later in the evening but O₂ therapy was continued by face mask until the next morning.

Because of the possibility of TRALI, the two female donors were recalled and tested negative for HLA and granulocyte antibodies. The two male donors had no history of transfusion and were not further investigated. The patient did not have detectable HLA antibodies.

The retrospectively tested pro Brain Type Natriuretic Peptide (pro BNP) level on this patient pretransfusion was 11ng/l and the level taken 2 hours post transfusion was 124ng/l giving a pre/post transfusion BNP ratio of 11.2.

The overall clinical findings together with pre/post transfusion BNP ratio >1.5, rapid improvement with volume reduction (diuretics and positive pressure ventilation) are consistent with TACO rather than TRALI in line with the algorithm developed by Gajic et al (2006).

**Investigations and diagnosis**

Diagnosis of overload was based on chest x-ray investigation in 13 cases, and auscultation of patient’s chest in 11 cases. In one case, diagnosis was based on none of the above investigations, but was based on clinical assessment.

A completed fluid balance was maintained in only four cases reported and the patient’s weight was not reported in nine cases. Pro BNP results pre and post transfusion were only available in one case (Case History 17).

**Outcome of Transfusion**

In 94% (17) cases, patients made a complete recovery. Recovery time was reported between 40 minutes and 48 hours in 14 cases. In two cases, recovery was reported at five and ten days respectively. Both patients in these cases had an
underlying history of cardiac failure, and admission to a coronary care unit was required in both cases. The prolonged recovery time reflects discharge from the coronary care unit in both cases.

In one case (Case History 18) following a transfusion of red cells, the patient developed overload and required admission to the Intensive Care Unit (ICU) and subsequently died. This patient’s death was possibly attributed to transfusion.

**Case History 19 (TACO)**

A patient with congestive cardiac failure and anaemia was admitted to hospital for transfusion. The chest x-ray prior to transfusion had shown evidence of pulmonary oedema and she had received a diuretic prior to red cell transfusion. The nurses contacted the doctor when the patient developed severe symptoms of overload. The patient required admission to intensive care unit, and was administered O2 therapy and intravenous (IV) medication. A review of the case revealed the patient had not been prescribed an adequate dose of diuretic pre-transfusion. While a post transfusion diuretic had been prescribed, the dosage of diuretic was inadequate and was prescribed orally instead of intravenously. As the patient had become drowsy post transfusion, she was not able to take the diuretic. The death was considered by the reporting hospital as possibly associated with the transfusion.

**Reactions occurring in patients as a result of error**

This is the first year this data has been available, and notably in nine (50%) cases, TACO was reported to have occurred following error. Human error was cited as a cause of error in all nine cases. This included failure of the caregiver to adhere to policies/procedures, to monitor the patient correctly, to co-ordinate and communicate care, and also human slips, where a diuretic was not administered prior to transfusion.

In addition, system failure was noted as cause of error in one case, where the organisation culture was reported as a cause of error. In this case, the junior doctor admitting the patient failed to prescribe adequate diuretics for the patient. The reporting hospital felt that the organisation facilitated this error by poor clinical supervision practices for junior doctors.

**Recommendations**

- All patients, especially those at risk, should be assessed pre-transfusion to assess their risk of developing TACO. At risk patients are those of older age, low body weight, or may be physiologically compromised, e.g. history of cardiac, respiratory or renal insufficiency or chronic anaemia. These patients should be transfused slowly at a rate of 1 ml/kg/hour (Popovsky, 2001). Consideration should also be given to transfusion on a unit-by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component.

- Single unit transfusions can result in TACO and therefore should be monitored as closely as multiple unit transfusion. In very low weight/at risk patients, it may be advisable to transfuse units with an interval of 24 hours between each unit, in combination with pre-transfusion diuretics. Some patients take as long as 24 hours to readjust blood volume particularly in those patients whose venous pressure is raised pre-transfusion. (Mollison et al 1997)

- Clinical evaluation of pre and post transfusion fluid balance and pre and post transfusion-terminal pro BNP (NTproBNP) BNP levels may be helpful in differentiating TACO from TRALI (Zhou et al 2005).

- In the massive transfusion setting, sudden dyspnoea and falling O2 saturations are often taken as a sign of TRALI but should also prompt evaluation for evidence of circulatory overload particularly in young females.
Suspected Transfusion Transmitted Infection

The NHO collects and investigates reports of

- All suspected transfusion-transmitted viral infections relating to blood components which have been transfused after the introduction of mandatory testing for that virus.

- Viral infections not covered by mandatory testing, e.g. Hepatitis A virus, CMV and Parvovirus, but which are suspected to be associated with a blood transfusion.

- The NHO also collects and investigates reports of transfusion-transmitted bacterial and parasitic infections.

Infections presenting weeks, months or years after a transfusion are termed post-transfusion infections. Bacterial or parasitic infections are usually associated with acute symptoms and come to clinical attention soon after transfusion. Viral diseases, however, may not be associated with any symptoms until some years later. Therefore, reports received within this category are not necessarily the result of components transfused during this reporting year.

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

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

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

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

  or

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

Much concern has been voiced in recent years regarding the risk of transfusion-transmitted infection and much quality assurance effort has been directed towards appropriate testing and handling of blood after collection. There is very good evidence that with continuous improvements in the donor selection/testing procedures and manufacturing processes used in Ireland, the risk of transfusion-transmitted infection is very small.

The risk of receiving an incorrect blood component is in fact much greater than the risk of receiving a transfusion-transmitted infection. Over the eight year period since UK SHOT began reporting, confirmed reports of TTI accounted for 1.8% of incidents in comparison to reports in the IBCT category, which accounted for 70% (Stainsby et al 2006). A review of Suspected TTIs investigated by the NHO shows that STTIs accounted for 2.4% (37) of all reports investigated by the NHO in the eight years of reporting in Ireland. Only 0.3% (3 bacterial considered probable/possible and two HBV where donor investigations could not be completed) have been confirmed, in comparison to IBCT/SAE which accounted for 57.5% of reports.

Viral infections Risk of HIV and HCV

The current estimated risk for HIV and HCV is less than one per four million components transfused, (O’Riordan 2004 personal communication). These residual risk estimates are based on serological testing and nucleic acid amplification testing (NAT) for HCV and HIV.
Even prior to the introduction of NAT testing the risk for Hepatitis C for screened blood was 1:500,000 which is estimated to be less than the risk of infection from nosocominal sources. (Ross et al, 2000, Gerberding et al, 2003)

The risk for HBV has been estimated at approximately 1:200,000 since the introduction of testing for antibody to Hepatitis B core in January 2002 (O’Riordan, 2004, personal communication).

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

Bacterial Infection

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

A recall of a component by the IBTS due to a positive bacterial culture (Bactalert) where the patient has a reaction or is put on antibiotics is collected by the NHO as a possible transfusion transmitted infection (TTI).

Findings

Eight reports of infection were reported in 2007, three viral and five bacterial. On investigation four (three bacterial, one viral) did not progress. (DNP)

Viral infections

Of the three viral infections reported, all related to HCV. One of the three cases was in a child receiving shared care where a weak positive HCV antibody reaction was found post transfusion in one hospital and was reported to the NHO. Further investigation showed that the patient had had a similar reaction when tested in another hospital prior to transfusion. The result was considered a probable false positive result, unrelated to transfusion and not progressed.

The remaining two cases were in females. One with a history of multiple transfusions in 2000, involving 27 donors and the second in 2004 with a history of a transfusion of multiple components involving 14 donors (STTI Case 1)

Bacterial infections

Five bacterial infections were reported. In three cases, all involving platelets, the report was as a result of a report to the hospital from the IBTS of a positive bacterial culture screen (Bactalert) in a component which had been transfused to the patient. No reaction was reported in any of these three cases which were not progressed.

In one of these cases, although there was a positive culture in the platelet component and the patient also had an infection of a vascular graft, the organisms grown were different (STTI Case 5)

The other two cases (STTI Case 6 and 8) were investigated as a result of a febrile reaction in the patient. In STTI Case 6 bacterial infection was considered unlikely but possible and in STTI Case 8 different strains of the organism were found in the patient and the pack suggesting contamination during culture.
**Recommendations**

- Investigations into STTI are difficult. They can involve considerable upset to donors who often have to be recalled and offered testing and they are resource intensive.

- Where pre-transfusion samples are available, these samples can provide significant help in investigation. Patients such as haematology patients undergoing chemotherapy who will require ongoing transfusion should be offered testing before therapy and at regular intervals with storage of samples wherever possible for further testing if necessary. In these patients, virology screening for HBV should include anti-hepatitis B core and surface antibodies in addition to HBsAG as reactivation of HBV may occur as a result of chemotherapy leading to a possible poorer outcome for the patient (Lalazar et al. 2007), nosocomial infection risks and unnecessary donor investigations

- Patients likely to require ongoing transfusion should wherever possible be offered vaccination for HBV.

**Table 26: Suspected Transfusion Transmitted Infection Viral 2007 (n=3)**

<table>
<thead>
<tr>
<th>Case No</th>
<th>Date of Incident</th>
<th>Gender &amp; Age</th>
<th>Infectious Agent</th>
<th>Components</th>
<th>Donors Implicated</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>STTI Case 1</td>
<td>2004</td>
<td>F Adult</td>
<td>HCV</td>
<td>Red cells, SD Plasma, Cryoprecipitate</td>
<td>14</td>
<td>13 donors returned and retested HCV negative. One donor tested HCV negative on archive samples. TTI unlikely.</td>
</tr>
<tr>
<td>STTI Case 2</td>
<td>2007</td>
<td>F Child</td>
<td>HCV</td>
<td>Red cells</td>
<td>2</td>
<td>DNP. Review of patient showed only weak positive reaction and HCV results were similar both pre and post transfusion.</td>
</tr>
<tr>
<td>STTI Case 3</td>
<td>Prior to 2000</td>
<td>F Adult</td>
<td>HCV</td>
<td>Red cells, Blood Products Fresh Frozen Plasma (FFP)</td>
<td>27</td>
<td>26 donors returned and retested HCV negative. One donor tested HCV negative on archive samples. TTI unlikely.</td>
</tr>
</tbody>
</table>
### Table 27: Suspected Transfusion Transmitted Infection  Bacterial n= 5

<table>
<thead>
<tr>
<th>Case No</th>
<th>Gender &amp; Age</th>
<th>Components Implicated</th>
<th>Implicated Organisms</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>STTI Case 4</td>
<td>M</td>
<td>Pooled Platelets</td>
<td>Diptheroid</td>
<td>DNP. No reaction. No morbidity</td>
</tr>
<tr>
<td>STTI Case 5</td>
<td>M Adult</td>
<td>Pooled Platelets</td>
<td>Staphylococcus captitis (unconfirmed)</td>
<td>DNP. No reaction at time of BacT alert. Investigation showed different organism in platelet and patients graft.</td>
</tr>
<tr>
<td>STTI Case 6</td>
<td>M Elderly</td>
<td>Red Cells</td>
<td>Coagulase negative staphylococcus</td>
<td>Febrile reaction. Most likely a contaminant TTI unlikely but possible</td>
</tr>
<tr>
<td>STTI Case 7</td>
<td>F Elderly</td>
<td>Pooled Platelets</td>
<td>Kocuria varians</td>
<td>DNP. No reaction at time of BactAlert. Patient not commenced on any new treatment. No morbidity</td>
</tr>
<tr>
<td>STTI Case 8</td>
<td>M Adult</td>
<td>Red Cells</td>
<td>Staphylococcus hominis identified in both pack and patient.</td>
<td>Febrile reaction Further investigation showed different strains - a and b. TTI excluded.</td>
</tr>
</tbody>
</table>
**Paediatric Serious Adverse Reaction (n = 12)**

Twelve (11%) of 107 SAR reports occurred in paediatric patients. Some of these have already been highlighted in the separate reaction categories but for ease of reference have been summarised in this section. Six involved platelets, five involved red cells and one case involved granulocytes.

There were two FNHTR, nine AA reactions and one case of TACO. Four reactions occurred in young children (1-4 years); two of the reactions were in children (5-11 years) and six in adolescents (12-17 years). The case of overload which occurred in a 16 year old girl is described in the TACO chapter (Case History 18).

**Figure 13: Breakdown of Paediatric Reactions by age (n=12)**

**Table 20 Breakdown Paediatric SAR by Category (n=12)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Component</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA</td>
<td>Platelets</td>
<td>Young child (1-4 years)</td>
</tr>
<tr>
<td>AA</td>
<td>Platelets</td>
<td>Young child (1-4 years)</td>
</tr>
<tr>
<td>AA</td>
<td>Red blood cells</td>
<td>Young child (1-4 years)</td>
</tr>
<tr>
<td>AA</td>
<td>Red blood cells</td>
<td>Young child (1-4 years)</td>
</tr>
<tr>
<td>AA</td>
<td>Red blood cells</td>
<td>Child (5-11 years)</td>
</tr>
<tr>
<td>AA</td>
<td>Platelets</td>
<td>Child (5-11 years)</td>
</tr>
<tr>
<td>AA</td>
<td>Red blood cells</td>
<td>Adolescent</td>
</tr>
<tr>
<td>AA</td>
<td>Platelets</td>
<td>Adolescent</td>
</tr>
<tr>
<td>AA</td>
<td>Platelets</td>
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Acknowledgements

As always, the NHO is indebted to a number of people in compiling this report, and their support is acknowledged.

The NHO Team members who compiled individual chapters – IBCT/SAE and TACO, Ms. Marina Cronin, Paediatric & Factor Concentrates Ms. Jackie Sweeney, SAR, STTI, Anti D Ms. Roisin Brady and for general document formatting and editing prior to printing, Ms. Cathy Scuffil.

Dr. Joan Fitzgerald for the Anti-D section and her contribution to the overall content and style of the report.

Dr. Joan O’Riordan for her general advice, particularly on the STTI chapter and on neonatal issues.

Mr. Don Mullahy and Mr. John Crumlish for their continued advice on laboratory and serological issues.

The NHO also thanks:
Dr. Joan Power, Dr. Nuala Moore and Dr. Michael Thomas of the Munster Regional Transfusion Centre (MRTC), Ms. Mirenda O’Donovan, Communications Officer, Mr. Peter McDonnell, Training Officer, Ms. Niamh O’Sullivan, Ms. Lucy O’Doherty, Ms. Janet Kelleher, Mr. Martin Cusack of Library Services, Ms. Deirdre Farrelly and Ms. Louise Owens of the IBTS IT Department.

Bernie Quirke and the staff of the Virology Laboratory, Ms. Carmel Sheridan, Recipient Tracing Unit, Ms. Pauline Coakley, Quality Assurance (QA) Manager IBTS, Ms. Marie O’Connell Director of Quality, IBTS and Mr. Jeff Connell and staff of the National Virus Reference Laboratory (NVRL), University College, Dublin for their assistance in suspected transfusion transmitted donor investigations.

Ciaran Dunne and the staff of the National Histocompatibility and Immunogenetics Reference Laboratory of the IBTS and Mr. Geoff Lucas and staff at the International, Blood Group Reference Laboratory, National Blood Group Reference Laboratory, National Blood Service (NBS), Bristol United Kingdom (UK) for their help in the investigation of donors involved in TRALI.

We also thank Ms. Ann Duffy, Clinical Risk Advisor, Clinical Indemnity Scheme for her advice with aspects of the IBCT chapter.
References

British Committee for Standards in Haematology, British Transfusion Taskforce, (1999) The administration of blood and blood components and the management of transfused patients, Transfusion Medicine, 9 (3), 227-38


Appendix 1
Management of an Acute Transfusion reaction

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

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

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

- **Febril non haemolytic reaction**
  Temperature rise > 1.50°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 (5.00 micrograms) IM into anterior aspect of naid 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 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 and seek expert haematological/medical advice.

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

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

Seek Haematological advice where severe acute reactions occur.
Appendix 2

This table provides a breakdown of SAR and SAE incidents in 2007 compared to previous years.

#### Breakdown of NHO incidents (2000-2007) n= 1570

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Since the NHO Report 2006, incidents formerly reported as Acute Haemolytic or Other Severe Transfusion Reactions (AHOSTR) have been recategorised as Acute Transfusion Reactions to include Acute Haemolytic and Febrile Non Haemolytic Transfusion Reactions. Severe Acute Anaphylactoid/Anaphylactic Reactions (AA) reports, although described in the ATR section of this Report continue to be collected as AA by the NHO as in previous years.