

# NHO

## REPORT

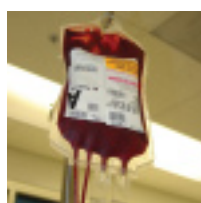
### 2008/2009





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# List of Abbreviations

AA	Severe Acute Allergic/Anaphylactic Reaction	ISO	International Standards Organisation
AABB	American Association of Blood Banks	IT	Information Technology
A&E	Accident and Emergency	IU	International Units
AGREE	Appraisal of Guidelines Research and Evaluation	IV	Intravenous
ALI	Acute Lung Injury	LDH	Lactic dehydrogenase
AML BB	Minimum Requirements for Blood Bank Compliance with Article 14 & Article 15 of EU Directive 2002/98/EC	LIS	Laboratory Information Systems
ANSARE	Annual Notification of Serious Adverse Reactions and Events	MERS-TM	Medical Event Reporting System for Transfusion Medicine.
AHTR	Acute Haemolytic Transfusion Reaction	MRTC	Munster Regional Transfusion Centre
APTT	Activated Partial Thromboplastin Time	NBC	National Blood Centre
ATR	Acute Transfusion Reaction	NBUG	National Blood Users Group
BBTN	Better Blood Transfusion network	NCHCD	National Centre for Hereditary Coagulation Disorders
BCSH	British Committee for Standards in Haematology	NHO	National Haemovigilance Office
BNP	Brain Naturetic Peptide	NI	Northern Ireland
CFC	Chlorofluorocarbon	NICE	National Institute for Clinical Excellence
CIS	Clinical Indemnity Scheme	NPSA	National Patient Safety Agency
CMV	Cytomegalovirus	NTproBNP	N Terminal pro Brain Natriuretic Peptide
CPAP	Continuous Positive Pressure Ventilation	O <sub>2</sub>	Oxygen
DAT	Direct Antiglobulin Test	OGD	Oesophago-Gastro-Duodenoscopy
DCU	Dublin City University	ORAS Gold-TM	Online Recording and Assessment System
DDAVP	DESMOPRESSIN (1-deamino-8-D-arginine vasopressin)	PAD	Pre-deposit Autologous Donation
DHTR	Delayed Haemolytic Transfusion Reaction	PAS	Platelet Additive Solution
DNP	Did Not Progress	PCC	Prothrombin Complex Concentrate
DOHC	Department of Health and Children	PR	Per rectum
DU	Duodenal Ulcer	PTP	Post Transfusion Purpura
EC	European Community (Commission)	PV	Per vagina
ECG	Electrocardiograph	RAADP	Routine Antenatal Anti-D Prophylaxis
EU	European Union	RCA	Root Cause Analysis
EUB	Effective use of blood	RCC	Red Cell Concentrate
F	Female	RR	Respiratory Rate
FFP	Fresh Frozen Plasma	RhD	Rhesus D
FNHTR	Febrile non-Haemolytic Transfusion Reaction	SAE	Serious Adverse Event
Hb	Haemoglobin	SAR	Serious Adverse Reaction
HBB	Hospital Blood Bank	SNBTS	Scottish National Blood Transfusion Service
HBV	Hepatitis B Virus	SD	Solvent Detergent
HCV	Hepatitis C Virus	SHO	Senior House Officer
HIQA	Health Information and Quality Authority	SHOT	Serious Hazards of Transfusion UK
HLA	Human Leucocyte Antibody	SI	Statutory Instrument
HTC	Hospital Transfusion Committee	SOP	Standard Operating Procedure
HVO	Haemovigilance Officer	STTI	Suspected Transfusion Transmitted Infection
IBCT	Incorrect Blood Component Transfused	TACO	Transfusion Associated Circulatory Overload
IBGRL	International Blood Group Reference Laboratory	TAD	Transfusion Associated Dyspnoea
IBTS	Irish Blood Transfusion Service	TA-GvHD	Transfusion Associated Graft-versus-Host Disease
ICU	Intensive Care Unit	TRALI	Transfusion Related Acute Lung Injury
IgA	Immunoglobulin A	TTI	Transfusion Transmitted Infection
IMB	Irish Medicines Board	UK	United Kingdom
INAB	Irish National Accreditation Board	UHI	Unique hospital identifier
INR	International Normalised Ratio	UTI	Urinary Tract Infection
ISBT	International Society of Blood Transfusion	vCJD	variant Creutzfeldt Jacob Disease
		WNV	West Nile Virus

# Introduction

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This year, the National Haemovigilance Office (NHO) had decided to produce a combined Annual Report to cover two years, 2008 and 2009, to complete ten full years of reporting of transfusion associated severe adverse events and reactions in Ireland.

Haemovigilance plays an essential role in developing safe clinical transfusion practice. The total number of reports received including those that 'did not progress' in 2008 was 375 and in 2009 was 314. This represents an increase of 26% and 6% on 2007 figures suggesting that reporting levels, which had fallen in 2007 probably associated with the focus on traceability and accreditation efforts, are back to 2006 figures. However in both years the number of reports of clinical adverse events is still markedly down on 2006. Reduction in reports may reflect changes in what is reportable (the NHO no longer accepts low level risk reports) but most likely reflects the continuing emphasis on laboratory errors and traceability at the expense of the clinical area.

The number of unnecessary transfusions reported since the European Union (EU) Directive reporting requirements, which focus on the quality and safety of the blood component and not on the clinical use of the component, has fallen by almost 50% since 2006. This may reflect improved clinical practice and increasing adherence to the 2001 National Blood Users Group (NBUG) guidelines for blood for surgical use, but it would be unwise to be complacent, as the unnecessary transfusions reported for haematinic deficiency in medical patients in 2008 in this report suggest a need to monitor blood use more carefully in medical patients. Although the risks of transmission of the known viruses of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) through blood transfusion is extremely low due to the vigorous testing regimes in place, avoidance of unnecessary blood transfusion remains the prime safety measure and this is enforced by potential new transfusion risks such as variant Creutzfeldt Jakob Disease (vCJD) and with the threat of

global warming, West Nile Virus (WNV) and Dengue Fever. It is recommended that key learning points highlighted in this Report be included as agenda items at Hospital Transfusion Committees (HTC) meetings.

Following the implementation of the EU Directive 2002/98/EC and European Commission (EC) Directive 2005/61/EC, the Haemovigilance Handbook has been available through the Irish Blood Transfusion Service (IBTS) website – [www.giveblood.ie](http://www.giveblood.ie). This document, jointly developed by the NHO and the Irish Medicines Board (IMB), aids consistent reporting and is updated with clarifications from the EC Working Group on Serious Adverse Events and Reactions – Blood and Blood Components.

The NHO acknowledges the support of a number of Health Care disciplines in its daily operations, especially the continued efforts of Haemovigilance Officers (HVO), Medical Laboratory Scientists and Consultant Haematologists/Pathologists. The advice of the Director of Human Medicines and the staff of the IMB – the Competent Authority is particularly acknowledged, as is the expertise of the staff of the IMB's Compliance and Pharmacovigilance Departments. The ongoing efforts of the Mr. Andrew Kelly, IBTS Chief Executive and Dr. William Murphy, Medical and Scientific Director and the staff of the IBTS in continuing to recruit voluntary blood donors and in developing increasingly higher standards in blood processing and distribution are the basis of the national Haemovigilance scheme.

We hope that you find this combined NHO Annual Report for 2008 and 2009 useful in your practice. Each year's events are described separately. In compliance with the Official Languages Act 2003 copies of this document are also made available in the Irish language. We welcome comments and feedback.

Dr. Emer Lawlor, Director, NHO

# National Haemovigilance Office

“Haemovigilance shall mean a set of organised and surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients and the epidemiological follow-up of donors” (EC Directive 2002/98/EC)

The NHO was established in 1999 within the IBTS 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. 2009 marked the 10th Anniversary of Haemovigilance in Ireland.

The 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 on the 8th of 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/incorrect blood component transfused (IBCT) to the NHO remains part of professional responsibility. Section 29.2 of the 7th Edition of the Medical Council Guide to the Professional Conduct and Ethics for Registered Medical Practitioner mandates reporting of any serious adverse event that harmed a patient (Medical Council, 2009).

The revised 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 and events 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 the audit function of hospitals in relation to transfusion practice.
- Promote the development of fully traceable transfusion records at hospital level.
- Report to the NBUG 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 Street, Dublin 8 and functions under the directorship of a Consultant Haematologist with four and half whole time equivalent HVOs, a Programme Administrator and Assistant Administrator. During 2009, the staffing levels of the NHO were reduced due to the Public Service recruitment embargo and the NHO lost the support of its Assistant Administrator. Ms. Marcia Kirwan, HVO transferred to Dublin City University (DCU) to follow a PhD programme.

## Definitions 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 or
- 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](http://www.giveblood.ie)

### **Irish Medicines Board**

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 2008 and 2009 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.

### **Haemovigilance Modules at DCU**

Since 2005 the NHO has addressed its education remit by providing, in partnership with the School of Nursing DCU, two five credit level 8 (degree) multidisciplinary professional development modules in Haemovigilance. Over the three year period (to 2008) 139 students have successfully completed these modules. In 2008-09, 73 students completed modules. While the modules were successful and positively evaluated, the feedback revealed a demand for professional development which will enable career progression for participants.

Following on from this feedback, an approach to DCU identified potential module developments. The NHO established a Curriculum Development Committee including representatives from both donation and transfusion practice and from education. This group focused on planning, development and delivery of education to meet needs of donation and transfusion practitioners. The objective of this process was to improve the breadth and depth of the available modules

This collaborative process has delivered a broader choice of programmes aimed at practitioners in both donation and transfusion services, from both nursing and scientific backgrounds.

The updated programme now encompasses three ten credit degree level modules:

- Blood donation and transfusion
- Haemovigilance practice
- Professional development for specialist practitioners.

Additionally resulting from this collaborative process was the development of two ten credit level 9 (post-graduate) modules. These modules can be taken as stand alone professional development modules or as optional modules along with four core modules to attain a Graduate Diploma in Nursing Practice/Health Care Practice. Students can proceed to complete a thesis in this area and achieve an MSc in Nursing /Health Care Practice (Haemovigilance). These modules are as follows:

- Advancing Transfusion Practice
- Developing a Quality Haemovigilance Service

Currently students are completing these modules. These practice based modules require support from hospital and transfusion services. The NHO and School of Nursing at DCU acknowledge the contribution of haemovigilance and specialist services at St. James's Hospital, Our Ladys Childrens Hospital Crumlin and the Irish Blood Transfusion Service. These developments deliver a recognised pathway for transfusion practitioners to develop their roles to specialist and advanced level. The NHO are currently reviewing these courses.

### **Scientific Meetings**

#### **NHO Annual Conference 2008**

The 7th NHO and IBTS Conference

"Haemovigilance-Supporting Quality Transfusion Practice" was held in the Castletroy Park Hotel, Limerick on the 14th & 15th October 2008.

A Root Cause Analysis workshop organised by the NHO and the Clinical Indemnity Scheme (CIS), examining ways of applying Root Cause Analysis (RCA) techniques to errors when reporting was held on the afternoon of 14th October, 2008. The workshop was delivered by Ms. Ann Duffy and Ms.



Ann-Marie Oglesby (Clinical Risk Advisors, CIS), through a series of interesting presentations and group work. Seventy people attended, primarily hospital based HVO, and the event was very successful with good participation and very favourable feedback. The NHO thanks CIS for facilitating this event.

The main conference covered a range of topics which generated much interest and lively discussion during the different question and answer sessions, chaired by Dr. Maeve Leahy, Consultant Haematologist, Mid-Western Regional Hospital Limerick, Ms. Antoinette English, HVO, St. John's Hospital Limerick and Ms. Mary O'Riordan, HVO Kerry General Hospital.

The key note speakers were Dr. Jonathon Wallis, Consultant Haematologist, Freeman Hospital, Newcastle United Kingdom (UK) who presented on Electronic Crossmatch and Mr. Tony Davies of the UK National Blood Service/Serious Hazards of Transfusion (SHOT) on Risks of Transfusion in Paediatrics, Lessons to be Learned. Other clinical presentations included Massive Transfusion Guidelines by Dr. Joan O'Riordan Consultant Haematologist, IBTS, Anti-D Guidelines, Dr. Joan Fitzgerald, Consultant Haematologist, IBTS and Respiratory Complications of Blood Transfusion, Dr. Emer Lawlor, Director, NHO.

Regulatory topics included presentations on Serious Adverse Reactions and Serious Adverse Events from the 2007 NHO Annual Report by Ms. Roisin Brady and Ms. Jackie Sweeney, NHO, Serious Adverse Events (Laboratory Errors) by Ms. Sheila Joyce Chief Medical Scientist Mid-Western Regional Hospital Limerick and Traceability – Findings from a 'Bag and Tag' trial at Munster Regional Transfusion Centre (MRTC) by Dr. Joan Power Regional Director MRTC, IBTS and an Update on Regulatory Requirements was given by Ms. Marie O'Mahony, Irish National Accreditation Board (INAB)

Presentations on educational initiatives undertaken by NHO included Advances in Haemovigilance Education in Ireland, by Ms. Marcia Kirwan (NHO) summarising the partnership project running since 2005 between DCU and the IBTS, including exciting new initiatives for the future, such as post-graduate opportunities (level 9) leading to the MSc in Healthcare/Nursing Practice. Ms. Marina Cronin's (NHO) presentation entitled

Competencies for Hospital Based HVO, described the assessment framework developed in collaboration with hospital based HVO.

A Poster Competition was also held, in conjunction with the NHO Annual Conference, giving hospital HVOs an opportunity to showcase their work. Mr. Andrew Kelly, IBTS Chief Executive (CE) presented the prize and commended the high standard of posters displayed. The winning entry 'Positive Patient Identification' was submitted by Ms. Geraldine Peelo and Ms. Nora O'Mahony in Naas General Hospital illustrating the work of the hospital interdisciplinary Positive Patient Identification Committee towards standardising the identity band and achieve hospitalwide cultural change in relation to positive patient identification.

### **NHO 10th Anniversary Conference (2009)**

The NHO 10th Anniversary Conference "Haemovigilance in Ireland -The First Decade – Promoting safety in Transfusion" was held in the Royal Hospital Kilmainham on Monday 5th October 2009. The Minister for Health and Children, Ms. Mary Harney was welcomed by Mr. Andrew Kelly IBTS CE and invited to officially open the event. Her speech highlighted the impact of the clinical and regulatory role of the NHO on both transfusion and patient safety, whilst congratulating all present on their contribution to the development of haemovigilance in Ireland over the past ten years.

The conference covered a range of topics, generating interest and discussion during the various question and answer sessions, chaired by Prof John Bonnar, Dr. Joan O'Riordan, Dr. Joan Power and Dr. Stefan Laspina, who also presented on Haemovigilance in Malta. The key speakers on aspects of patient safety were Dr. Tony Holohan Chief Medical Officer (CMO) Department of Health and Children (DOHC), - Patient Safety in Ireland - and Dr. Clare Taylor, Medical Director UK SHOT who presented on Haemovigilance and the Junior Doctor. Other presentations included Audit of current red cell transfusion practice in Northern Ireland Dr. Kieran Morris, Deputy Director Northern Ireland Blood Transfusion Service (NIBTS) and Blood Transfusion – the next 10 years by Dr. William Murphy, Medical and Scientific Director IBTS. The legal perspective was supplied by Dr. Kieran Doran, Senior Lecturer in Law, University College Cork who presented on consent. Other speakers Ms. Joan Jones, (Wales) Dr. Ellen

McSweeney, (IBTS) Dr. Patrick Hayden (Galway University Hospital) Ms. Gretta Boyle (HVO Connolly Hospital) focused on developing aspects of haemovigilance and the NHO team, Dr. Lawlor, Marina Cronin, Roisin Brady and John Crumlish (IBTS) presented a breakdown of the haemovigilance reports submitted for 2008.

Dr. Emer Lawlor, NHO Director when presenting the prize, commended the high standard of posters displayed. The winning entry 'Apheresis versus Pooled Platelets' was submitted by Ms. Anne Thompson and the Haemovigilance Team in Our Lady's Children's Hospital Crumlin which set out details of an audit undertaken to identify and compare the number of reactions caused by Pooled and Apheresis platelets over a four and a half year period. The results showed a decreased reaction rate to pooled platelets since the IBTS introduced Platelet Additive Solution (PAS) in July 2007.

The event attracted in excess of 190 delegates drawn from medical, nursing and scientific backgrounds throughout Ireland and abroad. From the evaluations, comments and feedback received, all attending enjoyed the event.

Both years there was a general consensus that this was an excellent opportunity to meet like-minded colleagues and develop network contacts with others working in the area of haemovigilance. Some of the suggestions received will help with the design of the programme for future conferences and IBTS Hospital Liaison Days.

The NHO team wishes to thank all involved in making arrangements for the conferences and for their assistance during the event. We especially thank those working within the Haemovigilance network who promoted the event with their colleagues. Those who contributed their time and effort in chairing sessions and who presented are especially acknowledged. The support and co-operation of the management and staff at our two venues, the Castletroy Park Hotel, Limerick and the Royal Hospital Kilmainham, Dublin is also acknowledged.

### **Presentations at International meetings EHS 2008**

The European Haemovigilance Seminar (EHS) was held in Frankfurt in 2008 and Dr. Lawlor was

invited to present at this event on Over Transfusion and a poster was submitted to EHS entitled 'An exploration of reported Transfusion Associated Circulatory Overload (TACO) and Transfusion Related Acute Lung Injury (TRALI) in Ireland 2000-2006' presenting an analysis of TACO and TRALI cases received by the NHO over a six year period. This confirmed that the reported incidence of TACO is up to 20 times more common than TRALI. The poster also highlighted the series of measures taken by the IBTS to reduce the risk of TRALI.

In 2008, M. Cronin presented a paper on evidence based practice at the British Blood Transfusion Service Apheresis and Blood collection Special Interest Group in Manchester.

In May 2008, the Society of Blood Transfusion in Spain invited the NHO to present at the National Congress on hospital based haemovigilance. M. Cronin presented a paper in Cadiz in Spain.

**EHS 2009** was held in Rome and Ms. Jackie Sweeney was invited to give an oral presentation on her abstract the 'Annual Notification of Serious Adverse Reactions and Events (ANSARE) Ireland 2006-2007' co-authored by Ms. Roisin Brady, Ms. Marina Cronin, Ms. Marcia Kirwan and Dr. Emer Lawlor. The key finding from this research showed that reports collected on ANSARE accounted for 285 (54%) of the total 525 (46%) reports analysed by the NHO for this reporting period, for just over half of the total number of reports received, and underestimate the overall rate of reporting as they do not cover clinical errors.

### **ASH 2009**

A poster entitled 'Incidents and Relevant Aspects of Transfusion Associated Circulatory Overload' co-authored by Dr. Andrea Piccin, Ms. Marina Cronin, Mr. Ciaran Murphy, Ms. Elva Eakins and Dr. Emer Lawlor was displayed at the annual American Society of Haematology (ASH) meeting held in New Orleans in December 2009.

The SHOT UK meeting was held in London in 2009, and Ms. Marina Cronin, Ms. Kathleen Heery and Dr. Emer Lawlor represented the NHO.

A poster entitled 'Education opportunities for blood donation and transfusion practitioners' presented a summary of the educational developments achieved by the NHO in DCU.

### **Open Days and IBTS crossmatch Service**

All newly appointed HVO are invited to the NHO Open Day where the workings of the NHO are explained, with particular emphasis placed on reactions and event reporting. One was arranged in 2008 at which 22 people attended and another was held in 2009 at which 14 people attended. Nationwide networking among HVO is also promoted through regular telephone/email communication and personal visits.

During 2008, new arrangements were put in place to facilitate the electronic completion of the ANSARE forms. HVOs were provided with an opportunity to attend an information and training session, arranged by the NHO and facilitated by the IBTS Information Technology (IT) Department. The purpose of this session was to familiarise HVOs with these arrangements and encourage participation with the new system. This system was continued in 2009, with all but five hospitals availing of this facility.

### **E Learning Programme**

The E Learning programme in blood transfusion practice was developed by the Effective Use of Blood (EUB) Group of the Scottish National Blood Transfusion Service (SNBTS). The programme consists of three levels, with an additional module for those working in the blood transfusion laboratory. It is aimed at practitioners working in transfusion practice and permits those unable to attend formal training sessions, to take part in continuing education in blood transfusion practice as well as enhancing face-to-face educational sessions.

In 2008 the programme platform moved from the ORAS™ Gold to the LearnproNHS site hosted by Learnpro Ltd. Access to the site is funded by the IBTS. The NHO is part of the editorial group of the continuing education programme of the Better Blood Transfusion for E Learning which reviews the programme content.

Following the successful pilot project, the results and strategy for national roll-out were presented at a one day event in June 2008 at the NBC. National implementation of the programme began in autumn 2008 and continued through 2009. During roll-out, key stakeholders were identified at each hospital as well as a programme administrator (in most cases the hospital HVO) to implement the project. Each administrator was

provided with training material and invited to attend a one-day training session to assist them in rolling out the programme.

In the latter part of 2008, three E-Learning training days were held as part of the programme expansion. Seventeen representatives from sixteen hospitals attended for training. The programme was extended to more hospitals during 2009.

### **Working Parties**

The Better Blood Transfusion Network (BBTN) 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. Dr. Emer Lawlor, Ms. Marcia Kirwan and Ms. Marina Cronin represented the NHO and IBTS during 2008 with Ms. Marina Cronin also attending meetings held in 2009. There were three meetings held during 2008 in Edinburgh, Dublin and Cardiff and a further three held during 2009 in Bristol, Edinburgh and in Dublin during the 10th Anniversary NHO celebrations.

Ms. Jackie Sweeney represented Dr. Lawlor at an EU Working Group Meeting on Serious Adverse Events and Reactions, co-ordinated under the Commission of the EC. Ms. Donna Harkin of the Irish Medicines Board also attended this meeting. This meeting was convened to discuss the first version of the common approach document which aimed to reach a consensus on the annual report of Serious Adverse Events and Reactions.

### **NHO News**

The information newsletter NHO News is circulated to HVOs to provide an informal forum to report initiatives from the NHO and individual hospitals, including local education and training events that may be of interest to other HVOs. Details and events of national and international interest are also reported. During 2008, three editions of the newsletter were issued and during 2009, one edition was issued.

Information on haemovigilance can be directly assessed on the IBTS website at [www.giveblood.ie](http://www.giveblood.ie) (Clinical Services–Haemovigilance).

# IBCT /SAE Key Points and Recommendations for 2008 - 2009

## General Recommendations

- Reporting of both mandatory and non mandatory events make important contributions to patient safety and attention needs to be refocused on the clinical areas of blood transfusion not covered by the EU Directive.
  - The reduction in reports from clinical areas probably reflects the emphasis on the requirements of laboratory accreditation and mandatory SAE reporting. However, the slight increase in reporting from the clinical area in 2009 is encouraging.
- The role of the bed side check as the last barrier to prevent transfusion errors must be highlighted to clinical staff. Several incidents reported could have been detected during the pre-transfusion check. Failure to do so raises concerns as to the attention paid to this critical step, and highlights the importance of continuous education programmes for clinical staff involved in blood transfusion practice.

## Training and education

- Ensuring training of staff especially medical staff is difficult. Implementation of a standardised transfusion programme for undergraduate medical students should ensure emerging clinicians will have an understanding of safe transfusion practice.
- Ongoing hospital based education delivered by HVOs, Consultant Haematologist and senior medical scientists is also critically important to integrate theory and safe practice. Initiatives such as audit, provision of feedback, presentations or acting as a "clinical /laboratory" presence by the Consultant Haematologist, hospital HVO and senior medical scientists in the hospital blood bank (HBB) are important in raising the profile of safe transfusion practice.
- Hospital Blood Banks should ensure that as required by ISO 15189 there is adequate training and competency assessment of staff, particularly staff who do not routinely work in transfusion.

## Learning from Errors

- Adverse event review and reporting is a very powerful way of organised learning in organisations in general and also in transfusion services. The information gained from the identification and analysis of adverse events will enable the identification of gaps in the transfusion service and perhaps other services in the hospital which require attention. This data can be used to identify trends and patterns of events which reoccur and have potential to cause harm to patients, and facilitate development of appropriate strategies to enhance patient safety (Commission on Patient Safety and Quality Assurance, 2008).
- Use of a formal root cause analysis protocol will ensure a systematic, comprehensive and efficient investigation, and will outrule the potential of simplistic explanations and routine assignment of blame.
- The NHO has worked with the clinical risk advisors in the Clinical Indemnity Scheme (CIS) to ensure all haemovigilance staff receives system analysis/RCA training. Furthermore the implementation of the recommendations of the patient safety commission will include a national roll out of an agreed approach to systems analysis to all health care organisations.

## Changes to practice/Follow up action

- Introduction of a change should include development of policies to support practice change, informing all relevant stake holders and provision of training to ensure that the information on change is disseminated and acted on.
- Haemovigilance and transfusion services should monitor these changes not only to evaluate the impact of the change in terms of transfusion service, but the potential to impact on other hospital services. This follow-up monitoring is crucial to ensure ongoing learning and improvement and is characteristic of a quality service.

### **Unnecessary transfusions**

- Underlying anaemia has been recognised as a cause of unnecessary transfusion and increased morbidity in patients undergoing elective surgery. A recent publication by the Network of Advancement of Transfusion Alternatives (Goodnough et al, 2010) made recommendations on detection, evaluation and management of pre-operative anaemia.
- Where several units are prescribed for transfusion, patients Hb should be checked between units. This will minimise risk of unnecessary/over transfusion.

### **Unnecessary Transfusion in nutritional anaemia**

- Each year, the NHO receives a number of reports of unnecessary red cell transfusion in patients with iron deficiency anaemia, and this is likely to represent significant under reporting.
- Asymptomatic patients with iron deficiency anaemia should be treated with iron therapy. Oral iron should be continued for at least three months after deficiency has been corrected so that iron stores are replenished. Ascorbic acid may enhance iron absorption.
- Intravenous iron preparations should be considered in cases where patients have either poor tolerance of oral preparations or there are compliance issues. It normalizes haemoglobin faster and more reliably than oral iron.
- Patients with megaloblastic anaemia respond very rapidly to vitamin B12 / folate and very rarely require transfusion.

### **Unnecessary transfusion due to failure of knowledge or lack of communication**

- Platelets should be given within one to two hours prior to a procedure, allowing for measurement of post transfusion values.
- Clinical teams caring for patients should communicate with the HBB to ensure patients do not receive blood components unnecessarily where procedures have to be cancelled or postponed.

### **Unnecessary Transfusion due to incorrect results**

- Laboratories should ensure that validated results are available to clinical areas in a timely manner to minimise the potential for unnecessary transfusion due to a delay in posting current haematology results or where posted results were not validated on the laboratory computer system (LIS).

### **Near Patient testing**

- Near patient testing may be necessary in emergency settings. Where this is used, maintenance and validation of equipment as well as ongoing training and competency of clinical staff must be ensured. Hb results leading to transfusion should be checked in the laboratory at a later stage.

### **Selection of Components**

#### **Caution crossing ABO groups in plasma rich components**

- Although Group O donors are considered 'universal' donors of red cells, Group O platelets have anti-A and anti-B in the suspending plasma which can cause haemolysis in A, B or AB patients even if tests for high titre haemolysins are negative.
- Group O apheresis platelets should only be used for Group O patients. Group O pooled platelets which are suspended in platelet additive solution are less likely to be associated with haemolysis if they have to be used for Group A or B patients where the patient's correct group cannot be provided as they have reduced amounts of plasma.
- Patients whose blood group is AB can be transfused with A or B red cells, but plasma components which contain anti A or B should be avoided.

### **Transfusion of antigen incompatible red cells**

- Patients who have had previous pregnancies or transfusions are at risk of developing antibodies. There should be robust systems to detect and reconcile patients' previous



histories and transfusion records. Very often the HBB can be unaware of patients' history and the potential for antigen incompatible transfusions can be high. Hospitals should have policies covering the transmission of a patient's antibody/transfusion history and special requirements when a patient is transferred to another hospital.

- Where reports of investigations are received from the reference centre indicating the presence of antibodies, HBB staff should check these against the patient's current transfusion needs, or in the case of an infant, the mother's antibody history, to ensure antigen negative blood is provided.
- Development of a national register of patients with antibodies would reduce the risks of transfusing antigen incompatible cells to these patients.

The UK Transfusion Collaborative (Chaffe et al, 2009) has recommended that the staffing levels and skill mix should be adequate to ensure the safe and effective delivery of routine and emergency services during all work periods.

### ***Transfusion of incorrectly stored units***

- Best practice guidelines indicate that a patient's status should be checked prior to bringing a unit of blood to the bed-side. Adherence to these guidelines will minimise the risk of transfusing units which have been out of controlled storage for too long and potential wastage of a scarce resource.

### ***Paediatric Practice***

- Almost 21% of all reports of IBCT/SAE in 2008 and 2009 related to paediatric patients.
  - Analysis of IBCT/SAE for both years in terms of potential to cause harm to patients showed that a majority of reported IBCT/SAE had high potential to cause harm in paediatric patients when compared with reports in the adult population, thereby highlighting risk to paediatric patients receiving transfusions.
- Where care is shared between hospitals, there should be policies in place indicating the procedure to follow for patients with special transfusion requirements.
- Paediatric patients are long term survivors of transfusion therapy. It is important that both clinical and laboratory practitioners working in paediatric centres continuously seek to minimise donor exposure for these patients.
- Several of the paediatric SAEs were associated with on-call scientists with a busy workload.

# SAR Key Points and Recommendations for 2008- 2009

## **Acute Non Hemolytic Transfusion Reactions (FNHTR ,AA)**

- Whenever possible, as a minimum, blood cultures and investigations for haemolysis should be taken on patients suffering a Febrile Non Haemolytic Transfusion Reaction (FNHTR) to exclude red cell incompatibility or bacterial contamination.
- Reaction Alerts in patient charts and/or on the hospital patient admittance system and IT system can be valuable in those patients with a previous Anaphylaxis/hypersensitivity (AA) or FNHTR reaction to ensure appropriate component selection and pre medication prior to future transfusions.

## **AHTR ( Acute Haemolytic Transfusion Reactions)**

- In an emergency it may be necessary to issue least incompatible blood for a patient but samples should also be sent to a reference laboratory for investigation and identification of the antibody and to ensure a supply of suitable compatible units for ongoing transfusion

## **Delayed Haemolytic Transfusion Reactions (DHTR)**

- It is likely that Delayed Haemolytic Transfusion Reaction (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, Lactic dehydrogenase (LDH), Direct Antiglobulin Test (DAT) and antibody screen) to exclude DHTR. In a number of the reports of DHTR in 2008 and 2009 the investigation was incomplete. The successful diagnosis also depends on accurate history taking and the eliciting of a history of recent transfusion.
- There should be robust systems /policies to detect and reconcile patients' previous histories and transfusion records. If a patient is transferred to another hospital, their antibody/transfusion history should be transmitted to the receiving hospital. This is supported by the recently published draft

National Standards for safer better health care document (HIQA 2010 ) which states that service providers share necessary information to facilitate the transfer or sharing of care in a timely and appropriate manner

- Patients who have had previous pregnancies or transfusions are at risk of developing antibodies. Very often the HBB can be unaware of patients' history and the potential for antigen incompatible transfusions can be high. Development of a national antibody register could address this risk by ensuring access to patients' antibody history. It would also reduce the requirement for repeat laboratory testing.
  - This would only be feasible with the implementation of a national UHI, a recommendation made by the HIQA (2009) and supported by the NHO. A UHI would facilitate improved and safer access to patients' records on a national antibody register thereby ensuring safer transfusion practice for patients.

## **Transfusion Associated Circulatory Overload (TACO)**

- Particular attention should be paid to patients with underlying conditions which may increase their susceptibility to TACO. These include;
  - Elderly patients
  - Infants and children
  - Patients of low body weight
  - Patients physiologically compromised particularly those with a history of cardiac respiratory or renal insufficiency or chronic anaemia.
- Transfusion should be on a unit by unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component. This assessment should include a;
  - careful estimation of the patient's hydration and cardiac status prior to the transfusion,
  - thorough review of the patient's fluid balance during the transfusion
  - possible need for diuretic therapy as this can reduce the risk of TACO and may be

necessary for those on regular diuretic therapy.

- In very low weight or 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).
- Doctors and nurses across all specialities should receive education aimed at the recognition and avoidance of TACO. In addition junior doctors should receive specific training in the area of transfusion medicine to ensure safe and appropriate decision making regarding transfusion and prescription of blood components/products.
- It is important that clinicians recognise that even healthy patients can develop circulatory overload in the massive transfusion setting and that fluid balance is carefully monitored to avoid over hydration /overload with components.

# Serious Adverse Reactions and Events 2008 and 2009

The NHO received 689 reports of Serious Adverse Events (SAE)/Incorrect Blood Component Transfused (IBCT) and Serious Adverse Reactions (SAR) in 2008 and 2009. The management of these reports is illustrated in Table 1.

**Table 1: Management of reports in the NHO 2008 and 2009 (n=689)**

Reports	2008	2009
Total received	375	314
Reports not progressed	82	46
Reports duplicated	3	1
Reports analysed	290	267

Reports were not progressed when they did not fulfil reporting criteria as outlined in the haemovigilance handbook. The number of reports which were not progressed dramatically reduced in 2009. A small number of duplicate reports were received on both years. The number of reports accepted for review reduced in 2009 largely due to a decrease in TACO and AA reaction reports. The breakdown of these reports is illustrated in Table 2.

**Table 2: Reports analysed by NHO 2008 and 2009 (n=557)**

Category of report analysed	2008	2009
SAE/IBCT	147	157
Anaphylaxis/hypersensitivity(AA)	41	28
Febrile Non Haemolytic Transfusion Reaction	38	37
Transfusion Associated Circulatory Overload (TACO)	39	18
Unclassified SAR	6	3
Transfusion transmitted bacterial infection	6	1
Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs)	4	14
Immunological haemolysis due to other allo-antibody (Acute < 24 hrs)	2	2
Hypotensive Transfusion Reaction	2	1
Transfusion Associated Dyspnoea	2	3
Transfusion transmitted viral infection ( HAV/HBV)	1	2
Transfusion transmitted viral infection (HCV)	0	1
Transfusion transmitted viral infection (HIV )	1	0
Transfusion related acute lung injury (TRALI)	1	0
<b>Total</b>	<b>290</b>	<b>267</b>

## Denominator Data

The number of blood components and SD plasma distributed to hospitals from the IBTS in 2008 and 2009 is illustrated in Table 3. Issue of granulocytes has increased noticeably from 87 units distributed in 2007 to 328 in 2009. This component is used by some hospitals in patients with severe neutropenia.

**Table 3: Blood and SD Plasma distributed by IBTS (n=394,693)**

Blood Components and SD plasma	Number Distributed/Issued	
	2008	2009
Red Cell/Whole Blood	<b>144,383</b>	<b>146,584</b>
Apheresis Platelets	13,754	17,173
Platelets Pooled in platelet additive solution	10,870	8,553
Platelets Pooled leucocyte depleted		602
Total Platelets	<b>24,624</b>	<b>26,328</b>
SD Plasma	<b>23,856</b>	<b>23,401</b>
Fresh Frozen Plasma	<b>474</b>	<b>475</b>
Cryoprecipitate (pooled)	<b>2,717</b>	<b>1,196</b>
Cryo depleted plasma	-	<b>43</b>
Granulocytes (issued as Leucocytes pooled)	<b>285</b>	<b>328</b>
<b>Total</b>	<b>196,339</b>	<b>198,355</b>

A cumulative review of reports analysed between 2000- 2009 are presented in Table 4.

**Table 4: Breakdown of NHO incidents accepted 2000-2009 (n = 2127)**

Year	IBCT /SAE	AA	TACO	DHTR	STTI	TRALI	PAD	Unusual/ Unclassified	AHOSTR <sup>1</sup>	TAD <sup>2</sup>	Hypotensive Reaction <sup>2</sup>	Total
2000	31	22	8	2	7	-	-	1	14			85
2001	69	35	16	1	2	3	3	3	12			144
2002	87	31	10	9	3	2	5	-	8			155
2003	115	23	14	9	4	1	6	-	8			180
2004	126	35	15	4	3	-	7	-	24			214
2005	173	22	25	5	6	-	3	-	32			266
2006	187 (32 <sup>3</sup> )	29	34	4	8	2	0	0	40			304
2007	115 (32 <sup>3</sup> )	40	18	6	4	0	0	5	34			222
2008	147 (53 <sup>3</sup> )	41	39	4	8	1	0	6	40	2	2	290
2009	157 (46 <sup>3</sup> )	28	18	14	4	0	0	3	39	3	1	267
<b>Total</b>	<b>1207</b>	<b>306</b>	<b>197</b>	<b>58</b>	<b>49</b>	<b>9</b>	<b>24</b>	<b>18</b>	<b>251</b>	<b>5</b>	<b>3</b>	<b>2127</b>

<sup>1</sup> Prior to 2006 Acute Transfusion Reactions (both Acute Haemolytic Transfusion Reactions and Febrile Non Haemolytic Transfusion Reactions) were reported as Acute Haemolytic or Other Severe Transfusion Reactions (AHOSTR).

<sup>2</sup> Collection of these reports commenced only in 2008

<sup>3</sup> Denotes Mandatory SAE. Two blood establishment errors were also included on ANSARE.

The incidence of SAE /IBCT and SAR per unit distributed from the IBTS in 2008 and 2009 can be found in Appendix 1.

### Annual Notification of Serious Reactions and Events ( ANSARE)

Commission Directive 2005/61/EC Annex II D and III C require reporting establishments to complete the Annual Notification of Serious Adverse Reactions and Events (ANSARE) form which collects mandatory SAE and SAR.

The majority of reporting establishments submit the report electronically with only smaller facilities opting to report by hard copy. The number of forms received varies slightly each year. In some instances, where a reporting establishment acts as a blood bank for another site, only one ANSARE form is returned. Other reporting establishments chose to submit a separate ANSARE, despite receiving blood components from another site. Finally some hospitals may no longer transfuse patients.



## ANSARE 2008

Seventy-six ANSARE forms were returned for the reporting year 2008. One hundred and ninety four ( 67%) of the 290 incidents (SAR/IBCT/ SAE) reported to the NHO met the criteria for mandatory reporting and were reported on ANSARE. Two blood establishment errors were also included on ANSARE.

Twenty two sites (29%) reported both SARs and SAEs. A further twenty one (28%) reported only SARs and six (8%) reported only SAEs. Twenty seven sites (36%) indicated that they had not reported any SAR or SAE during 2008.

## ANSARE 2009

Seventy-five reporting establishments submitted reports in 2009. One hundred and fifty four (58%) of the 267 reports accepted by NHO, were reported on ANSARE. At the time ANSARE was submitted one further case remained open for further investigation. Sixteen (21%) reporting establishments reported both SARs and SAEs. A further 17 (23%) reported only SARs and six (8%) reported only SAEs. Finally 36 sites (48%) had not reported any SAR or SAE during 2009.

## Comment

The ANSARE form does not collect non-mandatory clinical IBCT incidents. These non-mandatory events accounted for 32% of the total number of reports accepted by the NHO in 2008 and 41% in 2009 compared to mandatory SAEs which made up only 18% in 2008 and 19% in 2009. Therefore, the ANSARE returns underestimate the overall rate of reporting from reporting establishments to the NHO.

## Participation in Haemovigilance 2008 and 2009

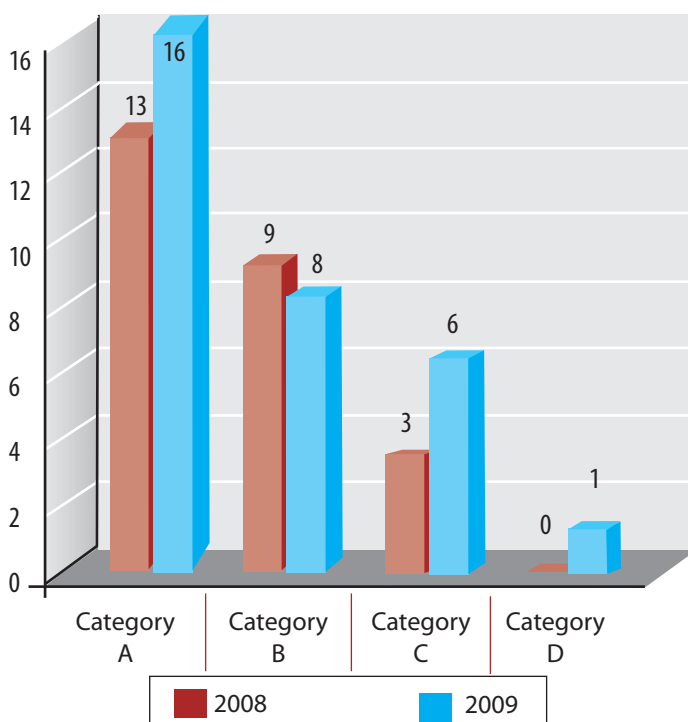
The NHO has examined reporting trends through out 2008 and 2009. Reporting establishments (RE) are classified in categories depending on the number of components issued each year, from the information on ANSARE. Seventy one reporting establishments issued blood for transfusion in 2008. Three facilities (hospitals who submitted an ANSARE form) did not transfuse blood components in 2008. In 2009, 72 reporting establishments issued blood components for transfusion. This excluded two blood establishments and one facility who did not transfuse blood components in 2009.

**Table 5 Reporting Establishment Categories**

Category	Components issued	No. of RE issuing blood for transfusion in 2008 (n=71)	No. of RE issuing blood for transfusion in 2009 (n=72)
Category A	Up to 1000 components	34	37
Category B	1000 to 3000 components	21	19
Category C	3000 to 6000 components	9	8
Category D	Above 6000 components	7	8

In 2008 nineteen reporting establishments did not submit any mandatory or non mandatory reports to the NHO. In 2009 twenty two reporting establishments did not submit any mandatory or non mandatory reports to the NHO. The majority of these reporting establishments are smaller organisations and fall within the category A group with less than 1000 units issued per annum.

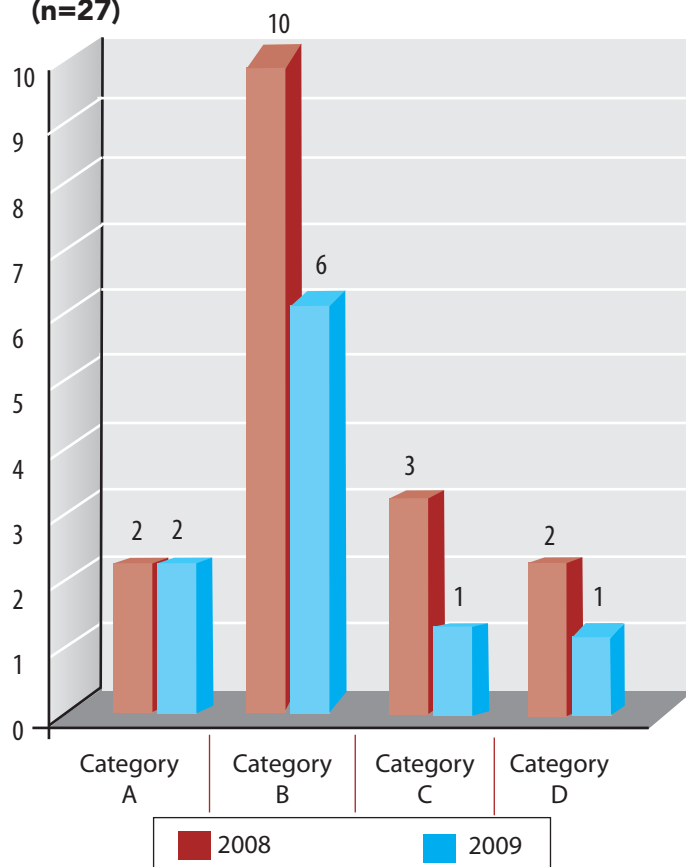
**Figure 1: Reporting establishments submitting between 1 to 5 reports in 2008/2009 (n=56)**



In 2008 25 (35%) reporting establishments submitted between 1 to 5 reports (Figure 1). Thirteen (50%) were in category A, 9 (36 %) were category B and three (12%) were category C hospitals.

Thirty one (43%) hospitals submitted between 1 to 5 reports in 2009 a slight increase on 2008 figures. Sixteen (52%) were category A, eight (26 %) were category B, six (19%) were category C and one (3%) was a category D reporting establishment.

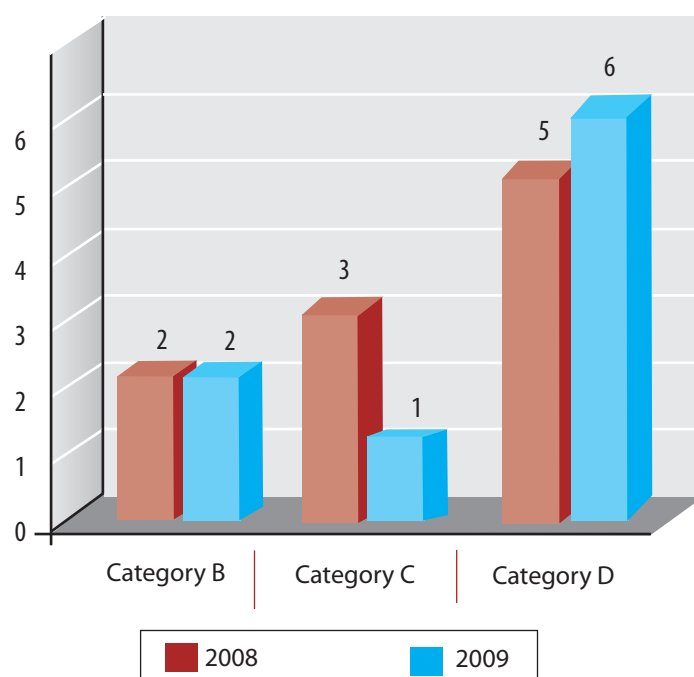
**Figure 2: Reporting establishments submitting 6 to 10 reports in 2008/2009 (n=27)**



In 2008 seventeen reporting establishments (24%) submitted 6 to 10 reports (Figure 2). Reporting establishments within category B category submitted 50% (10) of these reports.

In 2009 ten reporting establishments (14%) submitted 6 to 10 reports, again the majority of these reports were submitted from category B reporting establishments.

**Figure 3: Reporting establishments submitting more than 10 reports in 2008/2009 (n=19)**



In 2008 ten reporting establishments (14%) submitted more than 10 reports for review (Figure 3). The majority were as expected from Category D reporting establishments transfusing greater than 6000 units where five of the seven Category D reporting establishments submitted more than 10 reports.

In 2009 nine reporting establishments (13%) submitted more than 10 reports for review (Figure 6). The majority were again as expected from Category D reporting establishments with all six of the eight reporting establishments in Category D submitting more than 15 reports.

### Comment

Reporting of Haemovigilance IBCT/SAE and SAR apart from being mandatory is an integral part of transfusion safety and is evidence that there is active surveillance of transfusion safety.

While the reporting pattern of Category A, B and D reporting establishments reflects transfusion activity in 2008, the reports for the nine Category C (<6000) reporting establishments show a different pattern. Although all Category C reporting establishments reported an incident, the pattern was equally distributed between report

ranges with a third of the hospitals represented in each report range. This suggests that some Category C reporting establishments may be underreporting.

In 2009 the overall reporting of SAR/SAE has decreased slightly since 2008 and in certain reporting establishments the amount of components transfused has decreased which may account for this. However it would appear again that some reporting establishments in category C continue to under report as six of the eight category C reporting establishments submitted between one to five reports in 2009. Surprisingly one reporting establishment in category D submitted only 5 reports in 2009 and a second submitted only between 6 to 10 reports compared to over 15 reports in the other six category D reporting establishments.

**Trending Adverse Reaction and Event Reporting 2006-2009**

A review of haemovigilance reporting trends (on blood components including SD plasma) from 2006 to date is presented in Figure 7. Reporting on blood products e.g. anti-D and factor concentrates, both accepted by the NHO, have not been included in this analysis. Up to 2006, the numbers of reports analysed by the NHO continued to increase year on year since reporting commenced in 1999.

A more detailed analysis of this reporting period however clearly shows while greater numbers of events than reactions were reported year on year up to 2006, this was not the case since 2007. Reports of SAR have overtaken SAE/IBCT by 32 and 21 reports respectively.

While reporting of non mandatory adverse events (IBCT) occurring in the clinical area reduced by over 50% between 2006 and 2008, this trend is beginning to reverse in 2009, with 76 reports relating to non-mandatory clinical adverse transfusion events having been reported to the NHO, a small increase on 2008 but still considerably below 2006 figures.

**Key Points**

It is likely that the reduction in reports from clinical areas from 2006-2008 indicated the emphasis on the requirements of laboratory accreditation and mandatory SAE reporting. The slight increase in 2009 non mandatory reports is encouraging, suggesting this trend is being reversed.

Reporting of both mandatory and non mandatory events make important contributions to patient safety and attention needs to be refocused on the clinical areas of blood transfusion not covered by the Directives.

**Figure 7: Haemovigilance reporting 2006-2009 (n=993)**



# Incorrect Blood Component Transfused (IBCT)/Serious Adverse Event (SAE)

2008

## Introduction

The NHO collects Serious Adverse Events (SAEs) which are mandatory under legislation (EU Blood Directive 2002/98/EC) and Incorrect Component Transfused (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 cover the quality and safety of the blood components, focusing on errors occurring in the Blood Establishments (BE) and in the HBB and does not cover errors associated with blood products.

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).

An 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 patient or donors or which results in, or prolongs hospitalisation or morbidity'. EU Directive 2002/98/EC and Commission Directive 2005/61/EC.

While the NHO to date has not collected near miss events occurring in either the BE or HBB these events will be reportable from January 2010.

## Findings

In 2008, 147 IBCT/SAE related to blood components and blood products were accepted by the NHO, representing 51% of analysed reports. These reports were submitted from 39 reporting establishments.

Thirty six reports related to blood products (factor concentrates and anti-D) and these are separately assessed on pages 39 and 41 respectively.

## IBCT/SAE associated with blood components and SD plasma

The NHO analysed 111 reports relating to blood components and SD plasma. Elderly patients aged over 70 years were involved in 25% of reports. Almost 22% of reports involved paediatric patients under 18 years of age. Adverse events relating to paediatric patients are covered in detail on page 35.

Fifty three reports met the criteria of an SAE reportable under EU Directive 2005/61/EC. The remaining 58 were IBCT due to errors in the clinical areas.

## Mandatory SAE reports under Directive 2005/61/EC

This is the second year of reporting of mandatory events as set out in Commission Directive 2005/61/EC. The report is sent to the IMB for transmission to the European Commission. SAEs are classified by step in the work process e.g. testing of donations, storage, distribution etc. and cause of the adverse event as product defect, equipment failure, human failure or other (Directive 2005/61/EC Annex III). These mainly involved wrongly labelled units or storage issues.

In 2008, 53 SAE reports were submitted from HBB. Details of the report submitted to the EC are included in Appendix 2.

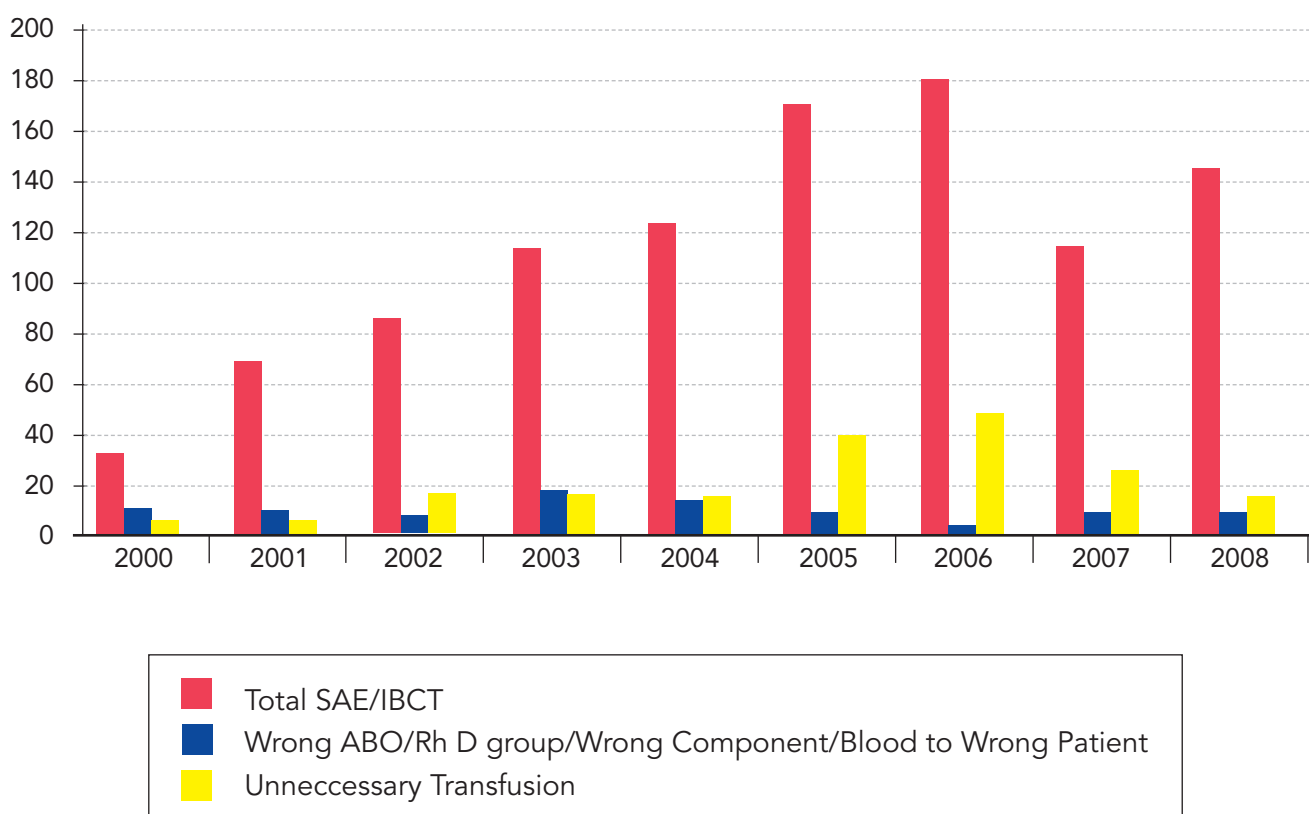
## Reporting trends of IBCT/SAE

Further analysis of adverse event reporting clearly shows that reporting of non-mandatory adverse events (IBCT) which are primarily events occurring in the clinical area, has substantially reduced. The number of SAE has increased in 2008, forming approximately 48% of overall adverse events, while reports of non-mandatory IBCT has continued to

decrease. Only 52% of reports of adverse events relating to blood components and SD plasma were IBCT, compared to 66% and 79% in 2007 and 2006 respectively.

The changing profile of IBCT/SAE reporting is illustrated in IBCT/SAE Figure 1. While the numbers of ABO/Rhesus (Rh)D SAE have remained relatively constant, numbers of Unnecessary Transfusions have also reduced since 2007 and again in 2008, with reduced reports of IBCT.

**IBCT/SAE Figure 1: Changing profile of IBCT reports 2000-2008**

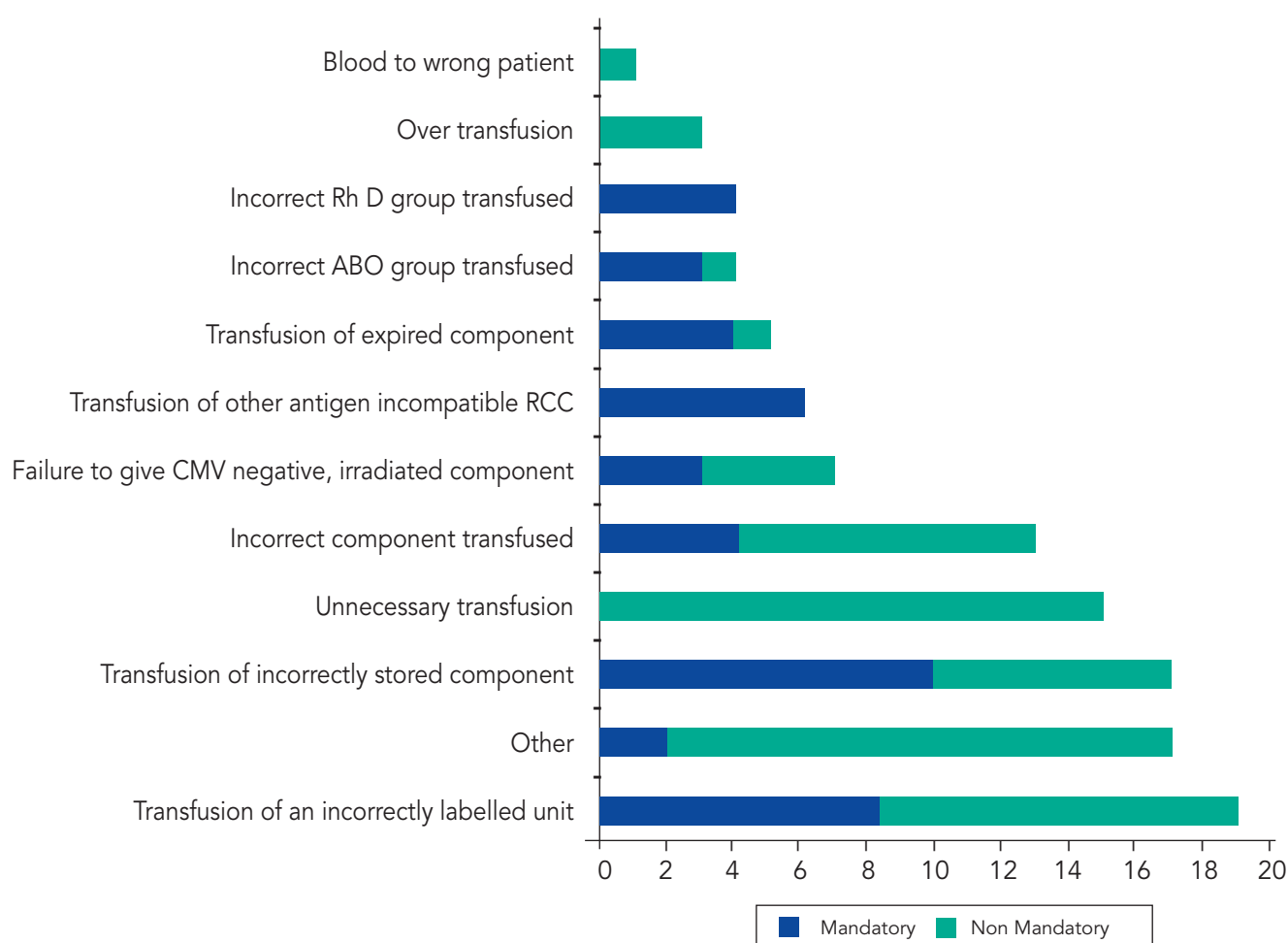


### **Categorisation of IBCT/SAE analysed by National Haemovigilance Office –What happened?**

All reports analysed by the NHO were initially categorised by the nature of the adverse event experienced by the patient. This maintains the clinical focus of the reporting system.



**IBCT/SAE Figure 2: Reports analysed by the NHO (n=111)**



### Major clinical findings

- There were fifteen reported cases of unnecessary transfusion, nine cases involving red cells, four reports involving SD plasma, one report involving platelets, and one report involving an unnecessary transfusion of both red cells and platelets.
- There were seven reports of patients not receiving cytomegalovirus (CMV) negative and/or irradiated blood.
- There were six reports of patients not receiving antigen compatible red cells.
- Thirteen reports involved the transfusion of the incorrect components/product to patients. Five cases involved red cells, five involved SD plasma, two cases involved platelets and one case involved fresh frozen plasma (FFP).
- The wrong blood was given to a neonate (IBCT/SAE Case 12).
- There were three cases where a neonate and infants were over-transfused (IBCT/SAE Case 17).
- Four patients received components which were the incorrect ABO group. One report involved red cells, two involved platelets and one SD plasma. There were no reactions.
- There were 17 reports captured as "Other". One case involved a failure to provide phenotyped units for a patient in sickle cell crisis (See Appendix 3).
- Four patients were transfused with blood of the incorrect RhD group.

### **Adverse events associated with errors at labelling, storage, administration and other miscellaneous errors**

- Nineteen cases were reported where the components were incorrectly labelled. Red cells were involved in 15 cases and SD plasma in two cases. Platelets and granulocytes were each involved in one case. The majority of these were classified as SAE.
- There were 17 reports of transfusion of incorrectly stored components, 11 involving red cells and three involving both SD plasma and cryoprecipitate.
- There were five reports of transfusion of expired components, all involving red cells. Four cases were considered SAE involving issues from the HBB and in the final case, a clinical decision was made to transfuse an expired unit of red cells in theatre.
- The remaining reports captured as "Other" included the following adverse events; use of incorrect giving set (3), transfusion exceeding 6 hours (7), pack perforated during transfusion (2), transfusion of uncross-matched red cells (1), clots reported in pack (1) (See Appendix II).

### **Unnecessary transfusion (n=15)**

The NHO received 15 reports in this category in 2008. This was a reduction of 11 reports on previous year. Nine reports involved red cells, four SD plasma, one involved platelets and one, multiple components (red cells and platelets). While reports of unnecessary transfusions in patients of all ages were received, 47% of the patients involved were over 70 years of age.

Most of these events occurred at the prescription/request step of the work process (n=13), one involved wrong results from the haematology laboratory and the final event occurred because of delay in bringing the patient for the procedure.

An overall review of these reports revealed unnecessary transfusions occurred as a result of:

- Decision making which deviated from clinical guidelines (n=10)

- Decision making based on incorrect or absent haematology results (n=4)
- Delay in transfusion (n=1)

### **Decision making which deviated from good clinical practice (n=10)**

Seven cases involved red cells; five of which were unnecessary transfusions administered to patients with iron deficiency anaemia. A further case involved a patient with megaloblastic anaemia due to vitamin B12 deficiency (IBCT/SAE Cases 1 and 2). The final case of over-transfusion in the context of haemorrhage is described in IBCT/SAE Case 3. All of these patients received these transfusions as results of errors made by medical staff prescribing blood components.

### **Unnecessary red cell transfusions**

#### **Transfusions for iron deficiency anaemia**

Two patients had iron deficiency anaemia as result of menorrhagia. One of these is described below (IBCT/SAE Case 1).

#### **IBCT/SAE Case History 1**

A 43 year old female patient developed an urticarial reaction post transfusion of red cells. On investigation, the HVO discovered the patient had a haemoglobin (Hb) of 7g/dl, due to underlying menorrhagia. She was asymptomatic and had not been commenced on iron. The cause of this error was lack of knowledge of the prescribing doctor.

In another case an elderly patient with iron deficiency anaemia received an unnecessary red cell transfusion, the cause of error was identified as a lack of knowledge by the prescribing doctor and absence of guidelines on management of patients with chronic anaemia.

There were three further cases where patients with chronic iron deficiency anaemia received unnecessary red cell transfusions. In one of these cases, the patient had been reviewed by the haematology team who had ordered intravenous (IV) iron for asymptomatic anaemia. It was unclear why this advice was not followed.

## Transfusion for megaloblastic anaemia due to vitamin B12 deficiency

### IBCT/SAE Case History 2

This young male adult patient was admitted via Accident and Emergency (A&E) from General Practitioner (GP) for investigation of anaemia with a differential diagnosis of B12 or folate deficiency. While this patient had a history of fatigue, he did not have dyspnoea or any history of haemorrhage. His Hb was reported at 6.3g/dl. Two units of red cells were prescribed by a junior hospital doctor working in the (ED) emergency department. This occurred outside routine working hours. One unit was transfused. When this patient was reviewed by the haematology team, the second unit of red cells was cancelled.

## Unnecessary transfusion for haemorrhage

### IBCT/SAE Case History 3

In the final case involving unnecessary red cell transfusion, a patient admitted with a Hb of 13.7g/dl and PR bleeding developed a tachycardia and mild hypotension 24 hours post admission. While there was further bleeding, the patient received five units of red cells without checking between units and had a Hb of 15.2g/dl post transfusion. Some of the units were unnecessary.

Three cases are reported in the paediatric section, where patients were over transfused (See IBCT/SAE Case 17).

## Unnecessary SD Plasma and Platelets

Two patients received unnecessary SD plasma transfusion caused by lack of hospital policies and knowledge of prescribing clinicians.

One patient on warfarin with an INR of 3.5 was transfused platelets instead of Vitamin K and PCC prior to insertion of a chest drain. This event occurred when the platelets were prescribed by a consultant who did not prescribe blood components routinely.

### Key Points

- Transfusions for anaemia due to haematinic deficiency accounted for 40% of all unnecessary transfusions and 5% of all IBCT/SAE reported in 2008.

- Asymptomatic patients with iron deficiency anaemia should be treated with iron therapy. Oral iron should be continued for at least three months after deficiency has been corrected so that iron stores are replenished. Ascorbic acid may enhance iron absorption. Where there are concerns about compliance, IV iron products should be considered. (Goddard et al, 2005)
- Patients with megaloblastic anaemia respond very rapidly to vitamin B12 and folate and very rarely require transfusion.
- Where several units are prescribed for transfusion, the patient's Hb should be checked between units. This will minimise risk of unnecessary/over transfusion (NBUG, 2001).

## Decision making based on incorrect or absent haematology results (n=4)

These decisions resulted in three unnecessary red cell and one platelet and red cell transfusion. In two cases, patients received unnecessary red cells when doctors failed to verify blood results.

In another case, a doctor ordered three units of red cells over three consecutive days based on Hb from the initial day. No Hb checks were done between units. The final event is described in the paediatric section (IBCT/SAE Case 16).

## Unnecessary transfusion because of a delay (n=1)

### IBCT/SAE Case History 4

This case involved the unnecessary transfusion of three units of SD plasma. A patient having a liver biopsy under radiological guidance was transfused SD plasma on the ward for an abnormal INR. Although the consultant radiologist requested that the patient attend the X-ray department at a certain time, this was delayed by the plasma transfusion. When he was transferred to the X-ray Department, it was too late to undergo the procedure as it is hospital policy that all patients have consultant delivered care for two hours post procedure, and this was unavailable because of the delay.

### Incorrect ABO group, RhD group, wrong patient and antigen negative blood transfused (n=15)

There were four cases involving transfusion of a component of the wrong ABO group, four involving errors in Rh group, one event where the incorrect patient was transfused and six involving failure to transfuse antigen negative blood.

### Incorrect ABO group transfused (n=4)

The NHO received four reports in this category. Although only one was associated with red cells, these cases were considered to have high potential to cause harm. However, there were no reports of SAR associated with ABO incompatibility in 2008.

**IBCT/SAE Table 1: Age and Component implicated in transfusion of ABO incompatible units (n=4)**

Component	Neonate (<28 days)	Infant	Adult
RCC	1		
Platelets		1	1
SD plasma			1

In three reports, the error was in the HBB and in the fourth case; the error was in the BE. All errors were discovered in the HBB by medical scientists, either during next crossmatch/issue, or during post transfusion review. In two of the four cases, the medical scientists involved did not routinely work in the HBB.

A neonate with haemolytic disease of the new born (HDN) received red cells of the incorrect ABO group. There was no reaction (IBCT/SAE Case 12).

### Plasma

#### IBCT/SAE Case History 5

In this case, a patient whose blood group was group AB negative was transfused group A SD plasma, when universal group SD plasma (Uniplas) was readily available. The medical scientist involved in this event routinely worked in the HBB. This error, caused by human error, occurred outside routine working hours.

### Key Point

- Patients whose blood group is AB can be transfused with A or B red cells, but plasma components which contain anti A or B should be avoided (British Committee for Standards in Haematology (BCSH), 2004).

Two cases involved the transfusion of group O platelets in error.

### Platelets

#### IBCT/SAE Case History 6

In this case an elderly man whose blood group was A RhD positive was transfused group O RhD positive pooled platelets. The medical scientist in the BE was informed of the patient's blood group when the platelets were ordered. While it was unclear what group was ordered by the hospital, three units of group O platelets were issued from the BE and one unit was transfused. Medical scientists in both the BE and HBB routinely worked in the laboratory, but the platelets were issued out of hours. The error was discovered by the medical scientist in the HBB, taking over from out of hours staff. A review of all units distributed identified all units were high titre negative for anti-A and anti-B.

**Error Cause:** Human error, i.e. failure to adhere to policies was identified as the root cause of this event.

The other case is described in the paediatric chapter (IBCT SAE Case 13).

### Key Points

- Although group O donors are considered 'universal' donors of red cells, group O platelets have anti-A and anti-B in the suspending plasma. This can cause haemolysis in A, B or AB patients even if tests for high titre haemolysins are negative, since these tests are not very sensitive.

- Group O platelets, unless they are suspended in platelet additive solution, particularly O apheresis platelets, should be reserved for group O patients.
- Transfusion of group O apheresis platelets to patients whose blood group is A, B or AB has potential to cause haemolysis. (BCSH, 2003; NHO, 2007; SHOT, 2009).

### **Incorrect RhD group transfused (n=4)**

The NHO received four reports in this category. All reports in this category involved red cells. Fortunately three of the four RhD positive red cells were transfused to male patients and the fourth was transfused to a post menopausal female.

All errors occurred in the HBB. Two errors were incorrect selection of RhD group, in another case a computer warning/flag was over-ridden and the final error resulted from incorrect transcription of results (IBCT/SAE Case 7).

#### **IBCT/SAE Case History 7**

The medical scientist working in the hospital bank carried out a manual group and crossmatch and recorded the result incorrectly. While the patient's blood group was correctly typed as O RhD negative, it was recorded as O RhD positive. This was an emergency crossmatch and, as this was out of hours, the automated grouper was not used, as training in its use had not been fully rolled out to all on-call staff. This error occurred when one medical scientist was on cross-call cover in the HBB. The error was discovered by another medical scientist at the next crossmatch.

**Error cause:** The root cause identified was a simple human lapse in concentration, where a medical scientist incorrectly transcribed results. That the automated grouper was not used outside routine hours most likely contributed to the error.

An overview of root causes across the remaining three cases identified one other system failure.

In this case, a system error was reported when a medical scientist working in the HBB, over-rode a computer flag and issued RhD positive red cells to a patient whose blood group was RhD negative. It was usual practice for patients in this hospital to be medically reviewed late in the day, and therefore cross matching was done out of hours. This was reported as an organisational systems failure involving hospital culture which contributed to less safe practice.

Human failures also contributed to patients being transfused with incorrect RhD group red cells. These included human slips, lack of knowledge, a failure to follow policies, co-ordination and communication.

In one case, where group RhD negative components were unavailable, the medical scientist selected RhD positive components without informing the Consultant Haematologist. This was not an emergency transfusion and was probably inappropriate, as the patient was being treated for iron deficiency anaemia. Had the case been reviewed medically, this transfusion would not have proceeded.

There were contributing factors reported in three cases.

Three adverse events occurred out of hours and in two of the three cases the medical scientist did not routinely work in the HBB. One case was an emergency crossmatch.

Corrective and preventative action was reported in three cases. This included the introduction of a computer flag to minimise the potential for issuing RhD incompatible components, a memo to all staff working in the HBB on component selection, a feasibility review of out of hours use of the automated grouper and a plan to review out of hours crossmatch and transfusions where requests were routinely received late in the working day.

### **Wrong blood given to a patient (n=1)**

This case is described in the paediatric section (IBCT/SAE Case 14).



### Transfusion of antigen incompatible red cells (n=6)

The NHO received six reports in this category. None of the patients had an associated transfusion reaction. One male patient was only 15 years of age and is described in the Paediatric Section (IBCT/SAE Case 15).

**IBCT/SAE Table 2: Transfusion of antigen incompatible red cells (n=6)**

Age	Gender	Patient antibody status
Adult 31-50 years	Female	Anti-Jk <sup>a</sup> antibody
Adolescent 12-17 years	Male	Anti-Jk <sup>a</sup> antibody
Adult 18-30 years	Male	Anti-Kell antibody
Adult 31-50 years	Female	Anti-Kell antibody
Elderly 70 years	Male	Anti-Fy <sup>a</sup> antibody
Adult 51-70 years	Female	Anti E (enzyme only)

In two cases, antibodies although present were not detected on the pre-transfusion crossmatch. In one case, the pre-transfusion test lacked sensitivity to detect Anti-Jk<sup>a</sup> antibodies. Although it can be particularly difficult to detect Jk<sup>a</sup> antibodies, in this case it was detected during retrospective testing of the pre-transfusion sample when a different test was employed. The lack of a sensitive pre-transfusion test was identified as the root cause of these events. This was classified as a system failure, materials.

In the second case, an Anti-Fy<sup>a</sup> antibody not detected prior to transfusion was subsequently detected on re-testing of the pre-transfusion sample. The reason for this was unclear.

In two cases, removal of a computer flag left staff unaware that a patient required antigen negative red cells. In another case, a female patient of child-bearing potential received a Kell positive unit of red cells. This occurred when a medical scientist failed to carry out a final check to ensure the patient's age and the Laboratory Information System (LIS) was not set-up to prompt this. In the final case, the medical scientist entered the incorrect result (IBCT/SAE Case 8).

#### IBCT/SAE Case History 8

In this case, a medical scientist processing a routine sample during on call hours

incorrectly entered the results of the cross-match as negative, when it was positive. An enzyme only anti-E was subsequently detected in the patient sample. Although enzyme only anti-E is unlikely to be clinically significant, the potential for harm of this error was high.

**Error Cause:** The root cause of this error was identified as a design systems failure. Had the blood group analyser been interfaced with the LIS, this error would not have occurred. Human error was also involved in this SAE as the medical scientist was working on-call and did not routinely work in the HBB. If the request had been processed during routine hours, the likelihood of this error occurring would have been reduced.

All of these events were discovered in the HBB, three at the next cross-match, two post transfusion either at the time of fating of units or authorisation of results, and one event was discovered when an analyser was undergoing validation.

#### Key Points

- Patients who have had previous pregnancies or transfusions are at risk of developing antibodies. Very often the HBB can be unaware of patients' history and the potential for antigen incompatible transfusions can be high. Development of a national antibody register could address this risk by ensuring access to patients' antibody history. It would also reduce the requirement for repeat laboratory testing.
- This would only be feasible with the implementation of a national unique health identifier (UHI), a recommendation made by the Health and Information Quality Authority (HIQA) (2009) and supported by the NHO. A UHI would facilitate improved and safer access to patients' records on a national antibody register thereby ensuring safer transfusion practice for patients.

### **Incorrect component transfused (n=13)**

The NHO received 13 reports in this category, which captures reports of patients who received an incorrect component, when another component would have been more appropriate. Of the 13 cases reported, five involved infants and these are separately discussed in the paediatric chapter.

Six cases involved plasma (SD plasma n=5, FFP n=1), five involved red cells and two platelets.

#### **IBCT/SAE Case History 9**

An adult patient received a unit of uncross-matched red cells. A medical scientist on call received a sample for grouping but cross-matched two units for a patient in A&E who was likely to require the blood. At this time, the crossmatch had not been requested, so the medical scientist did not label or issue the units to the patient. This medical scientist completed the on-call shift. When a crossmatch was later requested post midnight, a second on-call medical scientist labelled and issued two units of red cells, thinking they were the already crossmatched units. These units were transfused, but one of these units had not been previously crossmatched, as the medical scientist had selected the incorrect unit.

**Error Cause:** Systems failure-culture was identified as root cause of the error. The practice of anticipating the need for blood and cross matching red cells to assist colleagues without labelling them as cross-matched, was common practice in the HBB.

- There were five cases involving transfusion of SD plasma to reverse warfarin when prothrombin complex concentrate (PCC) would have been the correct product. All of these errors occurred at prescription/request and involved medical staff.
- One patient received FFP instead of SD plasma. This error occurred in a hospital where both FFP and SD plasma were stocked in the HBB. Clinical staff commonly referred to SD Plasma as FFP when requesting plasma so confusion arose when selecting the correct plasma.
- Two cases were reported where the incorrect platelet product was transfused. One case involved an adult patient who should have

been transfused with Human Leucocyte Antigen (HLA) matched platelets (IBCT/SAE Case History 10). The second case involved an infant who received a pooled instead of apheresis platelets.

#### **IBCT/SAE Case History 10**

A patient requiring HLA matched platelets was transfused two units of random platelets. In this case, the patient's consultant wanted HLA matched platelets for the patient to cover a procedure. A clinical nurse specialist caring for the patient ordered the HLA matched platelets from the BE some days ahead of the procedure, but did not inform the HBB. Platelets were issued from the HBB on the basis of this prescription which did not specify the requirement for HLA matched platelets.

#### **Site of Error**

First site of error was reported as prescription/request in 62% (8) of these cases and laboratory processing-blood transfusion in 31% (4) cases. One error was made at administration.

An overview of causal factors contributing to prescription/request errors identified primarily human failures such as lack of knowledge (6 cases), failure to adhere to policies (2 cases), failure of communication or co-ordination of care between disciplines (4 cases).

A review of these errors involving the HBB identified system failures in one case and human failures in all cases.

### **Transfusion of incorrectly labelled units (n=19)**

The NHO received 19 reports in this category. Fourteen reports were mandatory SAE where the error occurred in the HBB. In five cases the error occurred in the clinical area e.g. at initial clerking, sampling, collection and administration. In four reports, it was noted it was an emergency transfusion and in five cases the adverse events occurred out of hours.

Sixteen reports in this category involved red cells. platelets, SD plasma and granulocytes were each implicated in one report. Sixteen events involved adult patients and three paediatric patients. The errors were classified as follows:

- Transposition of labels within a single cross match (n=10)
- Incorrect data on label- patient identifiers, unit number (n=6)
- Unlabelled units transfused (n=3)

### IBCT/SAE Case History 11

In this case, unlabelled and uncrossmatched granulocytes were transfused to a patient. The component was ordered by the patient's primary care team from the BE, however, this request was not communicated to the staff in the HBB. This HBB had not had an order for granulocytes in a very long time and were aware that the haematologists in the hospital had never used granulocytes. They were unaware that on this occasion they were required for a patient in the hospital, and in fact, they believed that the granulocytes were intended for research. Therefore, the HBB did not accept the granulocytes, which were distributed directly to the patient in the ward, where a clinical decision was made to transfuse without crossmatch.

**Error cause:** Had the prescribing doctor communicated his request to the HBB, this adverse event would have been averted. The HBB failed to communicate with the clinical team or the BE prior to declining the granulocytes. The HBB did not have any policies to manage receipt, crossmatching and issuing of granulocytes, as they did not routinely use these components in the hospital.

### Transfusion of incorrectly stored units (n=17)

The NHO received 17 reports where patients received blood components or SD plasma which was incorrectly stored. Reports were analysed as follows:

### IBCT/SAE Table 3: Analysis of reports of incorrectly stored units transfused (n=17)

Analysis of incorrectly stored units	n	Mandatory SAE
Units returned to controlled storage after 30 minutes, subsequently removed and transfused greater than four hours after initial removal from controlled storage	5	4

Analysis of incorrectly stored units	n	Mandatory SAE
Units stored in uncontrolled storage	5	1
Problems with controlled storage	5	5
Other	2	1

Where reports involved either clinical personnel or SD plasma, these were captured as non-mandatory reports as outside the Commission Directive.

### Units returned to controlled storage after 30 minutes, subsequently removed and transfused greater than four hours after initial removal from controlled storage (n=5)

Red cells should be transfused to intended recipients within four hours of removal from controlled storage.

There were five reports in this category, all involving single unit transfusions. In each case, the unit of red cells was not returned from the clinical area to controlled storage within 30 minutes and was subsequently removed and transfused to the intended patient over four hours after initial removal from controlled storage.

These events occurred because the blood was brought to the bedside without checking the patient's status - two patients were pyrexial, one patient had incorrect information on his identity (ID) band, one patient had been moved to another unit and there were difficulties in gaining intravenous access.

These adverse events were primarily caused by human errors: failure to adhere to policies, lack of verification, lack of knowledge, task carried out incorrectly.

### Key Points

- Best practice guidelines indicate that a patient's status should be checked prior to bringing a unit of blood to the bed-side (BCSH, 1999, NBUG, 2004). Adherence to these guidelines will reduce such reports and minimise the risk of adverse events

and potential wastage of a scarce resource.

- If transfusion is clinically indicated, it should not be delayed solely because of pyrexia. Therefore, transfusions can be commenced on pyrexial patients, but these patients should be very carefully monitored throughout the transfusion.

### Units stored in uncontrolled storage (n=5)

There were five reports in this category. Two involved red cells, two cryoprecipitate, and one SD plasma.

Two units of red cells were stored in uncontrolled refrigerators. In the first case, a unit of red cells incorrectly scanned from the blood bank using an electronic blood-tracking system was subsequently placed in an uncontrolled fridge when the satellite fridge could not be accessed. This was done on instruction of the medical scientist in the HBB as the blood-tracking system did not recognise the unit of red cells. This system had just been introduced into the hospital and not all staff were trained in its use.

In the second case, a nurse on night duty placed a unit of red cells in an uncontrolled fridge in a ward area. She had not checked if the patient's IV canulae was correctly placed prior to ordering the blood. This was her first week of night duty in a new hospital, and she had not received formal training.

Three adverse events involved storage of cryoprecipitate and SD plasma in satellite fridges.

### Problems with controlled storage in the HBB (n=5)

All of these reports involved multiple units. Three cases involved red cells and two cases involved SD plasma and cryoprecipitate.

In three cases, red cells were stored in fridges which had not been validated by temperature mapping, or where temperature range was not controlled due to an equipment failure. All of these errors were reported as mandatory SAE.

In two cases, cryoprecipitate and SD plasma were stored in freezers where the temperature was outside the correct range.

### Key Point

- These cases highlight the importance of both initial haemovigilance orientation and ongoing training for clinical and laboratory staff in storage and handling of blood components.

### Other (n=2)

These reports involved multiple units of red cells and SD plasma. In the first case, red cells previously identified as been incorrectly stored were returned to controlled storage, reissued and transfused. In the latter case, units of SD plasma post de-frosting were stored in the clinical area prior to transfusion.

### Discovery Information - Who discovered the error?

This year, unlike previous years, 38% of adverse events were discovered by medical scientists, who discovered 55% of mandatory errors occurring in the HBB.

HVOs discovered 33% of all events and 48% of non-mandatory clinical IBCT.

Nurses discovered 17 (15%) adverse events following commencement or completion of a transfusion. Eight adverse events were discovered and reported by doctors, generally during clinical review of patients. These were mainly clinical (non-mandatory) errors. One event was discovered by an Inspector during the inspection process. This was a mandatory SAE.

### IBCT/SAE Table 4 Who discovered the adverse event? (n=111)

Who	n	Mandatory	Non Mandatory
Medical Scientist	42	29	13
HVO	37	9	28
Medical Scientist and HVO	6	4	2
Nurse	17	9	8
Doctor <sup>1</sup>	8	1	7
Other	1	1	0
Total	111	53	58

<sup>1</sup>Nurse and Medical Scientist also aware of this error.

### At what point in the work process were adverse events discovered?

Seventy two (65%) adverse events were discovered following the transfusion.

Medical scientists discovered 42 events during routine laboratory activity. The majority (34) were discovered at;

- Next crossmatch n=8
- Next issue within same transfusion event n=5
- Fating of units transfused n=5
- Post call check n=8
- Stock reconciliation n=8

Unnecessary transfusions were discovered by HVO (7), medical staff (4) and medical scientists (4) following transfusion.

#### Key Point

- This is the first year that HVOs did not discover the majority of reported adverse events. This probably reflects improved vigilance systems, either in terms of surveillance or reporting in the laboratories associated with

International Standards Organisation (ISO)15189.

- Yet again in 2008, a majority of errors were discovered during post transfusion surveillance activity. This indicates that potentially many errors could have been detected by staff in the transfusion process prior to completion of transfusion, highlighting the need for continuing education for clinical and laboratory staff involved in the transfusion process.
- Error discovery by doctors increased in 2008. While the numbers are still small, this is encouraging, indicating an increased awareness of the importance of reporting adverse transfusion events.

### Error occurrence-where did the error occur?

The site of first error in the work process where the adverse event occurred and the discipline of personnel involved is illustrated in IBCT/SAE Table 5.

**IBCT/SAE Table 5: Site in transfusion process where error first occurred & discipline involved in IBCT/SAE (n=111)**

Stage of Work Process	Total n	Discipline involved				
		Nurse	Doctor	Medical Scientist	Porter	Other
BE	1	0	0	1	NA	NA
Initial Clerking	1	NA	NA	NA	NA	1
Sampling	1	0	1	NA	NA	NA
Prescription Request	29	5	29 <sup>2</sup>	1	NA	NA
Laboratory (Other)	1	0	NA	1	NA	NA
HBB	40	15	2	40 <sup>3</sup>	2	NA
Storage	11	6	0	6 <sup>4</sup>	0	NA
Collection	6	4	0	0	2	NA
Administration	18	15 <sup>5</sup>	3	NA	NA	NA
Other	3	1	1	1	0	NA
Total	111					

<sup>2</sup>Nurses were also involved in five errors along with medical staff, and the HBB was also involved in one adverse event.

<sup>3</sup>All events occurring in HBB were not identified by nurses, doctors and porters, therefore they are also implicated in adverse event.

<sup>4</sup>One event involved staff in the blood transfusion laboratory and a nurse.

<sup>5</sup>One event involved a nurse and a doctor.



## Key Points

- A comparison of data between 2007 and 2008 shows that prescription/request, blood transfusion laboratory processing and administration continue to be the steps in the work process where most adverse events begin.
- However in 2008, reports associated with blood transfusion laboratory processing surpassed prescription/request for the first time since reporting commenced in Ireland, possibly reflecting the impact of quality systems in the HBB.

## Risk assessment

A risk assessment based on potential impact of harm and frequency of events. High risk activities can be identified by examining each step of the transfusion work process in terms of adverse event occurrence and examining the numbers of events with high potential to cause harm to patients.

IBCT/SAE Table 6 presents data on steps of the work process; number of adverse events, error incidence reported in 2008 and percentage of events with high potential for harm for patients.

**IBCT/SAE Table 6: Risk Assessment by steps of the blood transfusion process. (n=104)**

Step in work process	Total events at step in work process	% of events per step in the work process with high potential for harm
Prescription/Request	29	62%
Blood Transfusion Laboratory	40	52%
Storage	11	27%
Collection	6	33%
Administration	18	22%

More events with greater potential for harm to patients occur at Prescription/Request and in the blood transfusion laboratory. This includes events such as unnecessary transfusion, incorrect component/product transfused, incorrect ABO and RhD group transfused.

While the events reported with first site of error at administration did not have high potential to cause harm, the bedside check is the final barrier to identify and prevent adverse events (Reason, 2000). While administration practice appears safer than other areas, it is clear from reports examined in 2008 that this barrier may not be optimally functioning. Reported adverse events such as transfusion of incorrect ABO/RhD groups, units with transposed labels and unnecessary transfusions were not recognised at the bedside. As the NHO does not accept reports of clinical near miss events, the extent to which the bedside check is working is not clear. It is important to emphasise that the bedside check is crucial to identify and prevent transfusion adverse events.

## Key Points

- Based on analysis of data received in 2008, while all steps in the blood transfusion process have potential to cause harm to patients, *prescription/request* and *blood transfusion laboratory processing* are potentially more risky to patients.
- This analysis highlights areas of the work process where haemovigilance resources should be concentrated, with a clear objective of enhancing patient safety i.e. on prescribing/requesting, and HBB practices.
- The role of the bedside check as a barrier to unsafe transfusion practice must be highlighted to clinical staff, nurses, medical staff and perfusionists in haemovigilance education sessions.

## Overview of changes to practice

Following investigation and evaluation, the purpose of follow-up action is to address the root cause of the event. An analysis of reports received in 2008 indicated 50% (55) implemented corrective action, 41% (45) did not implement corrective action and in 10% (11), this information was not provided.

The requirements of the Directive 2005/61/EC require reports of corrective action following SAE. Corrective action was specified in 51% (27) reports of SAE. A review of reports where corrective action was implemented did not identify any trend in this area. Corrective action was implemented across all categories of reports, both mandatory and non mandatory, both high and moderate risk.

Reported follow-up action can be categorised as follows.

**IBCT/SAE Table 7: Follow-up action for IBCT/SAE (n=55)**

Category of follow-up action	Details	n
Process changes	Laboratory practices changed. Primarily an introduction of a further check	17
Education and Training	General haemovigilance training Targeted updates. Individual retraining General retraining E Learning	15
Communication	Memos to staff Development of posters Raising awareness	8
Development and revision of policies	Development of new policies Revision/change to current policies	6
Audit	Current clinical practice	2
Multiple follow-up actions	Including development/revision of policies, education, communication, clinical patient review etc.	6
Other	Order new equipment	1

## Key Points

- It is encouraging that reported follow-up action has increased from 37% in 2006 to 50% in 2007 of all cases analysed by NHO.
- The NHO recommends a systematic approach to follow-up action in terms of plan development and evaluation of changes to evaluate their impact on practice.

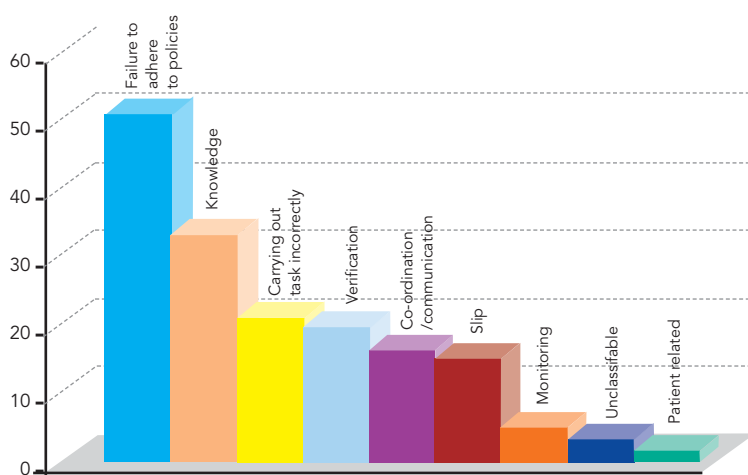
## Overview of causal analysis –Root cause of events

An analysis of reports where adverse events occurred at prescription/request, HBB, storage, collection and administration revealed multiple contributing causes.

## Human Error

Up to 167 human errors contributed to 104 events. The most commonly reported human errors were failure to adhere to policies (51) and lack of knowledge (despite training) (33) and carrying out tasks incorrectly (20). A detailed description of each classification of human error can be found in Appendix 4. These errors caused adverse events to occur at all steps of the work process reviewed.

**IBCT/SAE Figure 3: Human errors leading to events (n=167)**



The most frequently reported cause of human error in both clinical IBCT and SAE in the HBB was a failure to adhere to policies. Lack of knowledge was the second most common contributing factor to clinical IBCT. The third most common contributing factor was communication/coordination breakdown, reflecting the complex nature of clinical practice

with multiple teams and professionals caring for patients receiving transfusions. Lapses in concentration (slip) and failure to verify practice frequently contributed to reported SAE in the HBB.

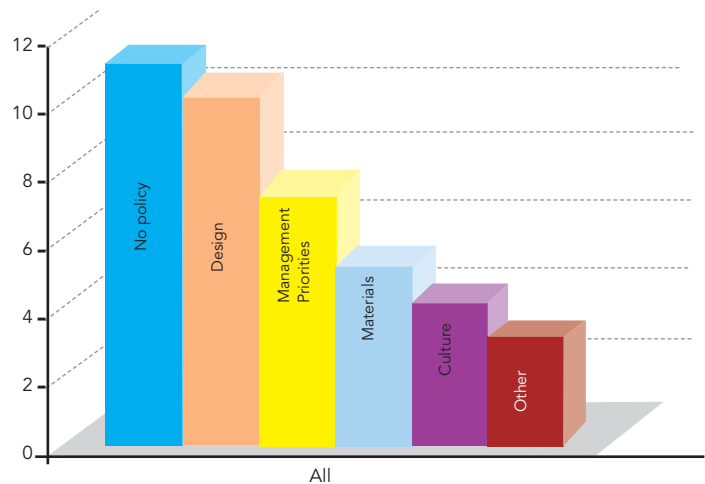
**IBCT/SAE Table 8: Recurring human error in clinical IBCT and SAE in HBB**

Clinical IBCT	SAE in the HBB
1 Failure to adhere to policies	Failure to adhere to policies
2 Knowledge	Slip
3 Co-ordination/ Communication	Verification

**System Error**

Up to 40 system errors contributed to 36 events. No system failures were reported in the remaining 68 events. The most commonly reported system errors were lack of policy (11), design of process/systems (10) and management priorities (7). A detailed description of each classification of system error can be found in Appendix 4.

**IBCT/SAE Figure 4: System errors leading to events (n=40)**



A comparison of the most frequently reported causes of system failure identified similar contributing factors to adverse events in both clinical area and in the HBB.

**IBCT/SAE Table 9: Recurring system failure in clinical IBCT and SAE in HBB**

Clinical IBCT	SAE in the HBB
1 Unclear or absent policy	Unclear or absent policy/Inadequate system-process design
2 Inadequate process design	
3 Failure of management to prioritise safety	Failure of management to prioritise safety

**Analysis of findings**

Examining frequently occurring contributing factors enables identification of factors common to most events. From reports received this year, human failures, failure to adhere to policies/procedures, lack of knowledge, system failures and lack of policies/procedures governing processes and design were the most frequently reported causes of events.

**1. HUMAN FACTOR - LACK OF KNOWLEDGE- TRAINING AND COMPETENCE**

Similar to NHO report (2007), the failure of knowledge although staff had received training, was the second most frequently reported human error this year, especially for clinical staff implicated in IBCT.

**a. Medical Staff**

Poor knowledge as a contributing factor to transfusion error is not new. Previous NHO reports have also identified this, and it is also comparable with studies on medication error (Leape at al, 1995). One option is to comprehensively address this deficiency during training, however, there is currently no agreed curriculum in transfusion at undergraduate level in medical schools in Ireland.

This leaves a gap which hospitals try to fill by providing appropriate and focused training in haemovigilance and blood transfusion to staff involved in transfusion, which is delivered by HVOs, medical scientists and haematologists. Although evidence of training of staff in blood transfusion is part of the INAB’s interpretation of ISO15189 at inspections, in many hospitals, there is still poor uptake of these sessions by medical staff especially at Senior House Officer (SHO), Registrar and Consultant level.

Other options such as collaboration between the academic institutions and hospitals should be explored. A recent study carried out at Beaumont hospital and the Royal College of Surgeons in Ireland (RCSI) (Robb et al 2009) showed increased confidence among medical students in undertaking clinical and practical skills following completion of an intensive two week “sub-internship” programme. During the two week duration of this programme, final year medical students assumed the role of “highly-supervised” interns, participating in clinical rounds, case conferences and event on-call schedules. Inclusion of transfusion at this point may focus on clinical transfusion skills of future interns working in hospitals.

### **b. Medical Scientists**

The requirement for training and competency assessment for all staff working in the HBB including out of hours staff has been clearly defined by both ISO15189 and AML-BB Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of SAR/SAE) of EU Directive 2002/98/EC and is audited during inspections.

More recently specific recommendations regarding training and competence for medical scientists working in the HBB have been made by the UK Transfusion Laboratory Collaborative (Chaffe et al, 2009). This collaborative is made up of both scientific and medical expertise and recent recommendations arose following analysis of adverse events reported to the UK SHOT scheme. The recommendations include:

- minimum qualifications for medical scientists in HBB,
- ongoing training and competency assessment for core and on call medical scientists in the HBB,
- availability of specialist scientific advice during on call hours.

These recommendations have considerable resource implications.

### **c. Competency Assessment**

Competency is a process which denotes not only knowledge, but also a technical proficiency (Office for Health Management, 2004). In the UK, the National Patient Safety Agency (NPSA)

launched competencies in defined aspects of the transfusion work process e.g. obtaining a venous blood sample, organising the receipt of blood for transfusion etc. (NPSA, 2006).

A recent pilot study in Scotland found both clinical assessors and practitioner’s experience of a formalised clinical competency on administration of blood components to be very positive (Pirie and Gray, 2007). This small study focussed on nurses and did not examine the perceptions of other staff in the transfusion process e.g. portering, medical scientists or medical staff.

Implementation of the NPSA standards has varied throughout the UK but they have been fully implemented in Northern Ireland (NI) with the support of the NI Regional Transfusion Committee. An evaluation of clinical practice following implementation of these standards would be useful.

Competency assessment for all clinical staff may be challenging especially to ensure engagement by multidisciplinary teams. It is also resource intensive and requires organisational support for the initiative at senior clinical and management levels.

### **d. Role of hospitals**

As detailed above, training programmes provided in hospitals are important in improving transfusion safety.

There is, however, a significant body of evidence showing that effective learning requires not only appropriate training, but also an organisational culture which reinforces this training (Senge 1990). Culture change can be internally led by local champions who support good practice. This may be the Consultant Haematologist, the HVO, the medical scientist or the anaesthetist in theatre supported by the hospital transfusion committee.

Hospital management must also support safe transfusion practice by developing a learning culture through ensuring protected time for education, accessibility to online transfusion resources and support for reporting and learning from adverse events.

#### **e. Role of NHO**

The NHO continues to deliver formal education opportunities in collaboration with DCU targeting primarily clinical and laboratory haemovigilance staff.

Since 2007, the IBTS/NHO in collaboration with the SNBTS actively encouraged hospitals to make the web based transfusion e learning/competency assessment programme Learnpro NHS available to their staff.

#### **2. System Factor-Policy Development**

While the initial response to an adverse event may be to develop new policies, in many cases failure to adhere to already existing policies was evident in both the clinical area and in the HBB. The NHO has reported similar findings both in 2007 and 2008. Political, organisational, scientific and cultural concerns ranging from inadequate staffing levels, busy rosters, concerns about limitations on clinical judgement all act as barriers to successful implementation of policies (The Appraisal of Guidelines Research and Evaluation (AGREE) Instrument, 2003; Bose et al, 2006; Napoli and Jagoda, 2007). Staff developing clinical and laboratory policies should be aware of these concerns.

#### **3. System Factor- Process/System Design**

Poor design of processes and systems was the second most frequently reported system error in 2008. This emphasises the importance of evaluation of all aspects of systems and their impact on practice, especially where changes have been introduced.

In terms of the HBB, a recent survey of the functionality of blood bank IT systems in the UK indicated that many of the systems were installed before 2000 and have only limited ability to support and improve transfusion practice (Murphy and Little, 2008). Similarly, restricted LIS are still in place in the vast majority of hospitals in Ireland. The recommendations are that HBB systems should interface with hospital information systems and have the potential to interface with bedside transfusion blood sampling and administration systems, and that they should also interface with blood centre systems to facilitate imposed blood stock management are fully applicable in Ireland. This recommendation has received further support in the recent report from the UK Transfusion Laboratory Collaborative (Chaffe et al, 2009).

#### **Key Points**

- Training of staff especially medical staff is complex. Implementation of a standardised transfusion programme for undergraduate students should ensure emerging clinicians will have an understanding of safe transfusion practice. The role of the practice education delivered by the HVO, Consultant Haematologist and senior medical scientists is also critically important to integrate theory and safe practice.
- Initiatives such as audit, provision of feedback, presentations or acting as a “clinical/laboratory” presence by the Consultant Haematologist, hospital HVO and senior medical scientists in the HBB are important in raising the profile of safe transfusion practice.
- HBB should consider their practices with regards to technology, staffing, training and competencies in view of recent recommendations of UK Collaborative (Chaffe et al, 2009).



In 2008, the NHO received 24 reports relating to IBCT/SAE in paediatric patients <18 years. The age profile of patients is presented in IBCT/SAE Table 10.

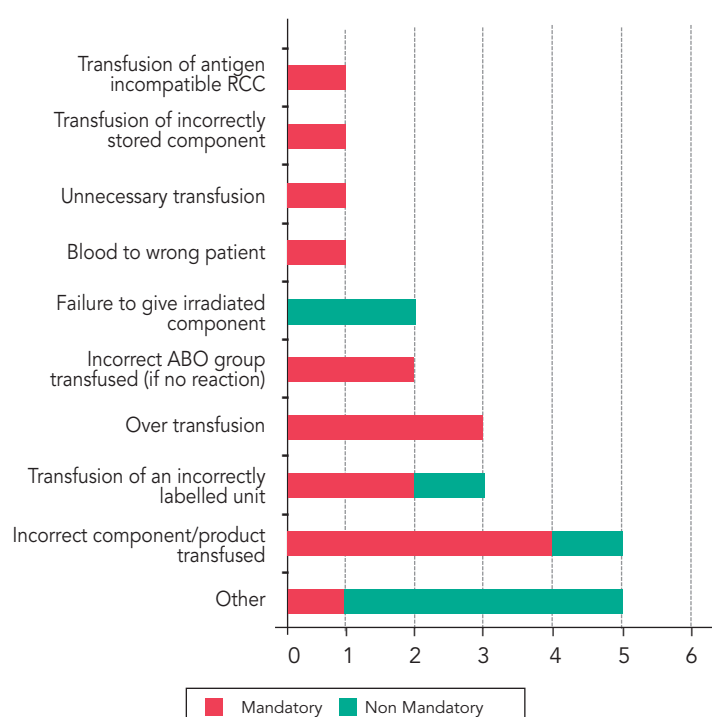
**IBCT/SAE Table 10: Age profile of paediatric patients (n=24)**

Age	n
Neonate (<28 days)	5
Infant (1-12 months)	8
Infant (1-4 years)	4
Child (5-12 years)	4
Adolescent (12-17 years)	3

## Categorisation of IBCT/SAE in paediatric patients

All reports analysed by the NHO, were initially categorised by the nature of the adverse event experienced by the patient and potential to cause harm.

**IBCT/SAE Figure 5: IBCT/SAE in paediatric patients (n=24)**



## Major clinical findings

### Incorrect ABO group transfused (n=2)

Two cases involved transfusion of incorrect ABO red cells to a neonate (IBCT/SAE Case History 12) and ABO platelets to an infant (IBCT/SAE Case 13).

#### IBCT/SAE Case History 12

This case concerned an 11day-old neonate whose blood group was group A RhD positive with immune (maternal) anti-A detected. In this situation the patient should have received group O red cells. The error involved the selection of incorrect group A red cells. This error was made in the HBB and was complicated by the multiple requirements of this particular patient. Follow-up investigation outruled haemolysis and there were no sequelae.

#### IBCT/SAE Case History 13

In this case, an infant whose blood group was group O RhD negative, but who had undergone a group AB positive bone marrow transplant, was transfused group O RhD negative apheresis platelets in error. The error occurred in the HBB and the medical scientist routinely worked in the laboratory. While there were flags in the LIS and the patient's history was on the transfusion request form, the medical scientist in this case did not review the flags. The error was discovered by a medical scientist when the patient was crossmatched ten days following the event.

**Error Cause:** One of the root causes identified was a system failure in the design of the LIS, where the medical scientist must access the flags on the patients' record, and where they do not automatically appear on a pop-up screen, forcing the medical scientist to acknowledge each flag.

Had the flags been reviewed at time of issue, this would not have prevented the issue of incompatible blood, as the purpose of computer flags is to alert and inform users decision process and not prevent actions.

## Blood to wrong patient (n=1)

### IBCT/SAE Case History 14

In this case, two neonate twins requiring transfusion were cared for in ICU. Nursing care in the unit was delivered on a one to one basis. The nurse caring for twin A collected the unit of red cells issued to twin B. This unit was transfused. The error was discovered by a medical scientist in the HBB when the nurse caring for twin B came to collect a unit for her patient. A review of contributing causes to this error identified that both patient identifiers were extremely similar. Both twins were of same gender, had identical names (as neither baby had a first name at the time) and dates of birth, and their medical record numbers were only differentiated by one digit.

**Error cause:** The root causes of this event were identified as human failures as follows; failure to follow policies – checking was remote from the patient, failure to verify the correct details against the patient, and human slip - nurses at collection and at checking missed the one digit difference in the medical record number.

## Transfusion of antigen incompatible red cells (n=1)

### IBCT/SAE Case History 15

An adolescent patient with an anti-Jk<sup>a</sup> antibody was transfused Jk<sup>a</sup> positive red cells. While this patient had previously been transfused and had a Jk<sup>a</sup> antibody history noted in the HBB, a flag identifying this history had been removed from the LIS. Further investigation failed to identify when or how this had occurred.

### Unnecessary transfusion (n=1)

This child received an unnecessary red cell transfusion, based on an incorrect haematology result.

### IBCT/SAE Case History 16

The event occurred when an incorrect Hb result was released from the haematology

laboratory and resulted in a child receiving an unnecessary red cell transfusion. The Hb was read on the laboratory analyser which was not in fact working properly, and the mandatory repeat which was undertaken to check the aberrant result was performed on the same analyser as the second analyser was out of service.

### Incorrect Component Transfused (n=5)

There were four cases of transfusion of incorrect red cells and one of platelets involving infants.

### Unnecessary Donor Exposure

In three cases involving red cells, infants received red cells, when there were assigned paedipacks in the HBB. This resulted in unnecessary donor exposure. In all cases, the crossmatched units were available for intraoperative use, and remained available in a satellite fridge after the patient was returned to the clinical area. In two of these cases, first site of error was prescription/request.

Two system failures were identified as contributing to one adverse event, a lack of training for doctors on prescribing red cells, and custom and practice, where red cells available in a satellite fridge for theatre were used for top-up transfusions to infants. In the final case the site of first error was the HBB.

In the fourth case, a unit of red cells was crossmatched for an infant. In the interim period, the baby's surname changed and when the red cells were issued to the clinical area, the nurse looking after the patient "updated" the compatibility label with the baby's name, instead of returning the unit to the HBB.

In the final case, an infant received pooled instead of apheresis platelets. This adverse event occurred out of hours and the medical scientist involved did not normally work in the HBB.

A further case of unnecessary donor exposure was reported as an over-transfusion (IBCT/SAE Case History 17).

### Over Transfusion (n=3)

These events occurred at the administration stage of the work process. A further episode of

over-transfusion was collected as an unclassified SAR, (SAR Table 3: Symptoms associated with unclassified reactions page 49 (Case 4)).

#### **IBCT/SAE Case History 17**

A critically ill three month old infant in an intensive care unit should have received 90 mls of red cells, but was instead transfused 200mls. This occurred when a nurse incorrectly calculated the transfusion rate on the infusion pump, thereby delivering increased volume to the infant. While this patient suffered no apparent sequelae, this over-transfusion would not have occurred had he received a readily available paediatric pack in the laboratory. While it was not clear why this occurred, it is noted the patient had been in theatre.

#### **Transfusion of incorrectly labelled units (n=3)**

There were three reports in which paediatric patients received incorrectly labelled components. These errors were not picked up at the bedside.

In one case, a medical scientist selected the incorrect donor number for label and printed the label. While the hospital compatibility label contained the correct patient demographic information, the unit number was incorrect.

In the second case, a doctor working in A&E incorrectly labelled a sample tube with the incorrect gender of the patient. The patient was unconscious. This was an emergency situation with multiple trauma and casualties.

The third case is separately described.

#### **IBCT/SAE Case History 18**

A 14 year old child was transfused with an unlabelled cell salvaged unit of blood. All cell salvaged units were routinely transfused in theatre, but in this case the unit was returned to the clinical area. A nurse caring for the patient transfused the unit. The reporting establishment deemed the site of first error to be administration, as the nurse should not have transfused this unlabelled unit. This non mandatory IBCT was discovered by the HVO.

**Error cause:** There were clear system failures underpinning this event. Firstly there

was only one experienced technician to manage intra-operative cell salvage in the hospital. In this case, he was unavailable and an inexperienced colleague managed this case. There was a failure of management to prioritise safety and invest in a full time deputy for the technician. Secondly, there were no policies in place to manage the cell salvage process in the hospital. Furthermore the patient was hurriedly returned from theatre and there was no supporting documentation or communication of the intra-operative cell salvage process.

#### **Failure to transfuse irradiated components (n=2)**

Both events involved red cells, and site of error was at prescription/request in one case and at the HBB in the second case.

#### **Transfusion of incorrectly stored red cells (n=1)**

This event involved transfusion of red cells over six hours following initial removal from storage.

#### **Other adverse events (n=5)**

The following events were included:

- Use of a non-filtered administration set at administration n=3.
- Patient in Sick Cell Crisis transfused with ABO and RhD compatible red cells, but units were not phenotyped due to error in the HBB n=1.
- Transfusion of red cells where pack was perforated n=1.

#### **Specific paediatric practice issues highlighted in reports of 2008**

In 2008, there were two cases where neonatal patients received blood components of incorrect ABO group, thereby not meeting the needs of these patients.

Both laboratory and clinical practitioners working in specialist neonatal and paediatric organisations must be aware of the specialist requirements of their patients.

Patient identification is central to safe transfusion practice. There are certain identification issues inherent in paediatric practice, which make it more challenging e.g. the case of the twin who received the wrong

blood, or where patients' names are changed.

Paediatric hospitals must be aware of these issues ensure that patients are correctly identified. Staff caring for patients must be reminded that "short-cuts" may result in unsafe practice.

In 2007 and again in 2008, the NHO reported cases where neonatal patients are unnecessarily exposed to further donors. In all cases, there were assigned paedipacks already available for patients. These errors tend to occur when blood is available in both the HBB and in a satellite fridge for patients, for use during surgery, which is not used and not returned to the HBB.

Hospitals should examine their work process to minimise these occurrences. In one reporting establishment, training and clinical updates highlighting this issue were increased to the clinical areas involved. This has resulted in an almost complete reduction in these adverse events in 2009.

Again in 2008, the NHO noted reports of over-transfusion in paediatric patients. While there were no associated reports of TACO, neonatal and paediatric patients are at risk of such an event. There was one report of an SAR in 2008 resulting from over-transfusion. All errors occurred at administration, where incorrect calculations resulted in these errors. In one case, an ambiguously documented prescription contributed to the error.

- Medical staff should ensure that prescribing rates and volumes of transfusions for these patients are unambiguous.
- Nursing staff should carry out independent cross checks of rate and volume prior to transfusion.

### Key Points

- Almost 22% of all reports of IBCT/SAE related to paediatric patients.
- Up to 12% of all IBCT/SAE reports involved patients aged less than one year.
- Analysis of IBCT/SAE in terms of potential to cause harm to patients showed that 63% of reported IBCT/SAE had high potential to cause harm in paediatric patients, compared with 39% of reports in the adult population, thereby highlighting risk to paediatric patients receiving transfusions.
- Paediatric patients are long term survivors of transfusion therapy. It is important that practitioners working in paediatric centres continuously seek to minimise donor exposure to these patients.

# IBCT Involving Factor Concentrates/Blood Products

2008

The NHO collects incidents involving errors involving factor concentrates and blood products as they relate to transfusion practice. Incidents involving anti-D are described in a separate chapter. Adverse reactions to factor concentrates and blood derived medicinal products fall under pharmaceutical legislation and as such are directly reportable to the Pharmacovigilance section of the IMB and therefore are not described in this report.

Serious adverse events involving factor concentrates are not reportable under the EU blood Directive. There were seven IBCT involving factor concentrates/blood products, one of which involved a paediatric patient. There were no sequelae in any of the reported incidents.

## Findings

### Wrong Product (n=4)

Four cases (57%) involved the wrong product being administered.

In the first case a young adult with Von Willebrand's disease presented at the emergency department (ED) following a head injury. The doctor on duty administered Vasopressin (DDAVP) used in many patients with Von Willebrand's disease to raise factor VIII levels. However, this particular patient does not respond to this product and should have received human derived factor VIII. The error was discovered on review of the case by the consultant haematologist who prescribed the correct product. Analysis of the incident identified that a contributory factor was failure of the prescribing doctor to contact the consultant haematology team for advice. In addition, the incident occurred out of hours when the patient's medical record was unavailable. An electronic record was available but the prescribing doctor failed to access it. There were no sequelae as a result of this incident.

The second case involved an elderly patient on warfarin therapy (INR=7.9) for an underlying

cardiac condition who presented with dyspnoea and wheeze following a collapse at home. The patient received recombinant Factor VIIa when the correct product should have been vitamin K (as stipulated in hospital guidelines). This was given the next day. The error was discovered retrospectively by the HVO. While there were no sequelae as a result of this error, the patient was exposed to recombinant Factor VIIa which should not be used outside the recognised indications because of high risk of complications

The remaining two cases were due to inappropriate administration of PCC. One case involved an elderly patient with multiple pathologies who was given PCC eight days following a surgical procedure. The patient was not actively bleeding, but her blood platelet count and coagulation screen were abnormal (Platelets=32: Activated Partial Thromboplastin Time (APTT) =150: INR =5.0). The product was prescribed following advice from the haematology registrar but the consultant haematologist, on review, decided this was incorrect.

The second case was attributable to failure to adhere to the hospital guidelines in place at the time. The prescribing doctor ordered PCC for post-operative bleeding (INR of 2.3) for a patient not on Warfarin. As the hospital policy has since been amended to allow the use of PCC in massive haemorrhage if the patient continues to bleed after administration of SD Plasma, retrospectively this cannot be considered as an IBCT, but was collected as such at the time.

### Wrong Dose (n=3)

Three cases (43%) errors involved the wrong dose of product being given. In one case the consultant haematologist gave a verbal order for a patient with a severe factor VIII deficiency to be given 3,000 international units (IU) of factor VIII. Prior to administration the product and dosage was checked by two nurses. During administration, however, the nurse realised she



had made an error and stopped the infusion but by then, 3,500 IU had been given. Contributory factors to this incident were that there was no written prescription for the product and the second nurse checking the dosage was unfamiliar with the product. There were no complications as a result of this incident.

In the remaining two cases the patients received a smaller dose than had been prescribed. In one case, a patient with a severe factor VIII deficiency had a gastro intestinal (GI) bleed. The doctor calculated that the patient required 4,000 IU of factor VIII. However, when removing the vials she took the wrong size vial from the fridge and administered only 3,500 IU. The error was discovered retrospectively by the HVO. Investigations identified that although the doctor checked the product with a nurse prior to administration, the nurse was unfamiliar with the product, and secondly, this event occurred at the end of a shift. There were no sequelae as a result of this incident. The second case is described in IBCT/SAE case history 19.

#### **IBCT/SAE Case History 19**

This case involved an infant with factor VIII deficiency. The infant had undergone a surgical procedure and was prescribed a continuous infusion of factor VIII (Advate) 4 IU per kg/per hour over a five day period. In error, the infusion was set at 2 IU per kg/per hour. This was not discovered until 48 hours later when a HVO was training clinical practitioners and noticed the infusion pump had been set at the incorrect rate. There were no sequelae as a result of this under treatment. A contributory factor was that the prescribed rate of infusion for this product was different to that normally used in this clinical situation. In addition, the incident occurred over a weekend when staff familiar with this product and protocols were off-duty.

#### **Recommendations**

- Several cases described in this report occurred due to lack of knowledge, unfamiliarity with the different products and a failure of clinical staff to adhere to policies and guideline. This was also highlighted in

the 2007 NHO Annual Report. The risk of errors when administering factor concentrates is a constant hazard, particularly if staff are unfamiliar with the available products. To reduce this risk there needs to be systems to ensure the correct product is administered 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's Hospital, Dublin 8.

- Where possible, staff familiar with coagulation and blood products should be involved in their checking and administration. If clinical staff are unfamiliar in treating patients with coagulation disorders, they must seek advice from a coagulation specialist.
- Verbal orders for coagulation factors and blood products are to be avoided. Instead there must be a written prescription reducing the risk of error.
- If a hard copy of the patient's record is unavailable out of hours, then staff should be trained and aware of where to find the electronic record. All staff involved in the prescription, issue and administration of factor concentrates and blood products should receive appropriate training.

# Adverse Events associated with Anti-D Immunoglobulin

2008

Incidents involving errors or omissions relating to anti-D Immunoglobulin (Ig) should be reported to NHO as non-mandatory IBCT as they relate to transfusion practice. They should also be reported internally within the hospital risk management procedures.

Adverse reactions related to the administration of anti-D Ig are reportable directly to the IMB under the Pharmacovigilance Scheme and if received by the NHO, are forwarded to the IMB. These are therefore not covered in this report.

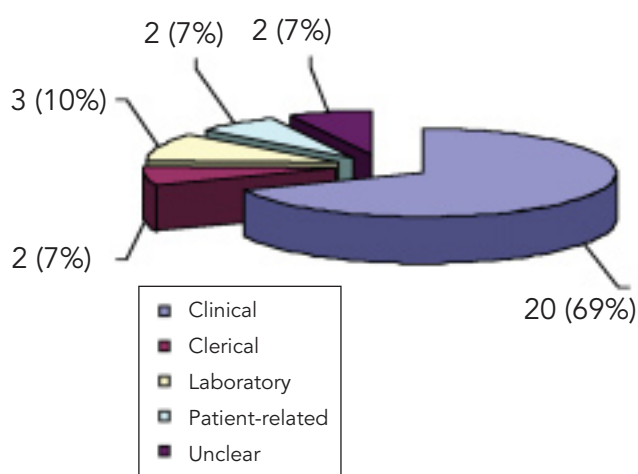
Serious adverse events related to anti-D Ig are not reportable under the EU Blood Directive.

## Findings:

There were 29 reports of serious adverse events associated with anti-D Ig administration. This represents an increase of 45 % compared to 2007. Twenty-eight cases were categorised as level 1 or high risk that is having real potential for sensitisation or harm. The remaining case was categorised as level 2 or moderate risk meaning it is unlikely to cause permanent harm to the mother or foetus immediately in the future as the patient did not fit the criteria for anti-D Ig.

The majority of errors were due to omission or delay in administering anti-D Ig, and most errors occurred in the clinical area as shown in Anti-D Figure 1. In some cases the error involved more than one department or person.

**Anti-D Figure 1: Where error occurred (n=29)**



## Omissions related to failure to give anti-D Ig in antenatal patients (n=12)

In 12 cases, anti-D Ig should have been given but was omitted. All cases were associated with human error and in two cases system failures were also identified. The reasons for the errors are shown in Anti-D Table 1. In two cases more than one error cause was identified.

**Anti-D Table 1: Breakdown error causes in anti-D Ig IBCT (n=14)**

Human Failure	n	System Failure	n
Knowledge	5	Culture	1
Co-ordination/Communication	1	Policies/Procedures	1
Failure to adhere to policies and procedures	3		
Unclassifiable	1		
Patient-related	1		
Slip error	1		

## Omissions related to failure to give anti-D Ig in antenatal patients (n=12)

All 12 cases involved Rh D negative antenatal patients who presented with bleeding per vagina (PV) or following trauma. Ten of these cases occurred in general hospital emergency departments (ED) and it is known that in at least two of these cases the patient has subsequently become sensitised.

In one case an Rh D negative patient attended for her first antenatal visit at 15 weeks gestation and reported that she had PV bleeding a few days earlier. She was grouped as Rh D negative and no antibodies were detected. Anti-D Ig was not administered but it was unclear if the omission was due to failure to follow-up on the result or due to lack of knowledge of the doctor at the antenatal clinic. Anti-D was detectable in her serum five months later. The patient subsequently delivered an Rh D positive baby but anti-D Ig was

not given as the patient had already been sensitised.

In a further case, both system and patient-related factors were involved when there was a delay in the doctor attending to administer anti-D Ig. The patient went home and refused to return for treatment. In the remaining cases either the patient's blood group was not checked or the junior doctors on duty felt anti-D Ig was not indicated despite the availability of hospital guidelines.

**Anti-D Case History 1**

In another case an Rh D negative mother of 34 weeks gestation attended an ED with PV bleeding. An emergency sample was manually grouped as Rh D positive. However, the next day during checking of the results of 'on call' work on the blood grouping analyzer, the patient was found to be Rh D negative. At the time of the incident there was no link between the manual and automated blood group result, this has since been corrected. Additional contributory factors were that the patient had two records with two different hospital numbers. In one chart it was noted the patient had attended the hospital complaining of a urinary tract infection with no mention of bleeding. In addition, the results of the emergency blood sample were filed in the wrong chart. The anti-D Ig omission was only discovered by chance when the patient was in labour, and the midwife happened to mention the error to the Haemovigilance Officer.

**Delay in administering anti-D (n=13)**  
In a further 13 cases, anti-D Ig administration was delayed beyond the recommended limit of 72 hours following a sensitising event. In one case there was no documentation to indicate why the error occurred. Human error was involved in all of the remaining 12 cases, and in two cases system errors were also identified. The findings of root cause analysis of these incidents are shown in Table 2. In six incidents more than one error cause was identified.

**Anti-D Table 2: Delay of anti-D Ig: Error cause (n=19)**

Human Failure	n	System Failure	n
Failure to adhere to policies and procedures	5	Culture	1
Knowledge	1	Design	1
Verification	1	Policies/Procedures	1
Co-ordination/Communication	8		
Carrying out task incorrectly	1		

**Anti-D Case History 2**

In this case the administration of anti-D Ig was delayed due to a difficulty in interpreting the cord bloods. Following delivery of a baby to an Rh D negative mother cord blood samples were sent to the laboratory at a weekend. The hospital blood bank scientist interpreted the cord blood sample as Rh D negative but was not completely satisfied with the result. A repeat sample showed a similar result, therefore cord blood samples and a sample from the baby were sent to the reference centre for further analysis. The reference centre found the cord sample to be Rh D positive (weak D type) but the delay resulted in the anti-D Ig being administered more than 72 hours post-delivery.

**Anti-D Case History 3**

In another case an Rh D negative mother was given anti-D Ig one day prior to delivery for an ante partum haemorrhage. The next day the mother gave birth to an Rh D positive baby. However, this was not seen as a further sensitising event requiring anti-D Ig. Consequently anti-D Ig was not given until more than 72 hours following delivery.

**Unnecessary Treatment with anti-D Ig (n=4)**  
There were four cases of unnecessary anti-D Ig administration to Rh D negative mothers. All of these cases were found to be due to human error, more specifically lack of knowledge, and in two cases a failure of communication contributed to the error.

### Anti-D Case History 4 & 5

In two cases anti-D Ig was given to previously sensitised patients. In the first case a patient had suffered a sensitising event several years previously and had developed antibodies. There was a record of this in the hospital laboratory records. At 24 weeks gestation in this pregnancy, following a fall, she attended the ED and was given anti-D Ig without checking her blood group or antibody status. The incident occurred at a weekend when it is practice at this hospital for clinical staff to collect anti-D Ig from the laboratory, and the patient's blood group and antibody status were not checked prior to administering the anti-D Ig.

In the second case an Rh D negative mother with known anti-D and anti-E antibodies was given anti-D Ig post-delivery of an Rh D positive baby. This indicated a lack of knowledge on the part of the clinical staff. A contributory factor was that the medical scientist did not question the issue of the anti-D Ig. This practice is now under review.

### Anti-D Case History 6

In another case an Rh D negative patient was found to have developed anti-D in her serum at 29 weeks gestation. The anti-D was quantitated on three further occasions by the reference laboratory and referral for fetal medicine assessment had been advised. At delivery a further maternal sample was taken and referred for quantitation. The baby was DAT positive and grouped as Rh D positive. However anti-D Ig was issued by a medical scientist who had just recently completed training. The error was discovered by another medical scientist when updating the patient's record.

### Anti-D Case History 7

The final incident involved a patient who underwent a caesarean section and subsequent hysterectomy for post-delivery complications. Anti-D Ig was issued from the blood transfusion laboratory who had not been informed that the patient had had a hysterectomy. Clinical staff were unsure whether to administer the anti-D Ig. The hospital did have anti-D Ig guidelines but they did not indicate what action should be

taken for Rh D negative patients post hysterectomy. After a clinical review it was decided to administer the anti-D Ig. The hospital guidelines have since been amended to include guidance on indications for anti-D Ig in Rh D negative women post- hysterectomy and tubal ligation.

### Follow up action

In a number of cases no changes to practice were reported. For those hospitals that did introduce changes several amended their training programmes for clinical staff on the indications for the administration of anti-D Ig. Other changes included:

- Better communication / informing all staff and departments involved in the early discharge of post-natal patients to ensure follow-up of Rh D mothers requiring anti-D Ig after discharge.
- Rechecking of manual and automated grouping.
- At one site where it is routine practice for doctors to administer anti-D Ig it is proposed that midwives give anti-D Ig to avoid delays in patients receiving anti-D Ig.
- Where ante-natal patients present with a history of trauma or bleeding in pregnancy hospital policies have been changed to indicate that they should not be discharged before their Rh D status has been established and the appropriate treatment given.

### Key Points

- A number of hospitals still do not have guidelines for the administration of anti-D Ig. Each hospital should have clear written protocols indicating when and how to administer anti-D immunoglobulin.
- Lack of communication or co-ordination within or between departments or individuals were notable factors in the delays and omissions of anti-D Ig prophylaxis cases. Similar findings were reported in 2007.

- Two cases of anti-D Ig sensitisation reported this year were attributable to a failure to administer anti-D Ig during a pregnancy. Several incidents demonstrated a lack of understanding or failure to adhere to guidelines for administration of anti-D Ig. Despite this being highlighted in previous NHO reports there still appears to be a deficit of knowledge among clinical staff of when to administer additional anti-D Ig for sensitising events following previous antenatal administration. There is a need for specific education in those instances when Routine Ante-natal Anti-D Prophylaxis (RAADP) is introduced (NICE, 2002; BCSH, 2006a).
- Two cases relating to unnecessary anti-D Ig reflect a lack of knowledge and protocols for the management of sensitised pregnancies and raise concern over possible failures to monitor pregnancies at risk of HDN.

negative card (BCSH, 2006b) with listed indications for prophylaxis to the patient.

- If the HBB Rh D typing results are inconclusive or discrepancies are identified then there should be a protocol indicating the procedure to follow. As noted in previous NHO reports (2004) such samples should be referred to a reference laboratory but the hospital must have systems in place to ensure that those patients requiring anti-D Ig receive it and that it is not omitted or delayed.
- Clear procedures for communication of the requirement for anti-D Ig prophylaxis should be implemented.
- Hospital guidelines need to clearly state that anti-D prophylaxis should be administered in response to sensitising events regardless of recent or planned administration of prophylactic anti-D.
- Anti-D Ig should only be issued by experienced trained laboratory staff who are able to interpret the results.
- Training of laboratory staff on when anti-D Ig should be administered is also required. An e-learning module for laboratory and clinical staff on anti-D Ig and antenatal testing is in preparation and will be added to the e-learning programme in 2010 (<http://www.learnbloodtransfusion.org.uk>) It is recommended that these modules are made available for training of clinical and scientific staff involved in antenatal testing and anti-D Ig administration and that they perform the competency assessments within the modules.

## Recommendations

- There should be clinical follow-up and retesting in 6 months of patients in whom anti-D Ig administration has been delayed or omitted. Any sensitisations arising should be reported to the NHO as well as internally. Similarly a review of the previous obstetrical history should be performed to determine if anti-D Ig was administered in accordance with prophylaxis guidelines in all new patients presenting with immune anti-D in their serum.
- The requirement for anti-D Ig prophylaxis must be included in the discharge checklist procedure for Rh D negative women, particularly in the case of early post-natal discharges.
- The patient should be informed of her Rh D negative status and situations requiring anti-D prophylaxis.
- There should be clear identification of the patient's Rh D negative status in both hospital and shared care files.
- Hospitals should consider using a Rh D



There were 196 SAR reports during the reporting year 2008. After review, 143 SAR reports were accepted by the NHO and the remaining 53 did not progress (DNP) as they did not meet reporting criteria. As in previous years, there were no reports of Transfusion Associated Graft versus Host Disease (TAvGHD), Post Transfusion Purpura (PTP) or adverse donor reactions related to predeposit autologous transfusion (PAD). There was one report received as TRALI.

## Acute Transfusion Reaction (ATR)

ATR are defined as those occurring within 24 hours of transfusion. Acute reactions include:

- Acute Haemolytic Transfusion Reactions
- Febrile Non-Haemolytic Transfusion Reactions
- Acute Allergic and Anaphylactic Transfusion Reactions
- Hypotensive Reactions
- Unclassified Reactions

During the reporting year 2008, 89 reports of ATR were reported. The breakdown is given in the table below.

**SAR Table 1 (n=89)**

Serious Adverse Reaction	Total number progressed
AHTR	2
FNHTR	38
Acute Allergic and Anaphylactic Transfusion Reactions	41
Unclassified	6
Hypotensive	2
Total	89

# Acute Haemolytic Transfusion Reactions (AHTR) (n=2)

2008

**Definition:** Acute Haemolytic Transfusion Reaction (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.

## Findings

Two AHTR reactions were reported in 2008. Both reactions were immunological haemolysis due to other allo-antibody. In the first case the patient with a history of anti-Fy<sup>a</sup> antibody was transfused with a Fy<sup>a</sup> positive unit due to an error in the HBB (SAR Case History 1).

## Immunological haemolysis due to other allo-antibody acute

### SAR Case History 1

This patient with a history of anti-Fy<sup>a</sup> antibodies required a transfusion of two units of red cells out of hours. Within one hour of commencing the transfusion the patient had a reaction. On investigation it was discovered that the patient had been transfused in error with a Fy<sup>a</sup> positive unit due to an error in the antigen typing.

**Error Cause:** The error happened on call over the weekend. The medical scientist who rotated through the HBB on a regular basis carried out the antigen typing incorrectly due to human error. Also due to a system failure there was insufficient documentation of the technical results during the procedure to enable checking of the scientist technique and results.

**Changes to practice:** As a result of the error, there was retraining of staff, amendments to the policies and procedures and a new stepwise recording system for all technical work implemented.

### SAR Case History 2

In the second case the patient had both an acute and delayed reaction. This case involved an elderly male patient who had required transfusion post operatively and required further transfusion support. A pretransfusion sample was sent and was found to be DAT positive (1+). (IgG(+w) and C3d(1+)). The patient had an anti-D and anti-Fy<sup>a</sup> identified but a non specific antibody reacting in IAT and Enzyme panels was also detected.

The least incompatible red cells RhD negative Fy<sup>a</sup> negative were issued for this patient and transfused the following day. Just over three hours into the transfusion the patient developed symptoms of hypertension, pyrexia and chills. On investigation of this reaction the patient had a raised bilirubin level, DAT was negative and antibody specificity on the post transfusion sample remained undetermined.

Ten days later the patient was readmitted for investigations and it was noted that there had been a fall in Hb associated with a transient elevation of bilirubin. The DAT was still negative and antibody investigation was inconclusive. Samples were sent to a Reference Laboratory for further investigation an anti-K, anti-Jk<sup>a</sup>, anti-Fy<sup>a</sup> and anti-S were identified.

### Clinical Outcome

Both patients made a complete recovery.

### Key Points

- Although it may be necessary to issue least incompatible blood, in an emergency, samples should be sent to a reference laboratory for confirmation.

# Febrile Non Haemolytic Transfusion Reactions (n=38)

2008

**Definition:** FNHTR is defined as a rise in temperature of  $>1.5^{\circ}\text{C}$  above the patient's (pretransfusion) baseline value, together with rigors or chills, rarely nausea, vomiting or dyspnoea occurring during or within four hours following transfusion without any other cause, such as haemolysis, bacterial contamination or due to 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.

## EU Notification Category

FNHTR is incorporated in the following EU category: Other – FNHTR

## Findings

There were 38 reports which fulfilled the criteria for FNHTR, an increase of eight reports on 2007. Thirty seven of the patients experiencing a FNHTR were adults, the majority of these were elderly and one further reaction occurred in a child. Thirty five reactions were associated with red cells and one each with apheresis platelets, pooled platelets and granulocytes. The major concern in evaluating these reactions is to exclude bacterial contamination of the unit or haemolysis due to incompatibility (Heddle & Kelton, 2001).

Analysis of the cases reported indicates that the majority of the cases were investigated for bacterial contamination. Thirty one (81.5%) patients had blood cultures taken. In 29 (76%) cases the pack was sent for culturing and in 26 (68%) cases both the patient and pack were cultured. However, only 15 (39%) cases were investigated for haemolysis and only 13 (34%) cases in total were investigated for both haemolysis and bacterial contamination.

In addition to the 38 FNHTR reports received, four further cases which presented with febrile reactions were captured as STTI (See cases 1,2 3, and 4 SAR Table 10 STTI Bacterial).

## Clinical Outcome

A clinical outcome was given for all but one case. The majority of patients (32) made a complete recovery, with the timeframe of recovery given in 23 cases. Of these 23 cases, the majority of patients recovered within five hours, one patient recovered within seven hours and the final patient took eight hours to recover. Four patients suffered minor sequelae as a result of the reaction; two of these patients required overnight admission, the third patient took 24 hours to recover and in the fourth case, the recovery time was not given. One patient died unrelated to the transfusion.

# Acute Allergic and Anaphylactic Transfusion Reactions (n=41)

2008

## Clinical Signs & Symptoms and Laboratory Definitions

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.
- A small number of 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).

## EU Notification Category

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

## Findings

There were 41 reports which fulfilled the criteria for this reaction. Twenty seven (27) reactions occurred in adults and 14 occurred in paediatric/adolescent patients. Eleven (27%) reactions were associated with red cells, 15 (37%) reactions were associated with apheresis platelets, 13 (32%) reactions to pooled platelets (three reactions to pooled platelets in plasma, ten

reactions to pooled platelets in PAS) and one (2%) reaction each to cryoprecipitate and SD plasma respectively. Similar to last year, no cases of AA due to IgA deficiency with antibodies were reported, but IgA levels were only reported in 25 cases.

**SAR Table 2: Acute Allergic and Anaphylactic Reaction per type of platelet component issued 2008 (n=28)**

Type of platelet issued	Number issued	Incident of reaction per unit issued
Platelets pooled in PAS	9,848	1 per 984 units issued
Leucodepleted Platelets pooled in plasma	1,009	1 per 336 units issued
Apheresis Platelets	13,754	1 per 917 units issued

As in previous years, the majority of these reactions were associated with platelets with the highest reaction rates associated with platelets pooled in plasma and with much lower rates associated with pooled PAS platelets and apheresis platelets.

## Clinical Outcome

The clinical outcome was given in all but three cases. The majority of patients (35) made a complete recovery, with a number requiring minor treatment. The final three patients had minor sequelae, with two requiring overnight admission as a result of the reaction. The final patient recovered following symptomatic treatment.

# Unclassified Reactions (n=6)

2008

**Definition:** Unclassified SAR is the occurrence of new adverse symptoms/signs with no risk factor other than the transfusion and which on its own does not allow the reaction to be classified within the defined categories of SAR.

## Findings

A total of 16 reactions were originally submitted as unclassified reactions. Following review, six cases were recategorised (two FNHTR, two AA, one TAD and one Hypotensive reaction), four cases did not progress and six reactions were accepted as unclassified. Four of the patients were adults and two were paediatric patients. Four reactions were associated with red cells and two reactions were associated with apheresis platelets.

The table below shows the symptoms each patient experienced

## Clinical Outcome

Four patients made a complete recovery following minor treatment. The fifth patient (Case 4) in paediatric section who was a young child and was over transfused required a venesection, but fully recovered following this procedure and the sixth patient (Case 2) died unrelated to the transfusion.

## Recommendations for management of ATR

- Whenever possible, as a minimum, blood cultures and investigations for haemolysis should be taken on patients suffering a FNHTR to exclude red cell incompatibility or bacterial contamination.
- Reaction Alerts in patient charts and/or on the hospital patient admittance system and IT system can be valuable in those patients with a previous AA/FNHTR reaction to ensure appropriate component selection and pre medication prior to future transfusions.

**SAR Table 3 – Symptoms associated with Unclassified Reactions (n=6)**

Case No	Age	Component	Temperature Rise	Hypertension	Falling O2 Saturation	Substernal discomfort	Restlessness /anxiety	Other Details
1	Child (5-11 years)	RCC	Yes	Yes			Yes	Leg pain, pins and needles and discomfort
2	Elderly (70+)	RCC			Yes		Yes	Consolidation present on chest Xray prior to transfusion
3	Adult (51-70 years)	RCC						Flushing along infusion site
4	Neonate (<28 days)	RCC		Yes				Plethoric/bronze in colour
5	Adult (31-50 years)	Apheresis Platelets				Yes		Pins and needles
6	Elderly (70+)	Apheresis Platelets						Bilateral leg pain



# Hypotensive Transfusion Reaction (n=2)

2008

**Definition:** Characterized by a drop in systolic and/or diastolic blood pressure of >30mmHg occurring during or within one hour of completing transfusion with no other symptoms.

## Findings

This is the first year the NHO has collected this type of reaction. Two cases that fulfilled the reporting criteria were accepted by the NHO. Both cases involved neonates with underlying complex cardiac conditions. The implicated component in both cases was cryoprecipitate.

### SAR Case History 3

In the first case a neonate was bleeding while undergoing surgery. Within two minutes of receiving the component, the baby developed severe hypotension and responded in a similar manner when given a second dose. When the infusion was stopped, the blood pressure returned to normal. It was felt that the reaction was clearly related to the cryoprecipitate and was due to citrate toxicity

### SAR Case History 4

In the second case the patient had recently returned from theatre to the intensive care unit (ICU) following complex surgery and was bleeding. The cryoprecipitate was being administered when the patient went into cardiac arrest. Again, the reaction which was probably related to the cryoprecipitate was considered due to citrate toxicity and a decision was taken not to administer cryoprecipitate to this patient again.

## Clinical Outcome

In the first case the patient recovered when the treatment was discontinued. In the second case the patient had serious sequelae as the patient went into cardiac arrest but subsequently recovered.

# Delayed Haemolytic Transfusion Reactions (n=4)

2008

**Definition:** 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)

For the purpose of analysis, the NHO grades such reactions by severity using the SHOT criteria. (SHOT, 1999) These are:

**Group 1:** Asymptomatic with 'antibody only' detected, with or without a positive DAT.

**Group 2:** Demonstrates evidence of haemolysis measured by falling haemoglobin levels and a positive DAT.

**Group 3:** Evidence of a falling Haemoglobin level associated with jaundice, with or without a positive DAT level.

**Group 4:** Graded as for Group 3, but with associated renal impairment

Group 1 (no evidence of haemolysis) reactions are not reportable to the NHO, it is however, recommended that a record of all Group 1 reactions are maintained at hospital level.

## Findings

There were four reactions which fulfilled reporting criteria in this category in 2008. All the patients were elderly. It was unknown in three of the cases if the patient had a previous transfusion history. Again, this year, unfortunately investigations for haemolysis were incomplete. It would appear that many hospitals do not perform LDH levels routinely as part of their general biochemistry screen.

**SAR Table 4 Details of DHTR Reported (n=4)**

Case No.	Age	Gender	Imputability	Findings	Antibody	Category	Outcome	Previous Transfusion History	Days post transfusion
1	Elderly (70+)	Male	Possible	No LDH available, fall in Hb, jaundice, positive DAT	Anti M	Group 3	Death unrelated to transfusion	Unknown	2-8 days
2	Elderly (70+)	Male	Likely/ Probable	Elevated LDH, DAT positive pre/post transfusion, jaundice, no Hb level at time of reaction	Anti Kell	Group 3	Death unrelated to transfusion	Unknown	6 days
3	Elderly (70+)	Male	Likely/ Probable	Fall in Hb, no DAT, elevated LDH, elevated bilirubin	Anti Jk <sup>a</sup>	Group 3	Death unrelated to transfusion	Yes	7-14 days
4	Elderly (70+)	Female	Likely/ Probable	Elevated LDH, fall in Hb positive DAT.	Anti Fy <sup>a</sup> , Anti S	Group 2	Complete Recovery	Unknown	8-18 days

In Case 3, the patient required an emergency transfusion of four units of uncrossmatched blood for haemorrhage. The patient had a previously detected Jk<sup>a</sup> antibody present. It was subsequently determined that the first unit transfused was Anti-Jk<sup>a</sup> positive. Although the presence of Jk<sup>a</sup> antibodies was known, in view of the urgency of the situation a correct clinical decision was made to transfuse the unit.

### **Clinical Outcome**

In three cases the patients recovered from the reaction but died due to their underlying condition, the final patient made a complete recovery.

### **Recommendations**

- It is likely that DHTR is under diagnosed. It is essential that any patient presenting with unexplained anaemia some days after a transfusion should be investigated for immunological haemolysis (bilirubin, LDH, DAT, haptoglobulins and antibody screen) to exclude DHTR. In a number of the reports of DHTR in 2008 the investigation was incomplete. The successful diagnosis also depends on accurate history taking and the eliciting of a history of recent transfusion.
- The NHO has, in previous reports, suggested the development of a national patient antibody register for patients with red cell antibodies.
- Patients who have had previous pregnancies or transfusions are at risk of developing antibodies. Very often the HBB can be unaware of patients' history and the potential for antigen incompatible transfusions can be high. Development of a national antibody register could address this risk by ensuring access to patients' antibody history. It would also reduce the requirement for repeat laboratory testing.
- This would only be feasible with the implementation of a national Unique Hospital Identifier (UHI) , a recommendation made by HIQA (2009) and supported by the NHO. A UHI would facilitate improved and safer access to patients' records on a national antibody register thereby ensuring safer transfusion practice for patients.

## Transfusion Associated Circulatory Overload

### NHO Definition

TACO is characterised by the development of acute pulmonary oedema secondary to 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

There were 39 reports of TACO, accounting for 13% of reports of serious adverse reactions accepted by the NHO. This is over 100% increase in the number of reports when compared to 2007. There were 33 cases associated with red cells, four with multiple components and one with apheresis platelets. A further case associated with SD plasma was initially thought to be a TRALI but on subsequent investigations was reclassified as TACO (SAR Case History 7). Twenty seven (69%) were attributed as likely/probable to the transfusion.

### Symptoms and underlying conditions

Onset of overload developed 15 minutes to 13 hours after transfusion with a median onset of three hours. Falling oxygen saturation levels were reported in 20 cases and 28 (72%) of the patients had complex medical problems. While the majority of cases were associated with red cells, one case was associated with apheresis platelets in a bone marrow transplant patient with multiple co-morbidities.

The most commonly reported symptoms are outlined in SAR Table 5.

**SAR Table 5 Most frequently occurring symptoms in TACO (n=39)**

Symptom	n
Dyspnoea	29
Falling O <sub>2</sub> Saturation	20
Hypertension	15
Tachycardia	14

Underlying conditions were reported in 20 patients and one patient was reported as having underlying cardiac, respiratory and renal conditions. The recovery time-frame for patients with multiple underlying conditions was considerably greater than those who had only one or no underlying condition. Four patients took four days to 12 weeks to recover and three of these had a pre-existing history of cardiac, respiratory or renal conditions. Ten patients recovered within one to eight hours with five of these having no or only one pre existing condition.

**SAR Table 6 Underlying conditions of patients who developed TACO (n=47)**

Underlying condition	No of patients
Cardiac	26
Respiratory	9
Renal	12

The ISBT definition of TACO is more restrictive than that accepted by the NHO. The ISBT definition (2006) requires any four of the following five symptoms/signs occurring within six hours of completion of transfusion:

- Acute respiratory distress
- Tachycardia
- Increased blood pressure
- Acute or worsening pulmonary oedema on frontal chest radiograph
- Evidence of positive fluid balance

The number of TACO cases accepted by the NHO would reduce greatly if the ISBT criteria were adopted. This is evidenced by the fact that only one

case received by the NHO in 2008 met their strict criteria. However this may be due to the fact that only 10 patients had a chest X-ray and 12 patients had a completed fluid balance chart. In 27 cases the fluid balance record was not complete and 17 of these recorded input only.

### TACO in elderly patients

The majority of reports of TACO (69%) occurred in the elderly. The age and gender of the patients implicated in these reports are outlined in SAR Table 7. The patient's weight was not recorded in 16 cases and in seven cases the weight was less than 60kg. Twenty patients were on regular diuretics and of these ten received diuretics pre-transfusion, four during transfusion and 16 post transfusion.

Twenty patients had received other components in the 24 hours prior to transfusion. TACO occurred in four cases, three of whom had received red cells in the previous 24 hours where only 50-100mls of the unit involved in the reaction had been transfused. Diuretics were administered pre and during transfusion to two of these patients, emphasising the need for close monitoring of elderly patients.

**SAR Table 7 Age/gender of patients implicated in TACO reports 2008 (n=39)**

	Adult (18-30 years)	Adult (31-50 years)	Adult (51-71 years)	Elderly (70+)
Male	0	1	4	13
Female	1	4	3	13

### TACO in bleeding patients

There were three cases where patients with severe haemorrhage requiring massive transfusion developed TACO; two of these patients had no underlying condition. The third patient had acute renal failure which may have contributed to the TACO. While TACO in young previously healthy adults is unusual, there have been six similar cases reported to the NHO between 2000 and 2008. Five cases were in females less than 30 years of age with massive haemorrhage associated with obstetric and gynaecological complications and the sixth in a 41 year old male. Two of the six cases were reported in 2008 (SAR Case History 5 & 6).

### SAR Case History 5 (TACO)

A 21 year old female patient with massive post partum haemorrhage and Hb of 3.9g/dl received 13 units of red cells, five platelet pools, 14 units of SD plasma, six pools of cryoprecipitate including colloid and crystalloid giving a total of 13 litres of fluid over six hours. Her estimated blood loss was 3,580mls and her urinary output was 2,800mls giving an overall positive balance of 6,620mls. Frusemide was given and she was transferred to the intensive care unit (ICU) in another hospital.

On arrival in ICU, the patient was hypertensive and oedematous and her O<sub>2</sub> saturations were decreased. She had bilateral creps on auscultation of the chest and the chest X-ray showed some shadowing throughout both lungs consistent with a degree of pulmonary oedema. She was commenced on Continuous Positive Airway Pressure (CPAP). During the next few days her urine output was poor, her creatinine was rising and she was in a positive fluid balance of 2-4L. On day three, her chest X-ray still showed pulmonary oedema. Frusemide was prescribed but not given as the patient started to produce large volumes of urine and was weaned from the ventilator. The retrospectively tested pro Brain Type Natriuretic Peptide (pro BNP) pre-transfusion was 103 pg/ml and post transfusion was 356 (ratio 3.4) on day of admission to ICU but rose to 950 on the next day.

### SAR Case History 6 (TACO)

A 41 year old patient with severe epistaxis received nine units of red cells and four units of SD plasma over a timeframe of five hours in the theatre. The patient developed a pyrexia, hypertension, stridor, wheeze and chest X-ray changes. The fluid balance was incomplete but he had an estimated intake of 10,000mls. He made a complete recovery after four hours with pulmonary oedema resolving without intervention and he did not require ICU admission.



### TACO with SD plasma – Still a problem!

**SAR Case History 7 (TACO):** This female patient (54kg) required four units of SD plasma for an INR of 1.5 which had not reduced with Vitamin K pre liver biopsy. The transfusion was prescribed over 3-4 hours. Due to poor intravenous IV access, there was a delay in administration of the first two units and in order to avoid wastage of thawed units all four units were administered in 1 to 1.5 hours instead of at the prescribed rate. On the fourth pack, when 100mls had been transfused, she developed acute dyspnoea, respirations were 40/min, and she desaturated to 60% on room air and required O<sub>2</sub> therapy. Initially TACO was considered unlikely as the volume transfused was only about 700mls and the Consultant Haematologist was asked to review the possibility of TRALI. The X-ray showed right sided atelectasis and a pleural effusion and the pre and post transfusion NT-pro BNP levels were markedly elevated (pre 1118, post 4897). In view of the patient's small size, rate of transfusion, X-ray findings and raised BNP, a diagnosis of TACO was made. In addition SD plasma is a pooled product which has not been convincingly implicated in TRALI.

### Reactions occurring in patients as a result of an error

TACO was reported to have occurred following an error in seven (18%) cases. Human error was cited as a cause of error in all seven cases and included the failure of the caregiver to adhere to policies/procedures, to co-ordinate/communicate and to monitor the patient's haemoglobin between units.

### SAR Table 8 Breakdown of errors resulting in TACO (n=12)

Human failure		System failure	
Failure to adhere to policies/procedures	4	Culture	2
Knowledge	1	Policies/procedures	1
Co-ordination/communication	2		
Verification	2		
<b>Total</b>	<b>9</b>		<b>3</b>

System failure was noted to be the cause of error in three of these cases. In two cases the culture within the hospital contributed to the error and in the third case lack of detail in the policy led to the error.

### SAR Case History 8 (TACO):

A low weight (52kg) elderly female patient with PR bleeding admitted as an emergency was commenced on IV fluids at 60ml/hr. Her haemoglobin was 3.9 g/dl. The patient had no history of underlying cardiac, respiratory or renal disease and the only relevant past history was diverticulitis. She was not on regular diuretics. She was transferred to ICU where three units of red cells were transfused uneventfully. The following morning her Hb was 8.2g/dl. She was then transferred to the ward where she received a further unit (4th unit) of red cells with no adverse outcome. On day three the patient received 4L of fluids as part of bowel preparation for gastro-intestinal investigations and the IV fluids continued at a rate of 60mls per hour. No fluid balance was maintained at ward level. Her Hb was 9g/dl and a further two units of red cells were prescribed by the consultant who prescribed diuretic cover if necessary. The units were given late in the evening. During the first unit (5th unit) her blood pressure (BP) started to rise with a systolic of 170mmHg and a diuretic was given post transfusion. Although the patient remained hypertensive and had a tachycardia the second unit (6th unit) was commenced without query by the nursing staff. After approximately 70mls had been transfused, the patient's condition had worsened, the consultant was then contacted and the transfusion stopped. A junior doctor reviewed the patient and found pedal oedema and bi-basal crepitations on examination. Diuretics and an anti-hypertensive were administered and the patient made a complete recovery within 12 hours. On review by the Consultant Haematologist, the 5th and 6th units were deemed unnecessary and a contributing factor to the overload. Both human and system failures were implicated in this reaction

### Human failures

- Verification: Failure to assess the patient's clinical condition prior to prescribing further units.
- Failure to adhere to policies: Hb check not carried out between units.

- Monitoring: Failure to document an accurate fluid balance.

### System failure

Culture: Nursing staff did not question consultant prescription although the patient was clearly symptomatic.

### Discussion and Recommendations

TACO is probably the commonest complication of blood transfusion with an estimated incidence of 1:200. Particular attention should be paid to identifying patients at risk. High risk patients include patients of low body weight, elderly, infants and children and physiologically compromised patients especially those with chronic anaemia, cardiac, renal and respiratory conditions.

The recipient's weight should be taken into account when deciding the number of units necessary. A unit of blood will raise the Hb by 0.5-2gms depending on the size of the patient, and the size of the unit, which can vary in size as much as 30-40% (Davenport 2005, Gilcher 2002, Hogman 2006). The size of red cell units issued by the IBTS is between 230mls to 350mls with a mean of 260mls. The Hb level therefore should be checked between units to avoid over transfusion, as a single unit may be sufficient.

Rapid transfusion also has been attributed as a factor for circulatory overload. The NBUG (2004) recommends an infusion rate of 2-4mls/kg/hr for red cells in non bleeding patients but slower rates may be required in small patients or in patients who have underlying cardiac disease or chronic anaemia. Popovsky (2001) suggests that patients at risk of TACO who are not haemorrhaging should be transfused slowly at a rate of 1ml/kg per hour with careful input and output monitoring before, during and after the transfusion.

The majority of transfusions - 24 (61%) - in this report were prescribed over three to four hours, however five (20%) of these were transfused between one to three hours and one patient, with a history of acute renal failure, received a volume of greater than 300mls in fifteen to thirty minutes.

### TACO in Massive Transfusion:

Four cases of TACO in young healthy female patients have been reported to the NHO between 2000 and 2007. The recognition of two further cases of TACO in 2008 in patients with massive haemorrhage and no history of underlying disease is of concern and accounts for 5% of TACO cases.

Estimation of blood loss is often difficult, and in bleeding patients, the Hb on its own may not be a good measure of rapid blood loss, as it may be artificially low if there has been over hydration with crystalloid or colloid although the red cell mass may be normal (Valeri 2006, Soni 2008).

### Key Points

Particular attention should be paid to patients with underlying conditions which may increase their susceptibility to TACO. These include;

- Elderly patients
- Infants and children
- Patients of low body weight
- Patients physiologically compromised particularly those with a history of cardiac respiratory or renal insufficiency or chronic anaemia.

Transfusion should be on a unit by unit basis, with a medical assessment of the patient prior to commencing transfusion and a Hb check/assessment before administering any further component. This assessment should include a careful estimation of the patient's hydration and cardiac status prior to the transfusion and a thorough review of the patient's fluid balance during the transfusion.

There is a possible need for diuretic therapy as this can reduce the risk of TACO and may be necessary for those on regular diuretic therapy.

In very low weight or 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).

Doctors and nurses across all specialities should receive education aimed at the recognition and avoidance of TACO. In addition junior doctors should receive specific training in the area of transfusion medicine to ensure safe and appropriate decision making regarding transfusion and prescription of blood components/products.

It is important that clinicians recognise that even healthy patients can develop circulatory overload in the massive transfusion setting and fluid balance should be carefully monitored to avoid overhydration/overload with components.

**Definition:** Transfusion Associated Dyspnoea (TAD) is characterized by respiratory distress within 24 hours of transfusion that does 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.

## Findings

This is the first year the NHO has collected this type of reaction and within this group we received two reactions that, following review, were captured as TAD. Both patients were elderly and both reactions were associated with red cells.

### SAR Case History 9 (TAD)

In the first case which was originally submitted as an unclassified transfusion reaction, a patient with underlying renal disease experienced a drop in O<sub>2</sub> saturation with an associated tachycardia within 15 minutes of commencing the transfusion. There was no evidence to suggest that the patient was in overload, nor did they show signs of an allergic type reaction. The symptoms resolved within one hour following administration of oxygen therapy.

### SAR Case History 10 (TAD)

The second case was originally submitted as TACO but as there were no changes on the patients chest X-ray from admission, it was subsequently reclassified. The elderly male patient, who was admitted with an underlying medical condition, was commenced on a unit of RCC. One hour 15 minutes post the transfusion, the patient became acutely short of breath, distressed and agitated. A diffuse wheeze was noted. It was not considered an allergic type reaction. The patient was treated with nebulisers and IV medication and subsequently required CPAP. The CPAP was discontinued six hours later and the patient made a complete recovery.

## Clinical Outcome

Both patients made a complete recovery.

Transfusion Related Acute Lung Injury (TRALI) is one of the leading causes of transfusion related mortality.

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

TRALI is characterised by the following

- Acute onset of symptoms
- Hypoxemia  $\text{SpO}_2 < 90\%$  on room air or other evidence of hypoxemia
- Bilateral infiltrates on frontal chest X-ray
- No evidence of circulatory overload
- No pre-existing acute lung injury (ALI) before transfusion or during or within six hours of transfusion
- No alternative risk factors for 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 female donors who have developed 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. 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 and granulocyte antibodies are permanently deferred.

## Findings

There was one case reported as a possible TRALI or TACO which was difficult to categorise but was finally captured as possible TRALI.

### SAR Case History 11 (TRALI)

This patient with newly diagnosed insulin dependent diabetes was admitted for stabilisation of diabetes following collapse at home. She had a past medical history of bowel disease, but no respiratory or cardiac history. Her condition improved and she was scheduled for discharge. On the day of discharge, however, she developed haematemesis and melaena and was in shock. Her haemoglobin was 6.5 g/l. She was transfused with three units of red cells prior to an OGD which identified a large bleeding duodenal ulcer (DU). Following this, the patient was transferred to ICU where she was transfused a further two units of red cells. On the following day (day 2) she was transfused two more units of red cells prior to transfer to theatre for emergency surgery. She then received two units of SD plasma and also received 1 litre crystalloid and 500mls of plasma expander (a total of about 2400 mls in about two hours). Her urine output was about 60mls/hr. She was stable intra-operatively with no obvious bleeding points and was successfully extubated. Her  $\text{O}_2$  saturations were documented at 100% on three litres  $\text{O}_2$ . She was prescribed 300mls of plasma expander for five hours post operatively, although it is unclear how much she received.

Half an hour after return to ICU the patient became acutely unwell. Her systolic blood pressure increased by 60mmHg and she had a

tachycardia of 110/min, frothy sputum and blood stained secretions in her mouth. Her oxygen saturations disimproved (94% on 100% O<sub>2</sub>). She was re-ventilated and given frusemide 40mgs with no noticeable increased diuresis. A chest X-ray at this time showed bilateral perihilar alveolar consolidation consistent with pulmonary oedema, shock lung or aspiration. Her central venous pressure was 20 and remained between 15-20 over the next eight hours. At 08.00hrs on day 3 she was in a positive balance of 2,396 millilitres. As her weight was approx 44 kg this was a considerable positive balance. She received further doses of diuretic between day 3 and day 6. Her chest X-ray on day 4 showed some improvement compared to the X-rays of day 2 but she continued to require ventilation until day 9.

#### **Differential diagnosis of Possible TRALI**

The findings of dyspnoea, hypertension, tachycardia, positive fluid balance and chest X-ray changes were consistent with the ISBT definition of TACO. There was, however, no evidence of a diuresis following administration of a diuretic. BNP pre or post transfusion levels which might be helpful and troponin levels for cardiac ishcemia were not performed. The electrocardiogram (ECG) showed no significant changes.

#### **Results of follow-up donor investigations**

There were three donors whose units were transfused within the six- hour time frame of the current definition of TRALI or possible TRALI. There was one male donor with no previous history of transfusion and therefore not investigated further. Both female donors were recalled and there was no evidence of either HLA I or II or granulocyte antibodies in either donor. Concurrently, HLA investigations of the patient were also negative.

The absence of HLA antibodies in the donors and the clinical features suggested TACO. Against TACO was the failure to respond to diuretics and the long period before recovery, and after discussion with the reporting physicians, the case was collected as possible TRALI.



# Suspected Transfusion Transmitted Infection

2008

The NHO collects and investigates reports of:

- All STTI 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 TTI – bacterial infections 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 STTI may 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 (SHOT 1999).

## Findings

In 2008 eight reports of STTI were collected by the NHO. A further case of possible rubella transmission was reported but this case did not progress.

### SAR Table 9 STTI collected in 2008 (n=8)

Type of STTI	n
Transfusion transmitted bacterial infection	6
Transfusion transmitted viral infection (HBV)	1
Transfusion transmitted viral infection (HIV)	1

### STTI - Bacterial (n=6)

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 issuing 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 TTI.

## Findings

Six cases of possible bacterial infection were reported. Four cases involved red cells and two cases were associated with pooled platelets. Four were considered possible bacterial infections and two were considered unlikely.

Possible bacterial TTI were reported in two patients who developed febrile reactions associated with transfusion and who had positive blood cultures, but where the pack was not cultured (Case 1) or cultured negative (Case 2). However, further investigations at hospital level suggested that these results were due to contamination during the blood culturing process and bacterial infection was considered unlikely. These reactions were probably FNHTR.

In another two cases, both involving RCC where bacterial infection could not be excluded, a coagulase negative staphylococcus was identified in the first patient, but the segment line from the pack was cultured with no growth (Case 3). In another case (Case 4) a pantoea species was cultured from the patient, (who had severe drug induced neutropenia) the pack and the administration set. However, the segment line cultured negative.

Two reports of possible bacterial infection involved cases where neither patient had a reaction but were commenced on antibiotics by the clinical team because of a report of an unconfirmed positive bacterial screening test from the IBTS (Cases 5 and 6).

**SAR Table 10 STTI - Bacterial (n=6)**

Case No.	Age	Gender	Component	Implicated Organism	Outcome	Imputability
1	Adult (31-50 years)	Male	RCC	1.Streptococcus Gordoni. 2.Coagulase negative staphylococcus identified in the patient. Pack not cultured	FNHTR. Bacterial Culture -considered most likely a contaminant	Unlikely
2	Elderly (70+)	Male	RCC	Gram positive bacillus identified in the patient. Pack and segment line culture was negative	FNHTR. Bacterial Culture -considered most likely a contaminant.	Unlikely
3	Elderly (70+)	Male	RCC	Coagulase negative staphylococcus identified in the patient. Pack not cultured however segment line was cultured with no growth	Febrile reaction	Possible
4	Elderly (70+)	Female	RCC	Pantoea species cultured from patient, pack and administration set. Culture negative from segment line.	Febrile reaction in patient with severe neutropenia	Possible
5	Adult (31-50 years)	Male	Pooled Platelets	Coagulase negative staphylococcus	Unconfirmed positive Bactalert. Patient had no reaction but was commenced on antibiotic therapy	Possible
6	Adult (31-50 years)	Female	Pooled Platelets	Coagulase negative staphylococcus	Unconfirmed positive Bactalert. Patient had no reaction but was commenced on antibiotic therapy	Possible

### Clinical Outcome

All the patients made a complete recovery.

### STTI – Viral (n=3)

#### Findings:

Three cases of viral infections were reported to the NHO in 2008 of which two progressed. The first case, a case of HBV (Case 1) involved multiple components and a large number of donors. Following investigation, TTI was considered unlikely.

The remaining two cases involved RCC only.

In case 2, a case of HIV, the three donors returned and retested HIV negative and TTI was excluded.

In case 3, a male patient developed rubella eight days following transfusion. Transfusion transmission of rubella has never been reported and on investigation of the donors, both donors were found to be immune to rubella prior to donating. Closer questioning of the recipient indicated he had been exposed to rubella some days earlier. This case did not progress.

**SAR Table 11 STTI - Viral 2008 (n=3)**

Case No.	Serious Adverse Reaction	Age	Gender	Transfusion Date	Components	Donors Implicated	Comments	Imputability
1	HBV	Adult (51 - 70 years)	Female	1-Apr-08	RCC, SD Plasma, Apheresis Platelets, Pooled Platelets	98	91 donors returned and retested HBV negative. 7 donors tested HBV negative on archive samples.	Unlikely
2	HIV1/2	Adult (31-50 years)	Female	9-Apr-08	RCC	3	All three donors returned and retested HIV negative.	Excluded
3.	Transfusion transmitted viral infection - Other-Rubella	Adult (31-50 years)	Male	23-Oct-08	RCC	2	Recipient had exposure to rubella prior to transfusion Both donors were immune to rubella prior to donating. Case Did Not Progress	Excluded

# Serious Adverse Reactions occurring as a result of an error

2008

This is the first year that this data has been available for all the reactions reported. In 10 of the 143 reactions reported the reaction occurred as a result of an error (SAR Table 12).

**SAR Table 12 Reactions occurring as a result of an error (n=10)**

Type of Reaction	Number	Error Discovered
AA	1	Failure to administer prescribed premedication
Immunological haemolysis due to other allo-antibody (Acute < 24 hrs)	1	Incorrect component issued - Fy <sup>a</sup> positive unit accidentally substituted for a Fy <sup>a</sup> negative unit and transfused
Unclassified SAR	1	Incorrect volume of RCC transfused due to a communication error
TACO	7	<p>Transfusion time too short n=3</p> <p>Prescribed and transfused too quickly n=1</p> <p>Transfusion based on an old Hb result and no prophylactic diuretic administered n=1</p> <p>Unnecessary Transfusion n=1</p> <p>Units administered too close together in a patient with underlying cardiac disease n=1</p>

The majority of the transfusions were administered in the general ward setting (7) and one each in A&E department, day ward and neonatal unit. All the errors occurred in the clinical area with the exception of one case where the patient had an AHTR due to an error in the HBB.

An analysis of the findings showed that in the majority of the cases several factors contributed to the errors. The causes of the errors were identified as follows: human error was cited in all ten cases with system failures also cited in five of these cases. The type of human error identified is outlined below in table 13.

**SAR Table 13 Human Failures identified (n=17)**

Human Failures	n
Knowledge	2
Co-ordination/Communication	4
Verification	3
Failure to adhere to policies/procedures	4
Monitoring	1
Slip	2
Carrying out task incorrectly	1

In eight of the cases, several human failures resulted in the error with co-ordination/communication and failure to adhere to policies and procedures listed as the most common causes of human error.

In five of the cases, system failures were also listed as a cause of error with one case listing both management priorities and culture as contributing factors in the error.

**SAR Table 14 System Failures identified (n=6)**

System Failures	n
Policies/Procedures	2
Management Priorities	2
Culture	2

### **Clinical Outcome**

The outcome was documented in nine of the ten patients. Six patients recovered fully, two patients had minor sequelae and one patient died unrelated to the transfusion.

**SAR Table 15 Clinical Outcome (n=9)**

Clinical Outcome	n
Complete Recovery	6
Minor Sequelae	2
Death	1      Unrelated to transfusion



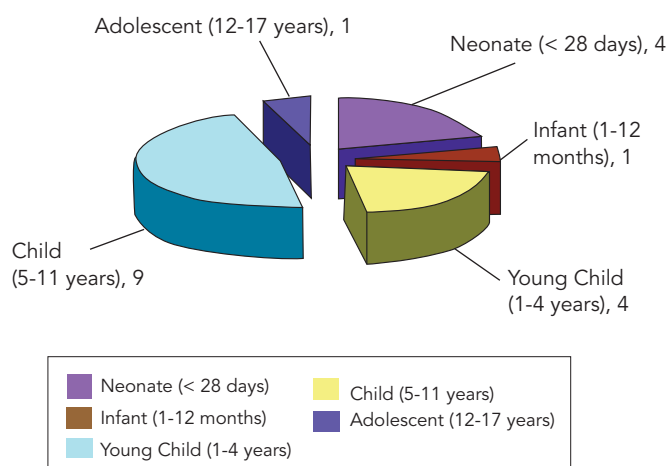
"The acute side effects of transfusion may be greater for small children than for adults, as a single unit of transfused blood with the potential to cause harm, may represent a much greater proportion of their blood volume than that in an adult" (New 2006 P.2)

This year 19 (13%) out of a total of 143 reactions occurred in paediatric patients. Four reactions occurred in neonates (<28 days), one in an infant (1-12 months), four in young children (1 to 4 years), nine reactions occurred in children (5–11 years) and one reaction occurred in an adolescent (12-17 years). The figure below shows the percentage of reactions occurring in paediatric patients in each of the reported categories.

**Paediatric SAR Table 1 Paediatric Reactions (n=19)**

Category	Paediatric Reactions	% of Total Reactions Received
AA	14	34%
OSR-Febrile Non Haemolytic Transfusion Reaction	1	3%
OSR-Hypotensive Transfusion Reaction	2	100%
OSR-Unclassified SAR	2	33%

**Paediatric SAR Figure 1 Breakdown of paediatric reactions by age (n=19)**



Some of these reactions have already been highlighted in their respective reaction categories, but for ease of reference they have been summarised in this section.

The majority of reactions were AA, 14 in total. There were two unclassified reactions, two hypotensive reactions and one FNHTR.

**Paediatric SAR Table 2 Breakdown of Paediatric Reactions by Component Category**

	Component	Age
AA	Platelets Apheresis	Neonate (<28 days)
AA	Platelets Apheresis	Infant (1-12 months)
AA	Platelets Pooled	Young Child (1-4 years)
AA	SD Plasma	Young Child (1-4 years)
AA	Platelets Pooled	Young Child (1-4 years)
AA	Platelets Apheresis	Young Child (1-4 years)
AA	Platelets Pooled	Child (5-11 years)
AA	Platelets Apheresis	Child (5-11 years)
AA	RCC	Child (5-11 years)
AA	Platelets Pooled	Child (5-11 years)
AA	Platelets Pooled	Child (5-11 years)
AA	Platelets Apheresis	Child (5-11 years)
AA	Platelets Apheresis	Child (5-11 years)
AA	Platelets Apheresis	Adolescent (12-17 years)
OSR-FNHTR	Granulocytes	Child (5-11 years)
OSR-Hypotensive Transfusion Reaction	Cryoprecipitate	Neonate (<28 days)
OSR-Hypotensive Transfusion Reaction	Cryoprecipitate	Neonate (<28 days)
OSR - Unclassified SAR	RCC	Neonate (<28 days)
OSR - Unclassified SAR	RCC	Child (5-11 years)

Of the 14 AA reactions, 12 involved platelets (seven reactions to apheresis platelets, five reactions to pooled platelets – three suspended in plasma, two suspended in PAS) one reaction to RCC and one reaction to SD plasma. Both Hypotensive reactions

were to cryoprecipitate, both unclassified reactions were associated with RCC and the one FNHTR was associated with the transfusion of granulocytes.

**Clinical Outcome**

A clinical outcome was given in 17 of the cases. Fifteen patients made a full recovery, one patient had minor sequelae and one patient had serious sequelae but subsequently recovered (see SAR Case History 4).

**Paediatric SAR Table 3 Clinical Outcome for paediatric reactions (n=17)**

Clinical Outcome	n
Complete Recovery	15
Minor sequelae	1
Serious sequelae	1

# Incorrect Blood Component Transfused (IBCT) Serious Adverse Events (SAE)

2009

## Findings

In 2009, 157 IBCT/SAE related to blood components and blood products were accepted by the NHO, representing 58% of analysed reports.

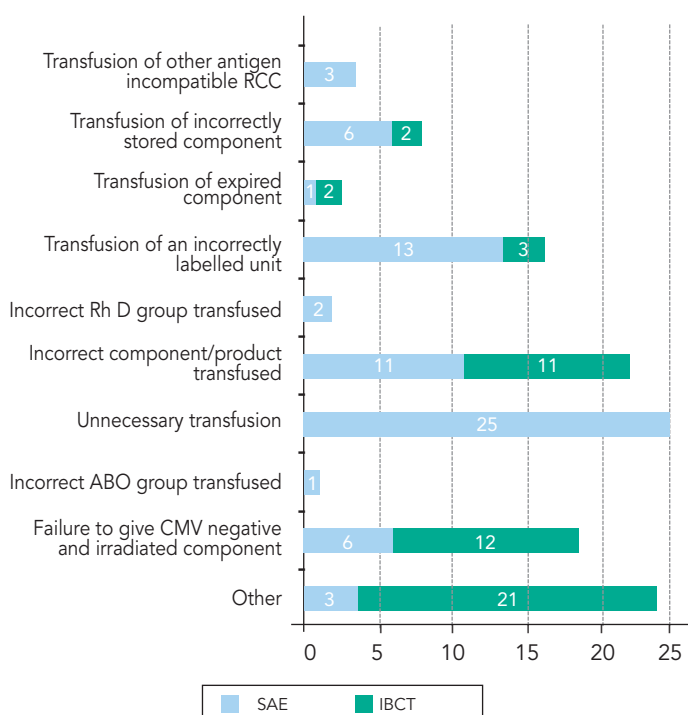
Thirty five reports related to blood products (factor concentrates and anti-D) and these are separately assessed on pages 89 and 91.

## IBCT/SAE associated with blood components and SD plasma

The NHO analysed 122 reports relating to blood components and SD plasma. These reports were submitted from 41 reporting establishments

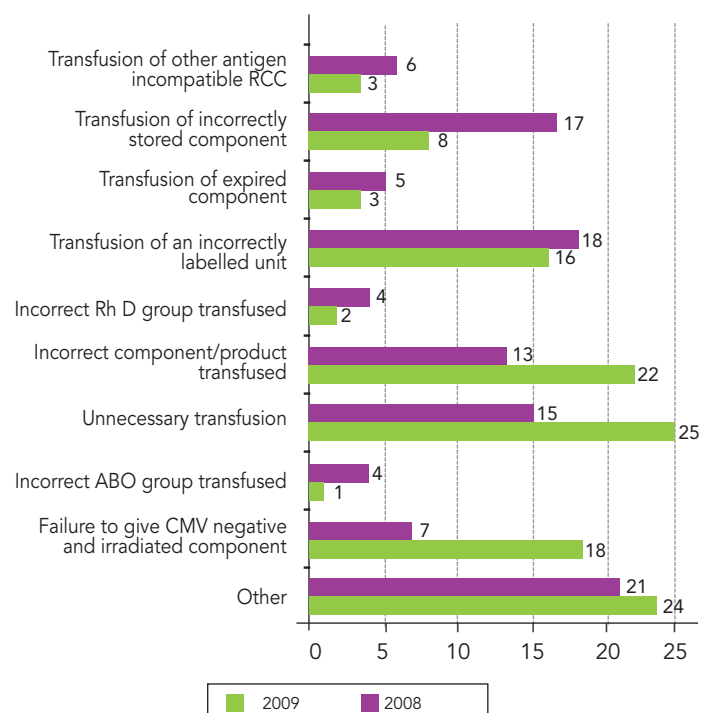
- Elderly patients aged over 70 years were involved in 20% of reports. Twenty one (10%) reports involved paediatric patients <18 years. This is a reduction on 2008, where 22% of reports received involved paediatric patients.
- Forty six reports met the criteria of an SAE reportable under EU Directive 2005/61/EC. The remaining 76 were IBCT due to errors occurring in the clinical areas.

**IBCT/SAE Figure 6: SAE /IBCT 2009 (n=122)**



A review of reports in 2008-2009 showed increased reports of unnecessary transfusions and failure to administer special requirements, with fewer reports involving incorrect ABO, Rh D groups, storage and labelling errors.

**IBCT/SAE Figure 7: SAE/IBCT 2008 and 2009 (n=232)**



# Mandatory SAE reports under Directive 2005/61/EC (n=46)

2009

Mandatory SAEs do not include errors related to clinical aspects of blood transfusion practice, but are related to activities in blood establishments (BE) and HBB<sup>6</sup>. These can be deviations in testing, storage, materials, distribution or other aspects of BE/HBB activity.

The format of mandatory event collection is based on the EU Directive therefore some cases are captured in different categories to those of the NHO. This means that some SAE /IBCT are

described under different headings in the narrative SAE and IBCT and Paediatric sections of the report.

## Findings

Forty-six mandatory SAEs were reported to the Competent Authority in 2009 (IBCT/SAE Table 11). This table is in the format set out in EU Directive 2005/61/EC. Mandatory SAEs were 38% of all SAE/IBCT a 13% decrease compared to 2008. Thirteen (52%) SAEs involved paediatric patients, and are described in the Paediatric section on page 84. None involved sequelae for the patient.

**IBCT/SAE Table 11: Mandatory SAE 2009 (n=46)**

Deviation	Total	Component				Specification	
	n (%)	RCC	Platelet	FFP	Cryo	Human Error	Other
Testing of donations	3 (7)	3				3	
Storage	7 (15)	7				6	1
Materials	1 (2)	1					1
Transfusion of an incorrectly labelled component	13 (29)	11	2			13	
Non-irradiated/and non- CMV negative components transfused *	6 (13)	6	1			5	1
Incorrect ABO Group transfused (no reaction)	1 (2)	1				1	
Transfusion of other antigen incompatible RCC (no reaction)	3 (7)	3				3	
Incorrect component transfused (no reaction)	8 (17)	4	3	1		8	
Incorrect Rh group transfused	1 (2)	1				1	
Transfusion of expired component	1 (2)	1				1	
Other	2 (4)	1			1	1	1
<b>Total</b>	<b>46 (100)</b>	<b>39</b>	<b>6</b>	<b>1</b>	<b>1</b>	<b>42</b>	<b>4</b>

<sup>6</sup> Mandatory SAEs related to the quality and safety of blood components are reportable to the NHO under legislative regulations detailed in the NHO handbook.  
(\*one case involved the transfusion of multiple components).

### Testing of Donations (n=3)

In one case, the pre-transfusion crossmatch identified anti-c and anti-E antibodies and an unidentified antibody. Five units of c negative E negative red cells were ordered from the supply centre. However, during the transfusion of the first unit the patient became pyrexial and developed tachycardia and dyspnoea. A check of on-call work showed that the unit involved had been positive on crossmatch but that the crossmatch card had been incorrectly read as negative and the unit issued. Post transfusion investigations showed no evidence of haemolysis or additional red cell antibodies, although the patient also had HLA antibodies. The reaction was considered unlikely to be related to transfusion.

The second case involved failure of the controls during crossmatch of the pre-transfusion sample. This went unnoticed and the unit was issued and transfused. Root cause analysis attributed this to human error. Post transfusion investigations found the unit to be compatible. These cases were categorised as "Other" when reported to the NHO. The final case is described in IBCT/SAE Case History 20.

#### IBCT/SAE Case History 20

This case involved a post-menopausal female who was typed as ORhD positive and issued with a unit of ORhD positive red cells. Following commencement of the transfusion, the patient informed the nurse she was RhD negative and the transfusion was stopped. Investigations found no record of this patient on the LIS, but a further search revealed a historical record with a different spelling of the surname. This case was complicated by an anomalous result of a weak D during RhD typing of the pre-transfusion sample. The pre-transfusion and repeat samples were subsequently referred to the reference centre which confirmed the patient's blood group as RhD negative. The patient suffered no sequelae.

### Incorrectly Stored Components (n=7)

Seven (15%) cases were implicated in storage errors. All involved red cells, six were due to human error and one to a systems failure. One case is described in the Paediatric section on page 85 under Increased donor exposure due to problems with paedipacks.

### Materials (n=1)

One case was reported as a deviation in 'materials'. This led to the recall of a paedipack by the supply centre due to a problem with materials used in the testing. The baby was not commenced on any antibiotic treatment, but was exposed to another donor. This is one of the cases detailed in the Paediatric section on page 85 in the category Transfusion of the Incorrect Component/Product leading to Increased donor exposure due to problems with paedipacks.

### Incorrectly Labelled components (n=13)

The largest category of mandatory SAEs (n=29) were incorrectly labelled components, all of which were attributable to human error. Eleven involved red cells and 2 involved platelets. One case is described in the paediatric section on page 86.

- Seven cases involved transposition of labels within the same crossmatch of red cells, and in one case transposition of labels occurred during labelling of platelets. In two instances several components were issued simultaneously and subsequently returned to stock. When an attempt was made to reissue the returned component, the LIS indicated it was already transfused.
- In another case, a unit of pooled platelets was issued and transfused without a compatibility label.
- In a further case, an incorrectly labelled unit of red cells was issued and transfused. When the Medical Scientist went to print a label, he used the last three digits from the pack to identify and select the unit on the LIS. The label with an incorrect unit number was printed and attached to the pack. The hospital label was not cross-checked with the supply centre label during issue, collection or pre-transfusion check of the component.
- The final case involved a patient with auto antibodies for whom three units of red cells were assigned. Two units were requested from the laboratory and the two least incompatible units selected by the medical scientist. However the label was incorrectly applied to the third unit in error.

### Non-irradiated/CMV Negative Components Transfused (n=6)

Six (13%) cases were captured in this category, all of which involved red cells and one case also involved



platelets. All were due to human error, and one case was attributable to both human and system errors.

### **Incorrect ABO Group Transfused (n=1)**

This case is described in the Paediatric section on page 85.

### **Transfusion of Other Antigen Incompatible RCC (n=3)**

Three (7%) cases were captured in this category, the first of which is described in the paediatric section. In the second case, a patient with a history of anti-E antibodies required an urgent transfusion of red cells. The on-call scientist was unaware that E negative units should have been selected based on the historical record. Screening of the pre-transfusion sample was negative and the units were crossmatch compatible but antigen negative units were not selected for issue. On retesting, a weak anti-E was detectable in the sample. It is unknown if the red cells issued were E antigen positive. The patient suffered no sequelae.

#### **IBCT/ SAE Case History 21**

In the final case a patient required an urgent transfusion of red cells for acute gastrointestinal haemorrhage. An on-call medical scientist who did not normally work in transfusion had difficulty in resolving the crossmatch in this case. On initial testing the antibody screen was negative and 2 units of red cells were issued. The scientist however, then noticed an anomaly in the results and repeated the crossmatch and antibody screen which was positive. A more senior scientist was then called who retested the sample and set up an antibody identification panel. This indicated that most probably anti-Fy<sup>a</sup> was present and Fy<sup>a</sup> positive components had been issued. It was discovered that the first unit had already been transfused. The patient suffered no sequelae.

### **Incorrect Component Transfused (n=8)**

In eight (17%) cases the incorrect component was issued. All were due to human error. Six cases involving paediatric patients are described in the Paediatric section on page 85.

- One case involved the issue of apheresis platelets instead of pooled platelets, to a patient with a history of previous SAR.
- In a further case, a patient was grouped as A RhD negative, but the HBB issued an O Rh D negative red cell unit marked as high titre anti A

and anti B which was not noticed by the medical scientist .

### **Incorrect Rhesus Group Transfused (n=1)**

In this case, two units of red cells were requested for an Rh D negative male patient. A busy on-call medical scientist did not heed a warning on the LIS system that a Rh D positive component was being issued to a Rh D negative patient. The error went unnoticed during issue, collection and at the pre-transfusion bedside check, and was only discovered prior to transfusion of the second unit.

### **Transfusion of an Expired Component (n=1)**

In this case, a patient was transfused with a unit of red cells which were issued two hours prior to expiry. Clinical staff were not informed of this and the transfusion was commenced two hours past the expiry time. This was not detected during the pre-transfusion check.

### **Other SAEs (n=2)**

The remaining two incidents were captured under the deviation 'Other'. One case involved a patient who received an insufficient dose of cryoprecipitate. Four units of pooled cryoprecipitate were prescribed, but due to a shortage of pooled cryoprecipitate single donor units were issued by the supply centre. The hospital medical scientist was unaware of this and issued four single donor units. As each unit of pooled cryoprecipitate contains five units the patient received an inadequate dose. The second case is described in the paediatric section on page 85 under 'Increased donor exposure due to problems with paedipacks'.

### **Cause of SAEs**

EU Directive 2005/61/EC states the cause of the SAE must be investigated through root cause analysis (RCA). In addition, the NHO assesses each case for its potential to cause harm. Sixteen (35%) SAEs were determined to have a major potential to cause harm. These included storage errors (3), materials (1), testing (1) and labelling errors (1), issue of the incorrect ABO group of red cells (1), issue of the incorrect component (5), issue of antigen incompatible components (3) and other (1). The remaining 30 (65%) mandatory SAEs were assessed as having moderate potential to cause harm. IBCT/SAE Table 12 shows a breakdown of error causes and their potential for harm. In some instances there was more than one or more error cause.

**IBCT/SAE Table 12 Root Cause Analysis (RCA) and Risk of Potential for Harm for Mandatory SAEs (n=86\*)**

Human Failure	Major n (%)	Moderate n (%)	Systems Failure	Major n (%)	Moderate n (%)
Failure to adhere to policies & procedures.	8 (9)	16 (19)	Policies/ Procedures	1 (1)	2 (2)
Verification	2 (2)	4 (5)	Design	2 (2)	3 (4)
Knowledge	5 (6)	5 (6)	Materials	2 (2)	
Carrying out task incorrectly	3 (4)	13 (15)	Other	2 (2)	1 (1)
Slip	6 (7)	4 (5)			
Co-ordination/ Communication	1 (1)	5 (6)			
Other	1 (1)				
<b>Total</b>	<b>26 (30)</b>	<b>47 (55)</b>		<b>7 (8)</b>	<b>6 (7)</b>

(\*RCA revealed more than one error cause for some cases)

### Follow-up Action

Preventative and/or corrective action was taken in 26(65%) of the 46 mandatory SAE. Measures taken included the re-education and/or training of staff involved in transfusion practice, and the introduction of new policies stipulating procedures, updating hospital LIS, for example to flag patients with special transfusion requirements.

#### Key Point

- Several mandatory SAEs were associated with on-call medical scientists with a busy workload.
- Over half (n=13,52%) of all paediatric events reported were mandatory SAEs.
- The UK Transfusion Collaborative (2009) recommends that laboratories have systems in place to ensure adequate skill mixes and staffing levels to ensure a safe and effective service to patients during both routine and 'out of hours' services

### Recommendations

- There should be robust systems to detect and reconcile patients' previous histories and transfusion records (SHOT, 2009).
- Antigen negative blood should be provided wherever the patient's condition allows, but in a 'Code Red' type emergency bleed, it may be necessary to transfuse patients who have antibodies with units from the emergency O Rh D negative stock although they may not be antigen compatible as the risks due to delay in transfusion caused by trying to find compatible blood out weigh the risks of a haemolytic reaction.
- Hospital blood bank staff must be particularly vigilant where patients have special requirements and adhere to hospital policy to ensure the correct components are issued.
- Clinical staff should be alerted if issued components are about to expire.

# Adverse Events in the Clinical Areas (IBCT/Non Mandatory SAE) (n=76)

2009

This section, describes the findings on the most frequently reported adverse events occurring in the clinical area.

## Unnecessary transfusions (n=25)

This captures adverse events where a patient is transfused with a blood component which was not required (NHO, 2007).

There were 25 reports of unnecessary transfusions in 2009, making up 20% of all SAE /IBCT reports, making unnecessary transfusion the highest single clinical adverse event to be reported. This compares to 15 reports in 2008 showing an increase of 10% on the 2008 report.

- Unnecessary transfusions involved red cells in 14 cases , platelets in six cases (one report involved both SD plasma and platelets, and the platelet transfusion was deemed unnecessary) and SD plasma in five cases.
- Twelve cases involved transfusion episodes where the entire transfusion was considered unnecessary. In two cases, the transfusion involved multiple units and in these cases only some units were considered unnecessary.
- Doctors were implicated in 88% (22) of cases with prescription /request reported as the site of error in 72% (18) of cases.
- Knowledge deficits were identified in 56% (14) of unnecessary transfusions predominantly involving doctors, but also involving other staff.

### Key Point

- The high incidence of knowledge deficits in unnecessary transfusions highlights the important role of education of clinical staff in the appropriate use of blood.

Unnecessary transfusions were classified as follows.

## IBCT/SAE Table 13: Classification of unnecessary transfusions (n=25)

Classification	n
Transfusion based on clinical decision not in conformity with guidelines	15
Transfusion based on incorrect or absent haematology result	9
Other	1

## Transfusion Based on Clinical Decision not in Conformity with Guidelines (n=15)

### Iron Deficiency Anaemia

- Five cases of unnecessary red cell transfusion in this category involved patients with iron deficiency anaemia who received transfusions. Four of these cases involved female patients aged between 29-49yrs.
  - Two patients had iron deficiency anaemia due to menorrhagia.
    - One patient had been referred by her GP for investigation of a one year history of menorrhagia. Her pre-transfusion Hb was 7.6g/l and her vital signs were stable.
    - The second patient was admitted with iron deficiency anaemia. She had a history of menorrhagia and was also a vegetarian, and was not compliant with oral medication. Her pre-transfusion Hb was 6g/dl. Intravenous iron therapy was not considered.
  - Two other patients had other conditions with co-existing iron deficiency anaemia where at least one of the units transfused was considered unnecessary.
    - One patient was admitted for cardiac investigations. Her pre- transfusion Hb was 7.2g/dl and she was transfused three units of red cells. Her post transfusion Hb was 12g/dl. This patient was not on iron therapy.
    - The second case involved a 37 yr old

patient with iron deficiency anaemia following previous extensive bowel surgery who received three units of red cells. A review at the hospital transfusion committee considered the final unit unnecessary. Intravenous iron therapy was not considered.

- A fifth patient with iron deficiency anaemia was given a second unit of red cells although the pre-transfusion Hb was 11 g/dl.

### Key Points and Recommendations

- Underlying anaemia has been recognised as a cause of unnecessary transfusion and increased morbidity in patients undergoing elective surgery. A recent publication by the Network of Advancement of Transfusion Alternatives made recommendations on detection, evaluation and management of pre-operative anaemia (Goognough et al 2010).
- In 2009, five patients<sup>7</sup> who were transfused unnecessarily had iron deficiency anaemia. Year on year, the NHO receives a number of reports of unnecessary red cell transfusion in patients with iron deficiency anaemia, and this is likely to represent significant under reporting. An audit of patients with iron deficiency anaemia managed in a tertiary care hospital identified that approximately 10% (3) of the study group were unnecessarily transfused, and that 30% (9) of patients had more than 1 unit where iron therapy could have been given instead of additional red cell transfusion (Egan et al, 2010).
- Nutritional anaemia due to iron, folate, vitamin B12 deficiency respond rapidly to appropriate haematinic therapy.
- Intravenous iron preparations should be considered in cases where patients have either poor tolerance of oral preparations or there are compliance issues. It normalizes haemoglobin faster and more reliably than oral iron (Ahmad, and Gibson, 2006).
  - Ferric carboxymaltose although more

expensive may deliver several potential advantages over other parenteral iron preparations. It is feasible to administer much higher single doses of iron over shorter periods of time, resulting in the need for fewer injections to replete iron stores and correct iron deficiency anaemia. It provides a rapid response in haemoglobin with few gastrointestinal side effects (Kulligg et al, 2008).

### Other unnecessary red cell transfusions

- Two cases of red cell transfusion were not based on best practice guidelines.
  - In one case a post-operative patient with a Hb of 9.6g/l received two units of red cell for "nausea associated with a low Hb". The post transfusion Hb was 11.6g/l.
  - The second case involved a four unit transfusion to a 56 yr old patient whose pre-transfusion Hb was 7g/dl. His post operative Hb was 12g/l. The Hb was not checked between units.

### Unnecessary SD plasma and platelet transfusions associated with procedures (n=7)

All cases involved a lack of clinical knowledge of either the guidelines or the practical requirements for components pre-procedures.

### Lack of practical requirements for pre - procedure administration

In four cases, patients were transfused blood components at the wrong time prior to planned procedures. In two cases, the procedure had not actually been arranged.

- In one case, the patient received a unit of SD plasma for a liver biopsy which had not been organised.
- In the second case, the haematologist asked to review a medical patient with evidence of bleeding and coagulopathy, ordered a platelet transfusion to be given prior to a planned procedure. Two units of platelets were transfused but the procedure had not yet been scheduled. Following review it was agreed that while the patient required one unit of platelets

<sup>7</sup> Final case reported as Transfusion based on Incorrect /Absent Haematology Result.

for a concurrent clinical condition, the second unit was unnecessary.

- In two further cases, the procedure had been organised but was repeatedly postponed in one case (IBCT/SAE Case History 22) and in the second, the patient was transfused on the day prior to the planned procedure.

#### **IBCT/SAE Case History 22**

A patient with a platelet count of  $12 \times 10^9 / L$  was scheduled to have a multilumen central line inserted under radiological guidance. Hospital guidelines state patients should have a platelet count of  $50 \times 10^9 / L$  prior to procedures but a member of the X ray department ordered that the platelet count should be  $70 \times 10^9 / L$  pre procedure. Three units of platelets were ordered and transfused. The post transfusion platelet count was  $88 \times 10^9 / L$ . Following the transfusion, it was discovered that a specific introducer, was required which was not available in the X Ray department and the procedure was postponed. On the next day, the patient's platelet count had dropped to  $58 \times 10^9$ , and the patient was transfused a further unit of platelets again on advice of the X ray department. On this occasion although the introducer was available, the patient's radiology slot was taken by an emergency patient and the procedure was again postponed. On the following day, the patient's platelet count was  $49 \times 10^9 / L$  and the patient was again transfused with a further unit of platelets. The HVO became aware of the problem through the weekly platelet audit and after drawing the attention of the X ray staff to the guidelines, the procedure was then carried out.

This case illustrates how failure to adhere to guidelines can delay procedures for patients and significantly increase donor exposure and costs.

- The second case involved a patient with a low platelet count who was seen by a haematologist prior to a liver biopsy. The haematologist ordered a unit of platelets to be given prior to the procedure but the clinical staff did not realise that the platelets should only be transfused shortly before the procedure as the platelets only last for a short time in the circulation and the patient was transfused on the day before the procedure. The patient then required a second

unit of platelets on the following day immediately prior to the procedure.

#### **Lack of knowledge of pre-procedure guidelines**

- A patient with a normal coagulation screen received an unnecessary unit of SD plasma prior to a guided ultrasound on instructions of a consultant not routinely used to prescribing blood components.
- In another case, a patient under care of both surgical and cardiology teams with a platelet count at  $384 \times 10^9 / L$  received an unnecessary platelet transfusion prior to planned neurosurgery. This patient was not taking medication which would potentially inhibit platelet function such as aspirin or clodiprogel. This patient also received two units of SD plasma for a slightly raised INR (1.7) for reversal of warfarin, where vitamin K might have been sufficient.
- In one case, two units of platelets were prescribed and transfused to a patient with a platelet count of  $97 \times 10^9 / L$  prior to a liver biopsy, to raise the platelet count to  $100 \times 10^9 / L$ . The platelets were ordered by a junior doctor who was unaware of hospital guidelines on clinical use of platelet transfusions and did not seek advice from senior clinical colleagues.

#### **Key Point**

- Hospital staff who work in specialised areas may not be aware of hospital guidelines for components and may need to have specially targeted education sessions.
- Platelets should be given within one to two hours (or as close as is practical to allow for measurement of post transfusion values) prior to the planned procedure.
- The nature of hospital activity can impact on planned procedures. Medical, nursing and other clinical teams caring for patients along with HBB staff should closely monitor the clinical activities and co-ordinate care to ensure patients do not unnecessarily receive blood components, where procedures are cancelled or postponed.



### Other unnecessary transfusions associated with inadequate knowledge (n=2)

Two unnecessary SD plasma transfusions were administered for bleeding.

- A patient who had a post partum haemorrhage who was stable in the recovery room, received two units of SD plasma. At this time the coagulation screen was within normal limits, but the prescribing anaesthetist recollected post haemorrhage “oozing”.

#### • IBCT/SAE Case History 23

In this case, a young male patient undergoing an elective revision of a hip replacement had a sample sent to the HBB prior to surgery. Antibodies were identified on the pre-transfusion sample and the HBB informed the surgical team that compatible blood would not be available and asked the team to delay the procedure. A clinical decision was made to proceed with the surgery. The patient bled and was transfused six units of SD plasma although emergency O Rh Negative blood was available. The rationale for this decision was not clear. The patient's pre-operative coagulation screen was normal.

#### Key Point

- The role of the HBB, not only as a support service, but as an active participant in delivery of safe patient care, is made clear in this case but this was not recognised by the surgical team caring for the patient.

### Transfusion Based on Incorrect or Absent Haematology Result (n=9)

Five cases involved unnecessary red cell transfusions following a failure to verify results.

- A transfusion was administered on the basis of an incorrect result from a blood gas analyser. This was not an emergency transfusion.
- A failure to verify that the Hb result was the most recent result led to a patient receiving an unnecessary red cell transfusion. This was complicated as haematology testing was carried

out at another site which resulted in a delay in the availability of current results.

- Incorrect transcription of results by an admitting doctor resulted in an unnecessary red cell transfusion.
- A patient with a Hb of 10 g/dl received an unnecessary red cell transfusion. The junior doctor who prescribed the unit of red cells, failed to verify the patient's correct Hb, when he was told by a nurse it was 7.8g/dl.
- An elderly female patient, with cellulitis and iron deficiency anaemia, was prescribed two units of red cells on separate days. Prior to the second transfusion, her pre-transfusion Hb was 11 g/dl and this result was not checked and the second unit was transfused<sup>8</sup>.

Three unnecessary transfusions occurred following sampling errors.

- Two unnecessary red cell transfusions occurred following sampling errors made by medical staff drawing blood for Hb testing. In one case, a sample was taken from a peripheral vein where intravenous fluids were infusing. In the second case, a doctor flushed a central line prior to taking the sample for FBC, discarded the FBC and inadvertently sent the diluted sample to the haematology laboratory.
- In the third case, SD plasma was transfused on the basis of an incorrect coagulation result from a haemodiluted sample. In this case, an inexperienced phlebotomist took the sample. While the error was identified by the coagulation laboratory and a further sample for coagulation screen had been requested by the laboratory, the result had not yet been phoned to the clinical area, prior to the administration of SD plasma.

In the final case, an oncology patient about to commence chemotherapy was prescribed platelets on the basis of a platelet count of  $13 \times 10^9$  /L. While this result was available on the LIS, it had not been validated. The validated result was  $57 \times 10^9$ , but by this time, the platelets were transfused.

#### Other (n=1)

One case involving a two month old infant involved multiple clinical failures to verify results and decision

<sup>8</sup> Previously referred to under unnecessary transfusion in iron deficiency anaemia

making which deviates from best practice guidelines. This case is described in the paediatric unnecessary transfusion section on page 86.

### Key Points

- Three cases of unnecessary transfusion involved either a delay in posting current haematology results to the LIS or where posted results were not validated. Laboratories should ensure that validated results are available to clinical areas in a timely manner.
- A further three involved transfusion based on results from haemodiluted samples, a recurring problem.
- Near patient testing may be necessary in emergency settings. Where this is used, maintenance and validation of equipment as well as ongoing training and competency of clinical staff must be ensured (NHO, 2006). Hb results which suggest a need to transfuse should be re-checked in the laboratory prior to transfusion wherever possible.

### Incorrect component/product transfused (n=21)

This category captures incidents where the patient required a blood component/ blood product but the most appropriate one was not administered.

- In 2009, the NHO received 21 reports in this category, eight relating to SD plasma, one to FFP, eight to red cells and four to platelets.
- Prescription/request and the HBB were reported as site of error for 18 SAE/IBCT, equally implicating doctors and medical scientists. Eight of these cases were mandatory SAE and are reported separately on pages 70.

### Inappropriate use of SD plasma for reversal of warfarin (n=7)

Seven reports related to the use of SD plasma for reversal of warfarin, where it would have been more appropriate to use PCC.

- Transfusion of one or two units was reported in five of these cases. Unless the patients were extremely small, this was unlikely to be a therapeutic dose.

Interestingly, two cases of the seven cases reported as unnecessary transfusion involved patients receiving sub-therapeutic doses of SD plasma.

- In one case, SD plasma was administered outside routine working hours when the junior doctor did not wish to disturb the Consultant Haematologist to prescribe the PCC.

### Transfusion of the incorrect component or SD plasma, which was inappropriate to needs of patients (n=9)

In three cases the incorrect red cell component was transfused.

- A nurse collected two emergency group O Rh D negative units from emergency stock, when fully crossmatched units were available. While the HBB telephoned the ED that cross matched units were available, this information was not passed on to the nurse looking after this particular patient.
- Two of these cases were mandatory SAE and are reported separately in paediatric and mandatory sections on pages 70 and 85.

There were four cases where the incorrect platelet was transfused to patients.

- Two cases involved transfusion of pooled platelets to paediatric patients instead of apheresis platelets.
- A doctor ordered HLA matched platelets from the supply centre, but did not inform the HBB. When the clinical area ordered platelets from the HBB, new HLA matched apheresis platelets were issued and transfused.
- An adult patient with history of previous SAR should have received pooled platelets, but due to an error occurring in the HBB, was transfused apheresis platelets and this was reported as a mandatory SAE on page 70.

In one case, the HBB issued FFP instead of SD Plasma to a paediatric patient. This was reported as a mandatory SAE IBCT/SAE Table 11 and is listed in the Paediatric Section.

In the final case, universal SD plasma (which remains unlicensed in Ireland) was issued instead of group specific SD plasma. This was reported as a paediatric IBCT/ SAE on page 85.

### Transfusion of red cells to paediatric patients leading to unnecessary donor exposure (n=6)

There were six cases where paediatric patients were exposed to red cell transfusions from additional donors due mainly to errors occurring in the HBB. These are reported in the paediatric section on page 85.

### Failure to transfuse special requirements (n=18)

This category captures incidents where a patient who required special requirements such as CMV negative and/or irradiated blood components, did not receive the required components.

In 2009, the number of reports in this category increased from seven reports in 2008 to 18 reports in 2009, accounting for 8% of all IBCT/SAE reports in 2009.

- The majority of patients were adult patients. Eight reports (40%) in this category related to patients within the category 51-70 yrs and two reports involved infants (1-12 months).
- Fourteen of the SAE/IBCT occurred at prescription/request where doctors did not prescribe/request special requirements for patients. Four errors occurred in the HBB, when CMV negative and/or irradiated components were not issued to the patient. Six reports were classified as mandatory SAE.

IBCT/SAE Table 14 contains a breakdown of the reports of failure to transfuse patients with blood components which were not CMV negative or irradiated.

### IBCT/SAE Table 14: Breakdown of the reports by indication for transfusion of special requirements n=18

Reports received in 2009	N
1. Transfusion of blood components which were not CMV negative and / irradiated to patients pre and post solid organ transplants <sup>9</sup> .	5
2. Transfusion of blood components which were not irradiated to patients with Hodgkins and non Hodgkin's lymphoma.	1
3. Transfusion of blood components which were not CMV negative and irradiated to patients with Non Hodgkin's lymphoma.	2
4. Transfusion of blood components which were not irradiated to patients with a history of either Hodgkin's or Non Hodgkin's lymphoma.	4
5. Transfusion of blood components which were not CMV negative and / irradiated to a patient with congenital deficiency.	1
6. Transfusion of blood components which were not CMV negative to pregnant patients.	2
7. Transfusion of blood components which were not CMV negative to a patient with HIV.	1
8. Transfusion of blood components which were not CMV negative and / irradiated to a patient with acute lymphocytic leukaemia.	1

<sup>9</sup>One patient with nephritic syndrome was prescribed but did not receive irradiated components. The reason for this prescription is assumed to be the potential for future renal transplant.

- Some reports received in this category related to transfusions which did not conform with local guidelines. Hospital and laboratory policies are very often broader than the published guidelines for transfusing CMV negative or irradiated components, such as those from McClelland (2007- See Appendix 1), AABB (2008 – for clinical indications for irradiated components)) and more recently the BCSH (2010).
- The objective of these blanket policies is to ensure that patients at risk receive blood meeting their specific requirements. However, it appears clear that national guidelines on appropriate use of irradiated and CMV negative blood components are required. In this context, hospitals are likely to revise their local policies.

### Key Points

- Reports relating failure to transfuse components with special requirements should only be submitted to the NHO where there is clear evidence for their use. Hospitals are encouraged to review against expert published guidelines.
- There is a need for a national policy on appropriate use of irradiated and CMV negative blood components.
- Studies have demonstrated that staff involved in adverse events may become very distressed and this impact may be long lasting. Very often there may be limited resources available to support staff (Wu, 2000; Scott et al, 2009). Therefore it is important that reports of serious adverse events relate to actual events and not to non conformances with local hospital policies. In cases where a hospital policy specifies special requirements outside expert guidelines such as those from BCSH, it is recommended these reports should be managed as non conformances in the hospital quality system, and not reported as SAE/IBCT.

### Other (n=21)

There were 21 non mandatory SAE/IBCT reported in the category of "Other". These all occurred in the clinical area.

- Nineteen occurred at administration stage of the transfusion process
- Two occurred at prescription /request.

**IBCT/SAE Table 15: Classification of non mandatory SAE/IBCT reported as "Other" (n=21)**

Report	Description of events	n
Incorrect transfusion time	<ul style="list-style-type: none"> <li>• Red cells transfused greater than 6 hours</li> <li>• Red cells transfused very quickly in patients at risk of developing a SAR.</li> </ul>	13
Incorrect transfusion administration set	<ul style="list-style-type: none"> <li>• Unit transfused using a standard fluid administration set.</li> </ul>	6
SAE affecting integrity of pack	<ul style="list-style-type: none"> <li>• Packs punctured at administration.</li> </ul>	2

### Discovery of SAE/IBCT (n=122)

This section of the report will focus on discovery of both mandatory and non mandatory events.

**IBCT/SAE Table 16: Who discovered SAE/IBCT? (n=122)**

Who discovered error?	N
Haemovigilance Officer	43
Medical Scientist	50
Doctor	7
Nurse	20
No information available	1
Unclear	1

SAE/IBCT were discovered by clinical and laboratory staff working in all aspects of transfusion.

- As in 2008, the majority of SAE/IBCT were discovered by medical scientists in the HBB during recheck of on-call work or at next testing event. Medical Scientists working as HVOs, in the

supply centre and in the haematology laboratory also discovered errors.

- Thirty five (80%) SAE/IBCT discovered by HVO were clinical events.
- Almost 10% (20) SAE/IBCT were discovered by clinical nursing staff following the transfusion. All of these events were related to a prolonged transfusion time.
- Seven SAE/IBCT were discovered by doctors. These were unnecessary transfusions, transfusion where the most appropriate component was not transfused and/or where special requirements were not transfused.

### Stage of the transfusion process where the adverse event occurred (n=122)

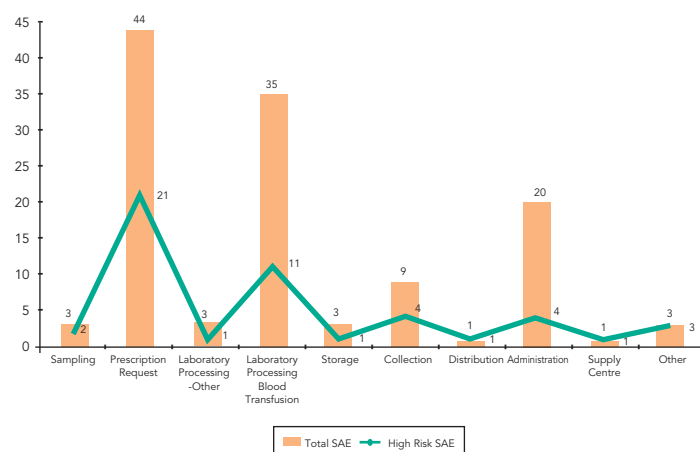
This section of the report will focus on the stages of the transfusion process where mandatory and non mandatory events occurred.

**IBCT/SAE Table 17: Adverse events by stage in the transfusion process flow (n=122)**

Work process	N
Sampling	3
Prescription Request	44
Laboratory Processing - Other	3
Laboratory Processing - Blood Transfusion	35
Storage	3
Collection	9
Distribution	1
Administration	20
Supply Centre	1
Other	3
Totals	122

As in previous years including 2008 , prescription /request is the stage of the work process where most adverse events (n=44) occur, followed by those occurring in the HBB (n=35) and at administration (n=20).

**IBCT/SAE Figure 8: Where did the SAE /IBCT with a high risk assessment occur? (n=122)**



Also as in 2008, most high risk events occurred at prescription/request. However, the events which occurred at distribution and at the supply centre along with all events which were classified as *Other* were high risk to patients.

### Overview of causal analysis –Root cause of events

#### Why did the SAE/IBCT occur?

This section of the report provides an overview of the causal analysis of both mandatory and non mandatory events occurred.

Both human and system errors contributed to SAE/IBCT reported in 2009. The cause of error was reported in 121 cases. The reason for the error did not become clear in one case of an unnecessary transfusion due to a delayed follow up as the event was only discovered during investigation of a suspected transfusion SAR.

#### System Errors

System errors were reported in 22 cases, and more than one error was reported in two cases (n=24 system errors).



**IBCT/SAE Table 18: System errors leading to events (n=24)**

Classification of system error	N	Comment
Lack of policies and procedures	7	<ul style="list-style-type: none"> <li>• Incomplete or no clinical policies on blood administration via blood warmer or in a specialist unit</li> <li>• Incomplete or no laboratory policies on specific steps e.g. pre/post cross match checks transfusion checks, aspects of temperature monitoring.</li> <li>• No details on one case</li> </ul>
Design	2	<ul style="list-style-type: none"> <li>• No alert for special requirements on LIS</li> <li>• Display of pending results or delay in displaying current results on haematology LIS</li> </ul>
Materials	3	<ul style="list-style-type: none"> <li>• Pack leaked in clinical area</li> <li>• Extremely similar packaging of both blood and IV fluid administration set.</li> <li>• Testing difficulties with platelet additive solution</li> <li>• Pipette failure</li> </ul>
Management	2	<ul style="list-style-type: none"> <li>• Clinical management of patient who received possibly two unnecessary transfusions</li> <li>• No system in hospital for haemovigilance and transfusion educational updates for consultants.</li> </ul>
Culture	2	<ul style="list-style-type: none"> <li>• Consultant doctors do not attend haemovigilance and transfusion educational updates</li> <li>• No details on one case</li> </ul>
Other	3	<ul style="list-style-type: none"> <li>• Training had not been provided <ul style="list-style-type: none"> <li>- on issue not solely related to transfusion,</li> <li>- to a single person (no training plan in place to identify this person had not previously attended)</li> </ul> </li> <li>• Information on an antibody status of a patient not available when patient transferred to another hospital</li> </ul>

The most frequently recurring system errors for both clinical IBCT and SAE in the HBB are presented and compared in IBCT/SAE Table 19.

**IBCT/SAE Table 19: Recurring system error in clinical IBCT and SAE in HBBs**

Clinical IBCT	SAE in the HBB
1 Lack of policies and procedures	Lack of policies and procedures
2 Materials	Materials
3 Management priority/Culture	Design

### Human Error

One hundred and eighty human errors were reported across 117 cases. There were more than one human error reported in 63 cases. No human error was reported in five cases.

**IBCT/SAE Table 20: Human errors leading to events (n=180)**

Classification of human error	N	Comment
Failure to adhere to policies and procedures	60	<ul style="list-style-type: none"> <li>Both clinical and laboratory staff failed to adhere to established hospital policies resulting in SAE /IBCT.</li> </ul>
Knowledge	47	<ul style="list-style-type: none"> <li>Both clinical and laboratory staff failed to apply knowledge resulting in SAE /IBCT.</li> </ul>
Co-ordination /Communication	21	<ul style="list-style-type: none"> <li>Communication failure on specific patient care issues / transfusion event within and between disciplines</li> <li>Failure to seek out or clarify specialist advice where practitioners lacked specialist knowledge on transfusion practices.</li> </ul>
Slips	17	<ul style="list-style-type: none"> <li>This type of error occurred predominantly in the laboratory but also in the clinical area.</li> <li>At least seven events (30%) occurred outside routine working hours and involved either laboratory staff (some of whom did not normally work in the HBB) or doctors.</li> <li>Five events occurred during an emergency and a further two events when clinical areas were extremely busy.</li> <li>One event occurred when the clinician involved sought to correct an error.</li> </ul>
Carrying out task incorrectly	16	<ul style="list-style-type: none"> <li>These errors occurred both in the clinical area and in the HBB.</li> <li>Examples include labelling errors in HBB, and collection and storage errors in the clinical area.</li> </ul>
Verification	11	<ul style="list-style-type: none"> <li>Verification errors occurred both in the clinical area and in the HBB.</li> <li>Examples include a failure to verify results prior to transfusion (clinical errors) and failure to verify unit numbers prior to issue (HBB).</li> </ul>
Monitoring	4	<ul style="list-style-type: none"> <li>All clinical errors.</li> <li>Failure to monitor administration of transfusion.</li> <li>Failure to monitor outcome of transfusion.</li> </ul>
Patient related	1	<ul style="list-style-type: none"> <li>Post natal patient caring for new born twins unable to comply with restrictions on arm movements, thereby prolonging transfusion time over six hours.</li> </ul>
Qualifications	1	<ul style="list-style-type: none"> <li>This error was made by a junior doctor on a team, who did not have a specialist qualification or knowledge of patient case load.</li> </ul>
Unclassifiable	1	<ul style="list-style-type: none"> <li>This case has been described - IBCT/SAE Case History 21.</li> </ul>
Other	1	<ul style="list-style-type: none"> <li>Details unclear in this case – knowledge deficit suspected in an unnecessary transfusion where a patient with iron deficiency anaemia received a red cell transfusion.</li> </ul>

The most frequently recurring human errors for both clinical IBCT and SAE in the HBB are presented and compared in IBCT/SAE Table 21.

**IBCT/SAE Table 21: Recurring human error in clinical IBCT and SAE in HBBs**

	Clinical IBCT	SAE in the HBB
1	Knowledge	Failure to adhere to policies and procedures
2	Failure to adhere to policies and procedures	Knowledge
3	Co-ordination / Communication	Slip

This analysis of error cause allows identification of contributing factors common to most events. Similar to findings in 2008, human failures – failure to adhere to policies/procedures and lack of knowledge and system failures – lack of policies/procedures governing processes and design were the most frequently reported causes of events.

### Key Points

- Adverse event review and reporting is a very powerful way of organised learning in organisations in general and also in transfusion services. The information gained from the identification and analysis of adverse events will enable the identification of gaps in the transfusion service and perhaps other services in the hospital which require attention. This data can be used to identify trends and patterns of events which reoccur and have potential to cause harm to patients, and facilitate development of appropriate strategies to enhance patient safety (Commission on Patient Safety and Quality Assurance, 2008).
- Use of a formal protocol will ensure a systematic, comprehensive, and efficient investigation, and will minimise the potential of simplistic explanations and routine assignment of blame (Vincent et al, 2008).

- The NHO has worked with the clinical risk advisors in the Clinical Indemnity Scheme (CIS) to ensure all haemovigilance staff receive system analysis root cause analysis training. Furthermore the implementation of the recommendations of the Patient Safety Commission will include a national roll out of an agreed approach to systems analysis to all health care organisations.

A review of reports received in 2009 indicated 56 hospitals reported 60 corrective actions and /or further review of practices, 51 hospitals reported no action following an adverse event and information was unavailable in 15 reports.

**IBCT/SAE Table 22: Follow-up action for SAE/IBCT ( n=60)**

Category of follow-up action	Details	N <sup>10</sup>
Process, IT and equipment changes	<ul style="list-style-type: none"> <li>• Change of current work process</li> <li>• Addition of alert sticker</li> <li>• Addition of an IT warning</li> <li>• Order new equipment</li> </ul>	14
Education and Training	<ul style="list-style-type: none"> <li>• Includes both general haemovigilance training and targeted updates.</li> <li>• Targeted all staff</li> <li>• Included an expansion of competency assessment</li> </ul>	21
Communication	<ul style="list-style-type: none"> <li>• Memos to staff</li> <li>• List of implicated patients to be sent to HBB</li> <li>• Direct follow-up with staff involved in SAE/IBCT</li> </ul>	13
Development and revision of policies	<ul style="list-style-type: none"> <li>• Development of new policies</li> <li>• Revision /change to current policies</li> </ul>	8
Audit and research	<ul style="list-style-type: none"> <li>• Audit of current clinical practice</li> <li>• Area of SAE /IBCT became research topic of an MSc student</li> </ul>	2
Other department	<ul style="list-style-type: none"> <li>• Report referred to the clinical risk</li> <li>• Movement of stock i.e. transfusion administration sets separated from fluid administration sets.</li> <li>• Contact made with supplier re possibility of a name change</li> </ul>	2

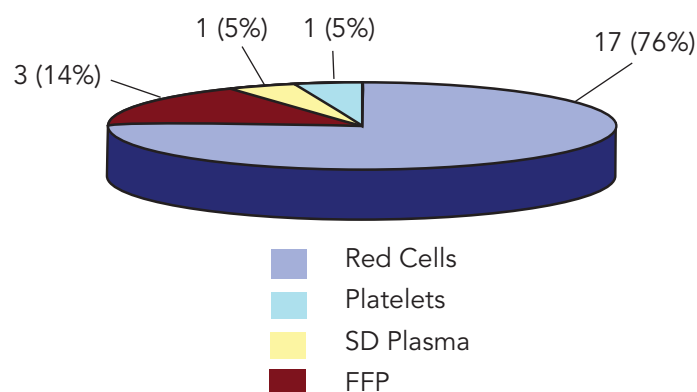
<sup>10</sup> Some reported SAE /IBCT had several follow-up actions including both corrective and preventative measures.

## Key Points

- The NHO recommends that change should be introduced following a systematic review of the event. Introduction of a change should include development of policies to support practice change, informing all relevant stake holders and provision of training to ensure that the information on change is both disseminated and acted on.
- Haemovigilance and transfusion services should then engage in monitoring not only to evaluate the impact of the change in terms of transfusion service, but the potential to impact on other hospital services. This follow-up monitoring is crucial to ensure ongoing learning and improvement, and is characteristic of a quality service.

Paediatric cases comprised 20% of all SAE/IBCT cases in 2009, with 25 reports accepted. Thirteen cases (52%) were mandatory SAEs and 12 (48%) cases were non-mandatory IBCTs. Two cases involved anti-D Immunoglobulin (Ig) and are described on page 91, and one case is described in the factor concentrates section on page 89. Of the remaining 22 cases the majority (n=17, 76%) involved red cells (IBTS/SAE Figure 9).

**IBTS/SAE Figure 9. Components associated with Paediatric SAE/IBCT (n=22)**



## Findings.

The categories and age groups of SAE/IBCT are summarised in IBTS/SAE Table 23.

**IBCT/SAE Table 23: Paediatric SAE/IBCT in Table 1: (n=22).**

Category	n	Major	Moderate	Neonate <28 days	Infant 1-12mths	Infant 1-4yrs	Child 5-11yrs
Failure to give CMV negative &/or irradiated component	2		2		2		
Unnecessary Transfusion	2	2		1	1		
Incorrect ABO group transfused	1	1			1		
Incorrect component / product transfused	11	8	3	4	5	1	1
Other	3	1	2	1	1		1
Transfusion of incorrectly labelled unit	1		1	1			
Transfusion of incorrectly stored component	1		1	1			
Transfusion of other antigen incompatible RCC	1	1		1			
<b>TOTAL</b>	<b>22</b>	<b>13</b>	<b>9</b>	<b>9</b>	<b>10</b>	<b>1</b>	<b>2</b>

### **Transfusion of the Incorrect Component/ Product (no reaction) (n=11)**

Eleven cases were captured in this category making up half (50%) of all paediatric cases.

#### **Increased donor exposure due to problems with paedipacks (n=6)**

- In the first case, red cells suitable for neonatal use were transfused instead of a paedipack. This occurred when a unit of red cells was issued to a satellite fridge for an infant who required a surgical procedure. The infant later required a top-up transfusion, but instead of requesting a paedipack from the transfusion laboratory, the red cells in the satellite fridge were transfused.
- In two further cases, infants were exposed to other donors, even though aliquots from a previous paedipack were still available. In the first case, an infant was transfused with two aliquots from a paedipack. The baby was then discharged and, subsequently readmitted. When the transfusion laboratory received a request for another transfusion, a second paedipack was ordered from the supply centre. The error was attributed to a lack of communication as the blood bank staff did not realise that aliquots from the first paedipack were still available.

In the second case, two errors occurred. The initial error was when a second paedipack was ordered although an aliquot from the existing paedipack was still available in the blood bank. A further error occurred when another paedipack was ordered even though three aliquots from the second paedipack were still in stock. Root cause analysis attributed this error to a considerable increase in the workload of the blood bank staff.

- In a further case, a neonate was exposed to an additional donor when an aliquot of a paedipack was issued and the remaining aliquots were not returned to controlled storage.
- Another case involved a neonate where the remaining aliquots from a paedipack were recalled by the supply centre for suspected bacterial contamination due to a false positive bacterial alert on an associated platelet component. This was a mandatory SAE and is captured under 'materials' on page 69.

- In an additional case which was categorised as a mandatory SAE, an on-call medical scientist ordered an incorrect component from the supply centre instead of a paedipack for an infant. Although the error was noted and queried by a medical scientist, a more senior scientist incorrectly advised it was suitable for issue. In this case, the baby required no further transfusions.

#### **Other (n=5)**

- In one case a unit of red cells was issued under the hospital neonatal policy, which permits the issue of uncrossmatched red cells. In this instance however, the infant was several days older than the age limit specified in the policy.
- In two cases, pooled platelets were issued instead of apheresis platelets, while another case involved the issue of fresh frozen plasma (FFP) instead of SD plasma.
- In another incident an on-call medical scientist issued universal SD plasma (Uniplas) instead of Group A SD plasma (Octaplas) for a group A neonate.

### **Transfusion of Incorrect ABO group (n=1)**

#### **IBCT/SAE Case History 24**

This case involved a one month old B RhD positive baby who required a transfusion of red cells. No maternal sample was available as the baby was referred from another hospital. In these circumstances either a crossmatch between the red cells and the neonatal serum must be undertaken to exclude passive A or B antibodies, or group O red cells must be used. In this case a B Rh D positive unit was selected without a crossmatch. Root cause analysis (RCA) found the error was made by an on-call medical scientist not normally working in transfusion. The infant suffered no sequelae.

### **Transfusion of Other Antigen Incompatible RCC (n=1)**

#### **IBCT/SAE Case History 25**

This case involved a neonate whose mother was RhD negative with anti-D, anti-E and anti-Jk<sup>a</sup> antibodies. Following delivery, the baby who was RhD positive developed haemolytic disease



of the newborn with associated jaundice and an elevated bilirubin. The patient was transferred to a neonatal unit in another hospital, and required a transfusion for a Hb of 7.9 g/dl. An O RhD negative paedipack was ordered from the supply centre, but no patient details were given, nor was the supply centre informed of the requirement for a Jk<sup>a</sup> negative component. The baby was transfused with a Jk<sup>a</sup> positive unit. On the day prior to the transfusion, the HBB had received an antibody report on the maternal blood sample from the supply centre indicating the previous antibody history. No connection, however, was made between the maternal sample and the unit for transfusion to the baby, who suffered no sequelae.

### Unnecessary Transfusions (n=2)

Two patients received unnecessary transfusions based on incorrect haematology results.

- In the first case, a neonate in a critical condition in ICU was given an urgent transfusion of red cells. An FBC checked in the haematology laboratory taken earlier in the day recorded the baby's Hb as 13.5 g/dl. However, later that night a sample was checked on a blood gas analyser which incorrectly read the patient's Hb as 8.8g/dl. No sample was sent to the haematology laboratory to verify this result as was hospital policy. A clinical decision was made by the anaesthetist to transfuse the patient. The error was discovered the next day when a medical scientist realised the Hb of 8.8 g/dl on the request form did not correspond with the Hb result recorded in the laboratory. The post transfusion Hb on the following day was 16.2 g/dl.
- In the second case, a two month old infant received one and possibly two unnecessary transfusions. The infant's Hb was recorded as 14.3 g/dl prior to surgery. However, the next day following a surgical procedure, the infant had a cardiac arrest, and was transfused with 45 mls of red cells based on a Hb of 11.2 g/dl processed using a blood gas analyser. A sample was taken the next day for an FBC, but it was clotted, therefore the baby was transfused with a further 45 mls based on results again using the blood gas analyser which read the Hb as 17.7 g/dl. Because repeated FBC samples were clotted and could not be tested, no further Hb

results were available until six days later, when the repeat Hb was 19.4 g/dl.

### Transfusion of Incorrectly Stored Component (n= 1)

There was one report of transfusion of a component that was out of controlled storage beyond the recommended time. The case involved a neonate whose condition deteriorated after the unit was removed from the fridge. This necessitated a procedure which delayed the commencement of the transfusion.

### Transfusion of Incorrectly Labelled Component (n=1)

#### IBCT/SAE Case History 26.

An aliquot of a paedipack was issued for a neonate in one name. However, there was a change in the baby's name and a second pre-transfusion sample was not requested or sent to the laboratory, as per policy. When a second aliquot of the paedipack was requested, the laboratory issued it using the original name listed on the request form. The error was further compounded as the patient did not have an identity band, although two identity bands were attached to the patient's cot. The error went undetected during the pre-transfusion bedside check and was only discovered during retrospective checking of 'on-call' work.

### Other (n= 3)

In three cases, there was a failure to use the correct filter. In one case, a blood filter was not used to transfuse a unit of red cells. In the second case, a blood filter was attached to a unit of red cells, but was by-passed and the component administered via a syringe. In the final case, a rare unit of HPA 1a negative platelets was wasted due to the selection of the incorrect filter. At the time there were no hospital guidelines to indicate the correct filter to be used.

### Failure to give CMV negative &/or irradiated component (n=2)

There were two cases in this category. In one case, the doctor failed to request a CMV negative/irradiated component for an infant with special requirements. In the second case, the clinician requested irradiated red cells for an infant but, the medical scientist issued non-irradiated red

cells in error. This patient may not have in fact required irradiated red cells and neither patient suffered sequelae.

### Root cause analysis

The majority of paediatric cases (n=13, 59%) were classified as 'major', that is, having a high risk of causing harm to the patient. The findings of RCA as presented in IBTS/SAE (Table 24) found all cases involved human error and system errors were found in four cases. In some cases more than one error occurred.

**IBCT/SAE Table 24 : Root Cause Analysis of Paediatric IBCT/SAE (n=40)**

Human Failure	n	System Failure	n
Failure to adhere to policies & procedures	10	Management Priorities	1
Knowledge	10	Policies/ Procedures	2
Co-ordination/ Communication	5	Materials	1
Verification	2	Design	1
Monitoring	1	Other	1
Slip	5		
Carrying out task incorrectly	1		
<b>Total</b>	<b>34</b>		<b>6</b>

### Who was involved in Paediatric IBCT/SAE and where did they occur?

Further analysis of Paediatric SAE/IBCT as shown in IBTS/SAE (Table 25) found half (50%) occurred in the laboratory. In some cases, more than one person/department was involved in the error.

**IBTS/SAE Table 25: Where Paediatric errors occurred and who was involved (n=24)**

Practitioner	n =24(%)	Department	n =24(%)
Nurse/ Midwife	5 (21)	Laboratory	12 (50)
Doctor	6 (25)	Ward	3 (13)
Medical Scientist	13 (54)	Neonatal Unit/ICU	6 (25)
		Supply centre	1 (4)
		Theatre	2 (8)
<b>Total</b>	<b>24</b>		<b>24</b>

### Key Points

- The actual number of paediatric cases from 2008 to 2009 remains almost unchanged, although the percentage of reports have decreased slightly from 22% in 2008 to 20% in 2009.
- Of concern, however, is that analysis of IBCT/ SAE in terms of potential to cause harm to patients showed that 59% (n=13) of paediatric cases had high potential to cause harm, compared with 36% (n=36) of reports in the adult population. This highlights the risks to paediatric patients receiving transfusions. Other haemovigilance schemes have reported similar findings (Stainsby, 2008).
- Of further concern is that 86% (n=19) of paediatric cases in 2009 involved neonates and infants.
- Further analysis also found that mandatory SAEs comprised more than half (n=13, 59%) of all paediatric cases compared to only 33% (n=33) of all adult cases.

- Several patients were unnecessarily exposed to another donor, despite the fact that aliquots from a previous paedipack were still available.

## Recommendations

- As highlighted in previous NHO reports, paediatric patients have specialised blood requirements and errors may have serious sequelae. The high incidence of errors categorised as 'high risk' and involving neonates and infants suggest the need for particular vigilance in this area.
- It is essential that hospitals have policies and guidelines on best practice, particularly for infants under four months as detailed in the guidelines Transfusion of Blood Components to Infants under Four Months published by National Blood Users Group (2007).
- Laboratories providing blood components for paediatric patients must be adequately staffed with well-trained personnel (UK Transfusion Collaborative, 2009).
- The BCSH (2009), guidelines on the administration of blood components stipulate that clinical staff involved transfusion practice receive regular education and training. This is particularly important where staff and skills may not be utilised on a daily basis. Various methods are suggested such as face-to-face, self-directed learning and e-learning. The paediatric module of the e-learning programme (<http://www.learnbloodtransfusion.org.uk>) in blood transfusion practice is a useful supplement for ongoing education requirements.
- There should be procedures in place to ensure all staff especially those on-call are aware if aliquots from a paedipack are still available in the HBB. Where aliquots are removed from controlled storage for issue, the remaining aliquots must be returned to the fridge immediately.
- Where antibody reports are received from the reference centre indicating the presence of antibodies, HBB staff should check these against the patient's current transfusion needs, or in the case of an infant, the mother's antibody history, to ensure antigen negative blood is provided.
- Wherever possible, blood components should be prescribed based on results from a sample analysed in the haematology laboratory, and not on results from gas analysers.

# IBCT Involving Factor Concentrates/Blood Products

2009

## Errors surrounding coagulation factor concentrate (n=8)

### Key Findings

- Three adverse events occurred in response to an emergency bleed.
- A majority of adverse events (71%) involved failure to follow specific hospital or checking policies.

## IBCT/SAE Table 26: Reports relating to coagulation factor concentrates (n=8)

Nature of Report	n	Site of Error
Incorrect patient received product	1	Administration
Incorrect product administered	4	Prescription/ Request  HBB error  Distribution
Incorrect dose of product administered	3	Administration (all)

### Incorrect patient received product (n=1)

- This occurred late at night, when a doctor, who had been working throughout the day, failed to carry out patient identification checks and administered coagulation factor concentrate (CFC) to the wrong patient.

### Incorrect product administered (n=4)

Two adverse events occurred at prescription request.

- A doctor in the ED ordered the incorrect product for a patient with inhibitors despite advice from the HBB. The HBB then issued the

incorrect product. Neither the doctor nor the HBB contacted the on-call haematology team for verification.

- The surgical team looking after a patient with liver dysfunction sought specialist advice from a haematology team in another hospital for treatment of bleeding and mild coagulopathy. The advice from the haematology team was to treat with SD plasma and platelets. However, the surgical team were confused and requested two vials of prothrombin complex (PCC) in error from the HBB. The patient received PCC (which should only be used in liver disease on specialist advice) without any adverse outcome. Both doctors involved in this event were confused by the similar names for PCC- "Octaplex" and SD plasma "Octaplas".
- In the second case, a medical scientist on-call issued plasma derived CFC in place of recombinant product which had been ordered.
- In the final case, the patient required an emergency delivery of CFC to his home. The pharmacist on-call did not complete all checks prior to distribution and the patient received the incorrect product.

### Key Point

- The similarity in the trade name for both SD plasma and PCC has caused confusion especially for clinical staff. In this year's report, the use of this resulted in the wrong product being issued to the patient.
  - Products should be ordered as SD plasma and PCC, rather than Octaplas and Octaplex, to avoid this type of event.
  - The NHO has made this concern known to both the manufacturer and the IMB.

### **Incorrect dose of product administered (n=3)**

- All adverse events occurred at administration. Two cases involved patients receiving a larger dose of CFC than required.
- The final case involved administration of PCC for warfarin reversal. The patient received less product than prescribed following an error made by a nurse when setting up the infusion pump. The pump was set to deliver 3mls/hour when it should have delivered 3mls/minute, resulting in significant under-dosage to the patient. Medications are usually administered in mls/hr, but clinical staff - especially nurses- should pay particular attention to medication orders.

### **Key Recommendations**

- Management of haemophilia patients with inhibitors is complex and expert coagulation advice should be sought.
- Medications are usually administered in mls/hr, but clinical staff especially nurses should pay particular attention to delivery of medication.
- All cases of incorrect dose of product involved calculating calculating correct dosage and rate of administration of product. Second checks must be independent of the first check to minimise the potential for passive checking by one or both persons involved in the check.

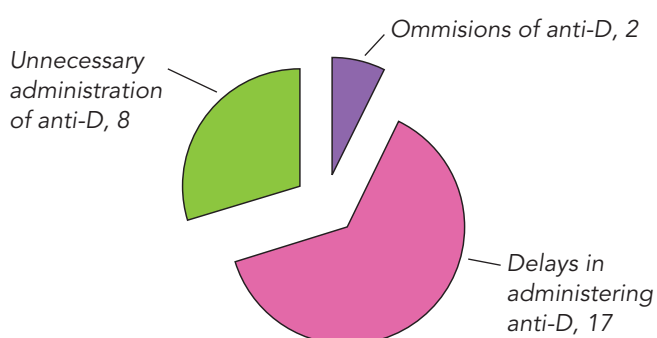
# Adverse Events associated with Anti-D Immunoglobulin

2009

## Introduction

Twenty seven reports were received in 2009. Seventeen reports related to delays in anti-D Ig administration, eight were unnecessary administration of anti-D Ig and two were omission of anti-D Ig.

## Anti-D Figure 2 : Reports received in 2009 (n=27)



## Reporting establishments

Twenty hospitals in Ireland offer maternity services to patients. Reports were received from 10 hospitals in 2009. All dedicated maternity hospitals submitted reports. No reporting pattern was identified based on hospital activity. However an active haemovigilance programme possibly increased reporting. A lack of awareness of reporting may exist especially in general hospitals with maternity units.

### Key Point

- Haemovigilance Officers working with the hospital transfusion teams should examine hospital systems for identifying and reporting adverse events relating to anti-D to ensure these are effective.

## Patients affected

Twenty seven patients were involved in reports in 2009 two patients were under 18 years of age.

## Anti-D Table 3: Patients affected by Anti-D Ig IBCT (n=27)

	Ante-natal	Post -natal
Delay in administering Anti-D Ig	14	3
Omission of Anti-D Ig	2	0
Unnecessary administration of Anti-D Ig	4	4
Total	20	7

Twenty (74%) of these SAE/IBCT occurred in antenatal patients in 2009.

## Delay in administering Anti-D Ig (n=17)

There were 17 reports of delay in administration of anti-D Ig in 2009. The majority of these reports (14) related to ante-natal patients, and three to post natal patients. Thirteen delays involving ante-natal patients occurred in either a Day Ward or Emergency Department (ED) setting.

There were at least five cases, where reports indicated patients were discharged prior to either results being available or anti-D Ig issued from the HBB. One case is described.

### Anti-D Case History 8

A 29 year old female patient, 24 weeks gestation, presented to the ED on Sunday morning, approximately 18 hours following a fall over a bank holiday weekend. A sample was taken for baseline blood group and antibody screen. The HBB did not process this sample until the following Tuesday morning. The request form did not include any details as to when the fall had occurred and anti-D Ig was issued later that evening which was greater than 72 hours following the sensitising event. The



patient was unable to attend the ED and only received anti-D Ig five days after the sensitising event.

There was no information available on whether these patients became sensitised following the delay in anti-D Ig administration.

#### Unnecessary Administration of anti-D Ig (n=8)

Eight cases of unnecessary administration of anti-D were reported in 2009. Four antenatal as well as four post-natal patients were affected. These reports were classified as follows.

#### Anti-D Table 4: Breakdown of unnecessary administration of Anti-D.

	n
Administered to a Rh D Positive Woman	1
Administered to mother of Rh D Negative baby	1
Administered to a previously immunised patient	5
Administered based on expired prescription	1

#### Administered to a Rh D positive female (n=1)

In this case, initial testing of the patient sample on an automated analyser suggested the patient was Rh D negative. Further manual testing showed the patient to be Rh D positive. This led to unnecessary administration of anti-D Ig to an antenatal patient.

#### Administered to mother of Rh D negative baby (n=1)

##### Anti-D Case History 9

In this case, a postnatal patient received anti-D Ig unnecessarily. Both the mother and baby were Rh D negative but anti-D Ig was prescribed in the patient's transfusion record. The reason for this prescription was never clarified. Anti-D Ig was issued by the HBB to the clinical area on the basis of the order. There was no policy in the HBB to check the patient's blood group prior to issuing anti-D Ig.

The nurses working administered the anti-D Ig to the patient. They assumed that when it had been issued from the HBB, the patient should receive it. The postnatal ward was covered by locum staff nurses from the gynaecology ward, where it would not be routine practice to administer anti-D Ig.

Since this event, the HBB staff must now check the patient's blood group prior to issuing anti-D Ig.

#### Administered to a previously immunised patient (n=5)

Three cases involved postnatal patients and two antenatal patients who were already sensitised and did not require anti-D Ig.

##### Post natal patients

- A patient known to have immune anti-D delivered a Rh D positive baby. Anti-D quantitation had been carried out about 8 days prior to delivery. Following delivery, the obstetric registrar on call contacted the haematology team and was advised not to administer anti-D Ig. However, the obstetric registrar subsequently prescribed anti-D Ig. The basis for the clinical decision remained unclear.
- In a second case, a Rh D negative patient had delivered a Rh D positive baby. Results of the final antibody screen were not filed in the patient's notes. While the final screen was positive, results from previous screening were negative. Anti-D Ig was administered on basis of results available in the clinical notes.
- In the third case, the patient's antibody status was not verified prior to either prescription or administration of anti-D Ig.

In the last two cases, a stock of anti-D Ig was maintained in the clinical area and therefore was not under control of the HBB.

##### Antenatal patients

These two events were caused by knowledge deficits of medical staff.

- In the first case, the doctor caring for a patient who had an antepartum haemorrhage did not wait for the result of the antibody screening test.
- In the second case, the doctor was aware that the patient had formed anti-D, but mistakenly thought administering anti-D Ig would prevent a further boosting of the level following a PV bleed.

### Administered based on expired prescription (n=1)

This antenatal patient attended with a urinary tract infection. She was administered Anti-D Ig unnecessarily on basis of an expired prescription, relating to a previous admission for a sensitising event.

### Omission of Anti-D (n=2)

There were two cases, both involving antenatal patients. Neither patient was reported as having become sensitised.

#### Anti-D Case History 10

A patient at 16 weeks gestation was having an amniocentesis. The clinical team received an incorrect verbal report from the HBB that the patient's blood group was Rh D positive and the patient did not receive anti-D Ig. Following this event, the HBB no longer provides clinical staff with a verbal report on the patient's blood group, and the clinical staff must now check it on the LIS.

#### Anti-D Case History 11

A patient at 14 weeks gestation attended the ED following a antenatal sensitising event. Although she was reviewed by a doctor and her bloods were taken for blood grouping, there was no follow-up of the results. The omission was subsequently discovered at the patient's (initial) planned booking visit to the same hospital, where it was noted the patient was RhD negative.

Following this event, a formalised follow-up procedure for the review of results and administration of anti-D Ig has been introduced in the ED.

### Where did the error occurred & who was involved?

A review of the 2009 reports revealed that the majority of SAE /IBCT 17 (63%) occurred in the clinical area. Doctors were involved in eight (47%) and midwives in three (18%) clinical SAE /IBCT. While it was evident a clinical health care professional was involved in the six remaining (35%) events, it was not clear whether it was a doctor or a midwife.

Three errors in the HBB resulted in patients experiencing a delay, an omission and an unnecessary administration of anti-D Ig.

The site of error in seven cases was classified as Other ( Anti-D Table 5).

**Anti-D Table 5: Site of error (n=20)**

	HBB	Clinical	Other
Delay in administering Anti-D Ig	1	10	6
Omission of Anti-D Ig	1	1	0
Unnecessary administration	1	6 <sup>11</sup>	1
Total	3	17	7

Site of error was described as Other in following cases:

- Five patients were discharged prior to receiving anti-D Ig. In all cases blood samples had been taken for screening
  - One postnatal patient was discharged from the labour ward. This patient had received anti-D Ig prior to delivery following a fall. Following discharge, the clinical nurse manager contacted the patient to return the following day for her postnatal dose. The patient did not return until 72 hours after delivery.
  - Four antenatal patients who attended the ED for sensitising events were discharged as samples were not processed in the HBB outside routine working hours. In two cases, patients indicated they were unable to return at the time advised. One of these cases is already described above in anti-D Case History 8.
- One patient had opted for shared care and attended her General Practitioner (GP) following a fall. The GP did not consider the fall to be a sensitising event and did not administer anti-D Ig. This patient received anti-

<sup>11</sup> Site of error for one AE was both the clinical area and HBB.

D Ig during a follow –up visit to her ante-natal clinic in her hospital.

- In the final case, an already immunised patient received an unnecessary dose of anti-D Ig. This occurred because the clinical staff were unaware of the more recent results, as the report had not been filed in the chart (previously described on page 92).

### Cause of error

Since 2007, the NHO has used root cause codes from Medical Event Reporting System-Transfusion Medicine (MERS-TM) to classify causes of IBCT/SAE.

A review of reports revealed multiple causes with both human and system failures contributing to IBCT/SAE.

### Key Point

There were five cases where the patient was implicated in the error. These cases involved patients who were discharged prior to availability of screening results, and these patients did not / were unable to return. Surprisingly the reporting hospital did not report the delay in sample processing or failure to process samples outside routine hours as a system failure.

The following human errors were reported.

**Anti-D Table 6 : Human error contributing to IBCT/SAE (n=35)**

Human Error	N
Failure to adhere to policies/procedures	15
Knowledge	10
Patient related	5
Carrying out task incorrectly	4
Verification	1

- Failure to adhere to hospital policies and knowledge deficits were the most frequently reported human errors. Clinical staff were mainly implicated.
  - Clinical staff (doctors n=5; midwives n=3, clinical healthcare professional n=5) were implicated in 13 of 15 cases where failure to adhere to hospital policies was indicated as a cause of error.
  - Where knowledge deficit was identified as a cause of error medical staff were implicated in six cases, midwives in three cases, and clinical healthcare professional (doctor, midwife or nurse) in three cases.

System errors were reported in seven cases as follows.

**Anti-D Table 7: System error contributing to IBCT/SAE (n=7)**

System Error	N	Comment
Lack of policy	2	<ul style="list-style-type: none"> <li>• The policy on prescribing anti-D was unclear (<i>Unnecessary Administration</i>).</li> <li>• There was no defined responsibility for collecting samples for blood group in theatre. In an emergency case, bloods were not taken (<i>Delay in Administration</i>).</li> </ul>
Management Priority	2	<ul style="list-style-type: none"> <li>• Staff shortages in postnatal ward, resulted in inexperienced staff (from a gynaecological speciality) working in this ward (<i>Unnecessary Administration</i>).</li> <li>• HBB is not staffed to process samples out-side routine working hours, resulting in a delay in processing of samples (<i>Delay in Administration</i>).</li> </ul>
Other	2	<ul style="list-style-type: none"> <li>• In one case, a doctor did not take a sample for blood group, when an ante-natal patient presented following a sensitising event. This was due to a lack of knowledge. The doctor had not received training. Medical training is provided at induction and is unavailable outside these times (<i>Omission of anti-D Ig</i>).</li> <li>• In the second case, results from the HBB were not filed in the patient's chart. In this organisation, anti-D Ig was not issued from the HBB, but was available from the clinical area. (<i>Unnecessary Administration</i>).</li> </ul>
Design / Equipment	1	<ul style="list-style-type: none"> <li>• In this case, an error in blood grouping resulted in an antenatal patient receiving anti-D Ig unnecessarily.</li> </ul>

## Silent Sensitizations

It is estimated that 1% of Rh D negative women develop anti-D antibodies due to small or silent bleeds occurring in the final trimester of pregnancy (Mollison et al 2005). Postnatal anti-D Ig administration is too late for these women. The efficacy of routine antenatal prophylaxis has been shown in many studies (Tovey et al, 1983; Lee and Rawlinson, 1995) and has been accepted by the National Institute for Health and Clinical Excellence (NICE) (2008). However, routine antenatal prophylaxis remains unavailable in Ireland.

The NHO does not collect incidences of silent sensitisations, but will continue to collect reports involving cases where sensitisations occur or have potential to occur following an adverse event especially if it relates to delay or omission in administration of anti-D Ig.

## Recommendations

- Recommendations from 2008 still apply.
- Of concern is the increasing number of reports of delay and omission of anti-D Ig administration to women in the antenatal setting. Anti-D Ig should be administered as soon as possible after a sensitisation and always within 72 hours after an event (BCSH, 2006a). Hospitals should review both clinical work processes and the prioritisation of laboratory testing for patients with potentially sensitising events. Where patients with potential sensitisation attend the emergency department /obstetric unit outside routine laboratory working hours and especially over long weekends or holiday times, it is important that robust procedures are in place to ensure that the appropriate samples are taken, analysed and results acted upon to ensure that anti-D Ig is administered within the recommended time frame. If patients are discharged prior to availability of results then this must be with the reassurance that follow-up will occur. Delay in sample taking and testing adversely impact on optimal time for administration of anti-D Ig for all patients especially those who may not immediately attend the ED/ obstetric unit.

- Midwifery, medical and blood transfusion laboratory staff need to be fully familiar with current best practice surrounding appropriate and timely administration of anti-D Ig. Clear protocols and criteria should be in place for anti-D-Ig administration and assumptions should not be made that because anti-D Ig has been issued by a HBB that the patient should receive it. This has implications for professional bodies, universities and hospital training departments including haemovigilance.
- Follow –up of potentially sensitised patients should be carried out locally.
  - The NHO recommends that hospitals should develop a system to monitor and record incidences and outcomes of silent sensitisations.
- Consideration should also be given to the possibility of establishing of national surveillance system for these events.

There were 110 SAR. There were no reports of Transfusion Associated Graft versus Host Disease (TA vGHD), Post Transfusion Purpura (PTP) or adverse donor reactions related to predeposit autologous transfusion (PAD). There was one report received as a possible TRALI however following extensive review this case was reclassified as TACO.

## Acute Transfusion Reaction (ATR)

During the reporting year 2009, 71 reports of ATR were reported. The breakdown is given in SAR Table 16 below.

**SAR Table 16: Acute Transfusion Reactions (n=71)**

	n
Febrile Non Haemolytic Transfusion Reaction	37
Acute Allergic and Anaphylactic Transfusion Reaction	28
Unclassified Reaction	3
Hypotensive Reaction	1
Acute haemolytic transfusion reactions	2
<b>Total</b>	<b>71</b>

# Acute Haemolytic Transfusion Reaction (AHTR) (n=2)

2009

## Findings

Two acute haemolytic transfusion reactions were reported in 2009. Both reactions were immunological haemolysis due to other allo-antibody.

### SAR Case History 12

In the first case the patient was admitted to hospital and was transfused on two occasions. There was no report of a transfusion reaction. Following this the patient was transferred to another hospital for further management and required additional transfusions. The pretransfusion antibody screen tested negative and the patient was transfused with two units of RCC. During the transfusion of the first unit, the patient developed a very slight temperature rise (0.5°C). The second unit commenced and approximately two hours into the transfusion the patient developed a temperature rise (1.2°C), nausea, vomiting and tenderness in right iliac fossa.

Later that day the patient required surgery. Intra-operative reported blood loss was 800mls and a further unit was transfused. There was no report of any transfusion reaction at this time. Investigations post transfusion identified an increase in bilirubin (42µmol/L) and LDH (3698u/L) and an anti-Cw was identified in the HBB.

Follow up serological investigations carried out at a reference laboratory identified anti-Cw and an anti-C weakly reacting in enzyme and IAT.

It is likely that the reaction was due to anti-C rather than the anti-Cw as anti-Cw rarely causes haemolysis. The reaction represented an acute haemolytic reaction on the background of a delayed haemolytic reaction due to the development of anti-C antibodies (+/-Cw) subsequent to the original transfusion in the first hospital.

### SAR Case History 13

In the second case a paediatric patient with an underlying congenital haemolytic anaemia required a transfusion for a Hb of 5.9g/dl. Three hours 45 minutes into the transfusion the patient developed a temperature rise, rigors and haemoglobinuria. Investigations post transfusion identified an increase in bilirubin and LDH. The units issued were compatible with the patient's sample.

Following referral to an international reference laboratory (IBGRL) additional antibodies were detected – anti-Le<sup>a</sup> + Le<sup>b</sup>. However these antibodies are not normally associated with haemolysis. On review, a clinical diagnosis of Hyper-haemolytic syndrome associated with congenital haemolytic anaemia was made on this patient. The patient received further transfusions since this incident with no sequelae.



# Febrile Non Haemolytic Transfusion Reactions (FNHTR) (n=37)

2009

## Findings

There were 37 reports which fulfilled the criteria for FNHTR in 2009. Thirty four of the patients were adults. Three reactions occurred in paediatric patients (page 112).

## SAR Table 17 Components implicated in Febrile Non Haemolytic Transfusion Reactions (n=37)

Component	n
RCC	32
Apheresis Platelets	1
Pooled Platelets (in platelet additive solution)	3
<b>Multiple Components</b>	
RCC, SD Plasma, Apheresis Platelets	1
<b>Total</b>	<b>37</b>

## Clinical outcome

The clinical outcome was given in all cases. Thirty three patients fully recovered, two patients had minor sequelae with one patient requiring overnight admission and two patients died unrelated to the transfusion.

# Acute Allergic and Anaphylactic Transfusion Reactions (AA) (n=28)

2009

## Findings

There were 28 reports which fulfilled the criteria for this type of reaction. Nineteen reactions occurred in adults and nine reactions occurred in paediatric/adolescent patients.

## SAR Table 18 Components implicated in Acute Allergic and Anaphylactic Transfusion Reactions (n=28)

Component	n
RCC	9
SD Plasma	1
Apheresis Platelets	14
Pooled Platelets (in platelet additive solution)	3
<b>Multiple Components</b>	
RCC+ Apheresis Platelets	1
<b>Total Reactions</b>	<b>28</b>

## Comment

As in previous years FNHTR were more common with red cells and AA were mainly associated with platelet components. The incidence of combined FNHTR and AA per type and dose of platelet transfused is given below in SAR Table 19.

## SAR Table 19 AA and FNHTR per type of platelet component issued in 2009 (n=21)

Type of platelet issued	Number issued in 2009	Incident of reaction per unit issued
Platelets pooled in Platelet Additive Solution	8553	1 per 1426 units issued
Leucodepleted Platelets pooled in plasma	602	No reactions reported to this component
Apheresis Platelets	17,173	1 per 1145 units issued

## Clinical Outcome

The clinical outcome was given in all cases. Twenty four patients made a complete recovery. The final four patients had minor sequelae but recovered following intervention.

# Unclassified Reactions (n=3)

2009

## Findings

A total of 13 reports were originally submitted as unclassified reactions. Following review, six cases were recategorised (1 DHTR, 2 AA and 3 FNHTR), four cases did not progress. Three reactions were accepted as unclassified. All three reactions involved RCC, SAR Table 20. One reaction occurred in a neonate and the other two reactions occurred in adults.

**SAR Table 20 Symptoms associated with Unclassified Reactions (n=3)**

Case No.	Age & Gender	Underlying Condition	Imputability	Interval between commencing transfusion and symptoms	Cardiac Symptoms	Respiratory symptoms	Chills/Rigors	Other	Clinical Outcome
1	Neonate (< 28 days) - male	Complex cardiac condition	Unlikely	3 mins	Bradycardia	Falling O <sub>2</sub> saturation		Decrease in respiration rate, unresponsive	Required CPR but recovered
2	Adult (51-70 years)-male	Abdominal surgery	Possible	4 mins	Tachycardia		Yes	Restlessness/anxiety	Complete recovery
3	Adult (51-70 years)-female	Chronic renal failure	Possible	45 mins	Hypertension, tachycardia	Dyspnoea	Yes	GI symptoms including cramps	Complete recovery

# Hypotensive Reactions (n=1)

2009

## **Findings**

One case was accepted this year. This elderly patient involved received a unit of RCC in recovery following surgery. Approximately twenty minutes after the transfusion commenced the patient became hypotensive. No other symptoms were noted. The patient was treated with intravenous fluids and recovered within thirty minutes.

## **Recommendations for management of ATR 2009**

### **Recommendations for 2008 still apply and in addition:**

- As noted in the 2008 report although it may be necessary to issue least incompatible blood for a patient, samples should be sent at the same time to a reference laboratory for antibody identification to minimise risks of transfusion of incompatible blood
- Reaction Alerts in patient charts and/or on the hospital patient admittance system and IT system can be valuable in those patients with a previous AA/FNHTR reaction to ensure appropriate component selection and pre medication prior to future transfusions.

# Delayed Haemolytic Transfusion Reaction (DHTR) (n=14)

2009

## Findings

This year there were 14 reactions which fulfilled reporting criteria in this category, a significant increase on previous years.

All the patients affected were adults, eleven were female and three male. Seven patients had a previous transfusion history, four patients had never been previously transfused and in three cases a transfusion history was not available. These three cases involved female patients and the antibodies may have been due to pregnancy.

## Reactions occurring as a result of an error

Two reactions occurred as a result of an error. System failures were highlighted in both cases with human failure also identified as the cause of error in the second case.

### SAR Case History 14

In this case the patient had an anti-Jk<sup>b</sup> which had previously been entered into her record but the antibody information had been removed inadvertently some years previously. As a result of this there was no computer flag identifying the patient's previous antibody status and a Jk<sup>b</sup> positive unit was issued and transfused as no antibody was detected on antibody screen. Approximately two weeks later, the patient had a Jk<sup>b</sup> antibody detected, positive DAT, and raised bilirubin. No LDH result was reported. The investigation revealed the antibody flag had been removed, but was unable to establish why the historical antibody record was altered.

### SAR Case History 15

In the second case the patient was admitted to hospital and required a transfusion. A sample was referred to a reference laboratory where an anti Fy<sup>a</sup> was detected. Two antigen negative units were issued and transfused. The patient's consultant was notified of the antibody. Following this, the patient was transferred to another hospital for further management and required additional

transfusions. The receiving hospital was unaware of the patient's previous history of transfusion and Fy<sup>a</sup> antigen negative units were not selected. Approximately five days later, the patient had a fall in Hb, fall in haptoglobin levels, a raised LDH and a positive DAT. Failure in communication and a systems failure were highlighted as the error causes in that there was no system in place to ensure that relevant transfusion history and relevant serological information were notified to the receiving hospital.

## Clinical Outcome

The clinical outcome was given in all of the cases reported. Thirteen patients made a complete recovery and one patient died unrelated to transfusion.

## Recommendations for DHTR 2009

The recommendations for 2008 still apply. Additionally, there should be robust systems to detect and reconcile patients' previous histories and transfusion records (SHOT, 2009). If a patient is transferred to another hospital, their antibody/transfusion history should be transmitted to the receiving hospital. This is supported by the recently published draft National Standards for Safer Better Healthcare document (HIQA 2010 ) which states that service providers share necessary information to facilitate the transfer or sharing of care in a timely and appropriate manner ( Standard 3.4 Criteria 3.4.2 and 3.4.3).

- An alert to medical and nursing staff about the presence of red cell antibodies should be entered on the patient's chart or electronic record. This draws attention to possible delays in provision of compatible blood and the need for transfusion advice.

**SAR Table 21 Details of Delayed Haemolytic Transfusion Reactions reported (n=14)**

Case No	Age	Gender	Imputability	Findings	Antibody	Category	Outcome	Previous Transfusion History	Days post transfusion	Reaction Caused by Error
1	Adult (51-70 years)	Female	Certain	Elevated bilirubin, positive DAT	Anti-Jk <sup>b</sup>	Group 2	Complete recovery	Not available	14 days	System Failure—design. System failure - other previous antibody flag removed from LIS in error
2	Adult (51-70 years)	Female	Likely / Probable	Elevated bilirubin, elevated LDH, fall in Hb, fall in haptoglobins	Anti-Jk <sup>b</sup> , Anti-E, Anti-c, Anti-CW, Anti-Fy <sup>a</sup>	Group 2	Complete recovery	Yes	11 days	
3	Elderly (70+)	Female	Likely / Probable	Elevated bilirubin, elevated LDH, fall in Hb, positive DAT	Anti-Fy <sup>b</sup> , Anti-S, Anti-Cw	Group 2	Complete recovery	Yes	6-9 days	
4	Adult (51-70 years)	Male	Likely / Probable	Elevated bilirubin, elevated LDH, fall in Hb, positive DAT	Anti-E, Anti-Lu <sup>a</sup>	Group 2	Complete recovery	Yes	7-12 days	



Case No	Age	Gender	Imputability	Findings	Antibody	Category	Outcome	Previous Transfusion History	Days post transfusion	Reaction Caused by Error
5	Elderly (70+)	Female	Likely / Probable	Elevated bilirubin, elevated LDH, fall in Hb, Positive DAT, fall in haptoglobins	Anti-E, Anti-c, Anti Jk <sup>b</sup>	Group 2	Complete recovery	No	7-8 days	
6	Elderly (70+)	Female	Likely / Probable	Elevated LDH, fall in Hb, fall in haptoglobins, positive DAT	Anti E, Anti-K, Anti Fy <sup>a</sup>	Group 2	Complete recovery	Yes	13 days	
7	Adult (51-70 years)	Male	Likely / Probable	Elevated LDH, fall in Hb, DAT positive. fall in haptoglobin level	Anti Fy <sup>a</sup>	Group 2	Death-unrelated to transfusion	Yes	2-5 days	Human Failure - co-ordination and communication-HBB unaware of recent transfusion in another hospital. System failure – Other - no system in place to ensure relevant history was notified to receiving hospital
8	Adult (18-30 years)	Female	Possible	Elevated LDH, elevated bilirubin	Anti-Hr	Group 2	Complete recovery	Yes	36 hrs	
9	Elderly (70+)	Female	Likely / Probable	Jaundice, elevated bilirubin, fall in Hb, positive DAT and associated renal impairment	Anti E, Anti-K, Anti-Jk <sup>a</sup> , Anti-S.	Group 4	Complete recovery	No	14 days	

Case No	Age	Gender	Imputability	Findings	Antibody	Category	Outcome	Previous Transfusion History	Days post transfusion	Reaction Caused by Error
10	Adult (51-70 years)	Female	Likely / Probable	Elevated bilirubin, fall in Hb, positive DAT pre and post transfusion. No LDH	Anti-S, Anti-Jk <sup>b</sup>	Group 2	Complete recovery	No	6-12 days	
11	Elderly (70+)	Female	Likely / Probable	Fall in Hb, positive DAT	Anti-K, Anti-S	Group 2	Complete recovery	Not available	13 days	
12	Elderly (70+)	Male	Certain	Jaundice, elevated bilirubin, elevated LDH, fall in Hb, positive DAT	Anti-Jk <sup>a</sup>	Group 3	Complete	Yes	4-9 days	
13	Adult (51-70 years)	Female	Likely / Probable	Elevated LDH, fall in Hb, positive DAT	Anti-Fy <sup>b</sup> , Anti-K, Anti-f	Group 2	Complete recovery	Not available	19 days	
14	Adult (31-50 years)	Female	Possible	Elevated bilirubin	Anti-S	Group 2	Complete recovery	No	1-2 days	

# Respiratory Complications of Transfusion 2009

2009

## Transfusion Associated Circulatory Overload (TACO) 2009 (n=18)

### Findings:

There were 18 reports of TACO, accounting for 14% of serious adverse reactions received by the NHO. This number represents more than a 50% decrease compared to 2008. Fifteen cases were associated with red cells, two with multiple components and one with apheresis platelets. This final case was originally submitted as TRALI but following review was reclassified as TACO (SAR Case History 18 TACO). Fourteen (77%) of the cases were attributed as likely/probable to the transfusion.

Twelve of the patients were females and six were males. The majority of patients (14) 70% were aged 70 years or more. The age and gender of the patients implicated in these reports are outlined in SAR Table 22.

### SAR Table 22 Age/gender of patients implicated in TACO reports 2009 (n=18)

	Infant (1-4 yrs)	Adult (18-30 yrs)	Adult (31-50 yrs)	Adult (51-71 yrs)	Elderly (70+)
Male	0	0	1	2	3
Female	1	1	1	0	9

### Symptoms and underlying conditions

Symptoms of overload developed 30 minutes to 7 hours after transfusion with a median onset of 3 hours. The most commonly reported symptoms are outlined in SAR Table 23.

### SAR Table 23 Most frequently occurring symptoms in TACO (n=18)

Symptom	n
Stridor/wheeze	6
Tachycardia	5
Hypertension	8
Dyspnoea	10
Falling O <sub>2</sub> Saturation	11

Sixteen patients 84% had complex underlying medical problems.

### SAR Table 24 Underlying condition of patients who developed TACO (n=16)

Underlying condition	No of patients
Cardiac	13
Respiratory	7
Renal	5

Underlying cardiac, respiratory or renal dysfunction was reported in 16 cases. In eight cases, patients were reported as having more than one underlying condition and in three patients were reported as having cardiac, renal and respiratory conditions.

### TACO in massive haemorrhage

Again as in 2008 two patients, a young woman treated with multiple components for massive obstetric haemorrhage and a male patient also treated with multiple components for a gastrointestinal bleed with no previous underlying condition both developed TACO.

#### SAR Case History 16 (TACO)

This young female patient who had no previous medical history had a normal delivery and subsequently developed a post partum haemorrhage. She was treated with multiple blood components and required surgery. During this time she received nine units of RCC, two units of platelets and eight units of SD plasma. She was brought to recovery but continued to bleed and required further surgery. Intubation on the second occasion was difficult and it was noted that she had pulmonary oedema. She was treated with frusemide 40mgs. Following this she received five more units of RCC and six units of SD plasma with out any further reaction noted.

### **SAR Case History 17 (TACO)**

In the second case a male patient was admitted to hospital with a gastrointestinal bleed and brought to theatre. He had no previous cardiac, renal or respiratory condition. In this time period he received seven units of red cells (2000mls approx), four units of SD plasma (800mls) and five and a half litres of IV fluids (5500mls) in total. Prior to extubation in theatre his O<sub>2</sub> saturation fell to 86%. His chest x-ray showed residual pleural effusion on the left side He was treated with frusemide 20mgs with good effect.

### **TACO with Single Unit Transfusions**

Single unit transfusions can also result in TACO and therefore should be monitored as closely as multiple unit transfusions (Andrzejewski and Popovsky, 2005). Ten patients developed TACO after a single unit transfusion. The patient's weight was available in only five cases and complete fluid balance information was not available in any of the patients. Nine patients had received diuretics post transfusion. Seven were on regular diuretics but only three received diuretics pre/or during the transfusion. Of these ten cases, four patients had not received any other components in the previous twenty four hours. Two of these four patients were under 70 years and had an underlying medical condition such as renal impairment, cardiac failure and respiratory disease. All four patients were on regular diuretics but only one received diuretics pre transfusion and two had their diuretics held prior to the transfusion.

The volume of an individual red cell unit issued by the IBTS is between 230mls to 350mls with a mean of 260mls. The volume of the units transfused to these four patients was between 276mls to 360mls each.

### **TACO with apheresis platelets.**

#### **SAR Case History 18 (TACO):**

The patient, a young child requiring haemofiltration and dialysis received 150mls of apheresis platelets for a low platelet count. The patient had been in a positive balance from eleven days to five days preceding the transfusion and, although there was evidence

of diuresis in the days preceding the transfusion, the patient remained in a cumulative positive balance. She had received a dose of frusemide at midnight and again at 10.00am on the day of the transfusion. She was noted to be oedematous but was in a negative 24 hour fluid balance of 300 mls. The patient had been extubated that day.

There was a slight increase in the respiratory rate (RR) during the transfusion and shortly after the transfusion was finished, but this returned to normal. The platelets were given over one hour and twenty minutes in the evening and IV frusemide was given in the early hours of the morning post the transfusion. The exact time was not documented. Six hours after the transfusion was complete, the RR increased again and when reviewed on rounds the following morning, the patient had mild stridor and increased O<sub>2</sub> requirements. A further dose of IV frusemide was given. No chest x-ray was taken on the day of the transfusion but one taken on the following day suggested presence of pulmonary oedema. Following a further x-ray the next day, a subsequent review suggested the changes were more likely to be due to infection.

### **Investigations and conclusions**

Because of the possibility of TRALI the female donor was investigated but no antibodies to HLA I or II, antigens or granulocytes were found. The overall clinical findings in this case were consistent with TACO rather than TRALI.

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

TACO was reported to have occurred following an error in two (10%) cases. Human failure was cited as cause of error and included knowledge deficit, failure to adhere to policies/procedures and failure to monitor the patient's Hb between units.

### **Discussion**

Consideration should be given by the IBTS to issuing units with a standard volume and Hb content or making packs with aliquots available similar to paedipacks. HBB should pick smaller units for susceptible elderly patient but this can be difficult in practice.

**Key Point**

At first patients should be given a diuretic prior to transfusion particularly those on regular diuretic therapy.

**Recommendations**

- Recommendations for 2008 still apply and in addition
- Doctors and nurses across all specialities should receive education aimed at the recognition and avoidance of TACO. In addition junior doctors should receive specific training in the area of transfusion medicine to ensure safe and appropriate decision making regarding transfusion and prescription of blood components/products.
- As mentioned in 2008 (page 56) it is important that clinicians recognise that even healthy patients can develop circulatory overload in the massive transfusion setting and that fluid balance is carefully monitored to avoid over-hydration/overload with components.

# Transfusion Associated Dyspnoea (TAD)

## 2009 n=3

2009

There were three cases of Transfusion Associated Dyspnoea (TAD) in 2009. Two cases were associated with red cells and one with pooled platelets. One patient suffered serious sequelae and required ventilation for five days (SAR Case History 19). Two patients had underlying respiratory conditions one, a pre-term infant also had a congenital cardiac defect and the remaining patient had renal impairment. The most commonly reported symptoms were dyspnoea, hypertension, tachycardia and falling O<sub>2</sub> saturations.

respiratory complications and an increase in systolic blood pressure possibly associated with the transfusion were suggestive of TACO. However, it did not meet the strict criteria of the ISBT (2006) definition of TACO, as there were no x-ray changes or evidence of positive fluid balance, this case was re-categorised as TAD. The patient made a full recovery.

### **SAR Case History 19 (TAD)**

The patient, a 31 year old male with complex medical problems and a previous history of respiratory failure and an active pulmonary infection, received two units of red cells on consecutive days. Approximately two hours into the second transfusion, the patient developed tachycardia, hypertension, cyanosis and decreased O<sub>2</sub> saturations reducing from 91% on four litres of O<sub>2</sub> to 75% on eight litres of O<sub>2</sub> and then to 45% on ten litres of O<sub>2</sub>. The patient was transferred to ICU for immediate ventilation to maintain airway and was administered antihistamine, steroids, nebulisers, anti-pyretics and frusemide. The patient remained ventilated for five days after which he made a full recovery.

### **SAR Case History 20 (TAD)**

A pre term neonate with a congenital cardiac condition who received red cells for a low Hb, developed a temperature rise one hour into the transfusion, and an hour later was noted to have rapid respirations and reduced O<sub>2</sub> saturations. Blood cultures taken on the baby after the transfusion were positive, but a full blood count taken with the culture showed a low white cell count and neutropenia. On review this was considered to be consistent with infection preceding the blood transfusion. Initially this case was categorised as a FNHTR but the development of



# Suspected Transfusion Transmitted Infection (STTI) 2009 (n=4)

2009

## Findings

This year four cases of suspected transfusion transmitted infection (STTI) were reported, three cases of suspected viral infection and one case of suspected bacterial infection.

The case of suspected bacterial infection was as a result of a report from the IBTS associated with a confirmed positive bacterial culture screen (BacT Alert) in a component transfused to the patient. As a precaution the patient started antibiotics following the recall.

## Suspected Viral Infections

There were three viral infections reported, one

report of hepatitis B and one of hepatitis C. In both cases, the donor investigations were negative, there were other risk factors and transfusion was outruled as the possible source.

The third case involved a case of possible hepatitis A (HAV) in a haematology patient who had a considerable number of transfusions and who was found, on routine screening to have HAV IgM and IgG antibodies. The patient was asymptomatic and had no evidence of abnormal LFTs. Further investigations showed that this result represented a false positive and transfusion associated HAV was excluded.

**SAR Table 25 Suspected Transfusion Transmitted Infection Viral 2009 (n=3)**

Case No.	Serious Adverse Reaction	Age	Gender	Transfusion Date	Components	Donors Implicated	Comments	Imputability
1	Transfusion transmitted viral infection- Other (HAV)	Elderly (70+)	Female	17-Jun-09	RCC	13	False positive result.	Excluded
2	Transfusion transmitted viral infection (HBV)	Adult (31-50 years)	Male	29-Mar-03	RCC, SD Plasma, Pooled Platelets Blood Products	17	15 donors returned and retested HBV negative. 2 donors did not return but tested negative at the time of donation – Other risk factors were identified.	Excluded
3	Transfusion transmitted viral infection (HCV)	Adult (51 - 70 years)	Female	21-Jan-00	RCC	13	All 13 donors returned and retested HCV negative – Other risk factors identified.	Excluded

### Bacterial Infections

One case of bacterial infection was reported. The patient who was transfused as a day case received a unit of pooled platelets for an underlying malignancy. No adverse reaction was noted at the time of transfusion. Three days later there was a recall on the unit due to a positive bacterial culture alert subsequently determined to be due to a propionibacterium acnes. As the unit had already been transfused, the patient was

contacted. The patient was afebrile and was advised to return the following day for review (four days after the transfusion of pooled platelets). The patient's overall condition had deteriorated and required admission. Antibiotic therapy was commenced, blood cultures on the patient were negative and suspected transfusion transmitted infection was considered unlikely.

**SAR Table 26 Suspected Transfusion Transmitted Infection Bacterial 2009 (n=1)**

Case No.	Age	Gender	Component	Implicated Organism	Outcome	Imputability
1	Adult (31-50 years)	Female	Platelets Pooled	Propionibacterium acnes	Confirmed positive BacT Alert. Patient had no reaction but was commenced on antibiotic therapy.	Unlikely

“Haemovigilance systems should aim at identifying specifically the number and types of adverse transfusion reactions that occur in the paediatric population because the incidence of the events may differ from the adult population” (Gauvin et al 2006)

## Findings

This year 16 (15%) out of a total of 110 reactions occurred in paediatric patients. Two reactions occurred in neonates (<28 days), one in an infant (1-12 months), four in young children (1 to 4 years), six reactions occurred in children (5–11 years) and three reactions occurred in an adolescent (12-17 years). The figure below shows the percentage of reactions occurring in paediatric patients in each of the reported categories.

**Paediatric SAR Table 4 Paediatric Reactions (n=16)**

Category	Paediatric Reactions	% of Total Reactions Received
Anaphylaxis/ Hypersensitivity	9	32%
Immunological haemolysis due to other allo-antibody (Acute < 24 hrs)	1	50%
Transfusion Associated Circulatory Overload	1	6%
Febrile Non Haemolytic Transfusion Reaction	3	8%
Transfusion Associated Dyspnoea	1	33%
Unclassified SAR	1	33%

Some of these reactions have already been highlighted in their respective reaction categories, but for ease of reference they have been summarised in this section.

Haematology/Oncology patients accounted for majority of patients affected (10 in total). Four of these patients had had previous reactions to platelets, two AA, one FNHTR and one unclassified reaction. Of the remaining six patients, four had underlying medical conditions, one patient was post cardiac surgery and the final patient was post general surgery.

The majority of reactions were AA, nine in total. Seven AA reactions involved platelets (five reactions to apheresis platelets and two reactions to pooled platelets suspended in PAS) and two reactions involved RCC.

There were three FNHTR, two associated with pooled platelets in PAS and one reaction to RCC. Three further reactions, one case of Immunological Haemolysis due to other allo-antibody (acute) ( SAR Case History 13) was classified as hyperhaemolysis syndrome ,one case of TAD (SAR Case History 20) and one unclassified reaction (SAR Table 20 Symptoms associated with Unclassified Reactions – case 1) were all associated with RCC. The case of TACO was associated with apheresis platelets (see SAR Case History 18)

**Paediatric SAR Table 5 Breakdown of paediatric reactions by component and age (n=16)**

Components				Age				
Serious Adverse Reaction	Red Cell	Platelet Apheresis	Platelet Pooled	Neonate (<28 days)	Infant (1-12 months)	Infant (1-4 years)	Child (5-11 years)	Adolescent (12-17 years)
Anaphylaxis/hypersensitivity (AA) (n=9)	2	5	2	1		2	3	3
Immunological haemolysis due to other allo-antibody (Acute < 24 hrs) (n=1)		1						1
OSR - Febrile Non Haemolytic Transfusion Reaction (n=3)	1		2		1		2	
OSR - Transfusion Associated Circulatory Overload (TACO) (n=1)		1			1			
OSR - Transfusion Associated Dyspnoea (n=1)	1				1			
OSR - Unclassified SAR (n=1)	1			1				

### Clinical Outcome

The clinical outcome was given in all of the cases. Twelve patients made a full recovery, three patients had minor sequelae and one patient had serious sequelae but subsequently recovered completely.

### Reactions occurring as a result of an error

This year no paediatric reactions occurred as a result of an error.

### Key Point

- Although in these cases there was no ongoing sequelae as highlighted in the 2008 NHO report paediatric patients are particularly vulnerable to transfusion-associated complications (Ohsaka, 2009).

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# Appendix 1:

## Incidence of IBCT/SAE and SAR per Unit distributed from IBTS

### 1. 2008

Category	Red Cell Concentrate (RCC) 144,383	Platelets 24,624	Plasma 24,330	Granulocytes 285	Cryoprecipitate 2,717	Total components issued from IBTS 196,339
IBCT/SAE (111)						1 per 1,769
Febrile Non Haemolytic Transfusion Reaction (38) <sup>1</sup>	1 per 4125	1 per 12,312		1 per 285		1 per 5,167
Immunological Haemolysis due to other alloantibody (Acute<24 hrs) (2)	1 per 72,192					1 per 98,170
Immunological Haemolysis due to other alloantibody (Delayed) (4)	1 per 36,097					1 per 49,085
TACO (39) <sup>2</sup>	1 per 4375	1 per 24,624	1 per 24,330			1 per 5,034 <sup>6</sup>
TRALI (1)						1 per 196,339 <sup>6</sup>
Transfusion Associated Dyspnoea (TAD) (2)	1 per 72,192					1 per 98,170
AA (41) <sup>3</sup>	1 per 13,126	1 per 879	1 per 24,330		1 per 2,717	1 per 4,789
Other Severe Reaction (OSR)- Unclassified SAR (6) <sup>4</sup>	1 per 36,096	1 per 12,312				1 per 32,723
Hypotensive Reaction (2)					1 per 1,359	1 per 98,170
Possible Transfusion Transmitted Infection (TTI)- Bacterial (4) <sup>5</sup>	1 per 72,192	1 per 12,312				1 per 49,085
Confirmed TTI - Viral (0)						

<sup>1</sup> FNHTR: RCC = 35 Platelets = 2 Leucocytes = 1

<sup>2</sup> TACO: RCC = 33 SD plasma = 1 Platelets = 1

<sup>3</sup> AA:RCC= 11 SD Plasma = 1 Cryoprecipitate = 1 Platelets = 28

<sup>4</sup> Unclassified Reaction: RCC = 4 Platelets = 2

<sup>5</sup> Possible TTI- Bacterial: RCC = 2, Platelets = 2

<sup>6</sup> Multiple Components: TRALI = 1; TACO = 4;

# Appendix 1:

## 2. 2009

Category	RCC/ Whole Blood 146,584	Platelets 26,328	Plasma 23,876	Granulocytes 328	Cryoprecipitate 1,196	Total components distributed/issued from IBTS 198,355 <sup>8</sup>
IBCT/SAE (157)						1 per 1,263
FNHTR (37) <sup>1</sup>	1 per 4581	1 per 6582				1 per 5,361 <sup>7</sup>
Immunological Haemolysis due to other alloantibody (Acute<24 hrs) (2)	1 per 73,292					1 per 99,178
Immunological Haemolysis due to other alloantibody (Delayed) (14)	1 per 10,470					1 per 14,168
TACO (18) <sup>2</sup>	1 per 9772	1 per 26,328				1 per 11,020 <sup>7</sup>
TAD (3) <sup>4</sup>	1 per 73,292	1 per 26,328				1 per 66,118
Anaphylaxis/hypersensitivity (AA) (28) <sup>3</sup>	1 per 16,287	1 per 1549	1 per 23,876			1 per 7,084 <sup>7</sup>
OSR - Unclassified SAR (3) <sup>5</sup>	1 per 48,861					1 per 66,118
Hypotensive Reaction (1)	1 per 146,584					1 per 198,355
Possible Transfusion Transmitted Viral Infection (1) <sup>6</sup>		1 per 26,325				1 per 198,355
Confirmed Transfusion Transmitted Viral Infection (0)						

<sup>1</sup> FNHTR: RCC = 32, Platelets = 4 ( a further case involved multiple components )

<sup>2</sup> TACO: RCC = 15, Platelets = 1 (two further cases involved multiple components)

<sup>3</sup> AA: RCC = 9, Platelets = 17, SD Plasma = 1 (a further case involved multiple components)

<sup>4</sup> TAD: RCC = 2 Platelets = 1

<sup>5</sup> Unclassified Reaction : RCC = 3

<sup>6</sup> Possible TTI: RCC = 1

<sup>7</sup> Multiple Components: FNHTR = 1, TACO = 2, AA = 1

<sup>8</sup> Total issue figure included 43 units of Cryo depleted plasma.

# Appendix 2:

## Classification of mandatory reports 2008 (n=55)

SAE - STEP IN WORK PROCESS	SPECIFICATION				
	Total	Product defect	Equipment failure	Human error	Other specify
Whole Blood Collection	0	0	0	0	0
Apheresis Collection	0	0	0	0	0
Testing of Donations	1	0	0	1	0
Processing	2	0	0	2	0
Storage	10	0	2	8	0
Distribution	2	0	0	1	1
Materials	0	0	0	0	0
Other - Transfusion of Incorrectly Labelled Component	13	0	0	12	1
Other - Non-Irradiated/CMV Neg Components Transfused	3	0	0	3	0
Other - Incorrect ABO group Transfused (No Reaction)	2	0	0	2	0
Other - Incorrect Component Transfused (No Reaction)	4	0	0	3	1
Other - Transfusion of Other Antigen Incompatible Component (No Reaction)	6	0	0	3	3
Other - Incorrect Rh group Transfused (No Reaction)	4	0	0	4	0
Other - Transfusion of Expired Component	4	0	0	4	0
Other - Error occurring in BE not covered above	1	0	0	1	0
Other (Specify)	3	1	0	1	1



## Appendix 3:

### Nature of adverse event categorised as "Other" 2008, (n=17)

Category	n	Mandatory SAE	Non Mandatory SAE
Inappropriate component transfused -Patient in Sickle Cell Crises transfused with ABO and RhD compatible red cells, but units were not phenotyped	1	1	0
Incorrect giving set used red cells and platelets.	3	0	3
Red cells transfused with incorrect unit number – default number on printer not adjusted to correct unit number.	1	1	0
Incorrect transfusion time	7	0	7
Other- transfusion of red cells where there were clots contained in pack. Unfortunately, the pack was discarded, and follow-up investigations on the pack could not be completed.	1	1	0
Other –Transfusion of red cells where pack was perforated.	2	0	2
Other - Patient transfused uncross- matched unit of red cells.	1	1	0
Other - Patient commenced on antibiotics following error in the BE and hospital blood transfusion laboratory.	1	1	0

# Appendix 4:

## Description of root cause codes

### HUMAN FAILURE

CONTRIBUTING FACTORS	DESCRIPTION
Verification	Errors which occur following incomplete assessment of a situation including related conditions of the patient/donor and materials to be used before beginning a task. Examples would be failure to obtain positive patient ID at the bedside, failure to verify most recent test results prior to prescribing and failure to verify current results against historical results where applicable.
Knowledge	An error occurs when the individual is unable to apply their existing knowledge to a novel situation. Examples would be a trained medical scientist who is unable to solve a complex antibody issue, or a trained nurse who fails to take into account the patient's blood group prior to commencing a transfusion.
Co-ordination / Communication	An error occurs due to a lack of communication or co-ordination within a team for example where an intention to cancel a prescription is not communicated resulting in the patient receiving an inappropriate transfusion.
Monitoring	Errors occur where there is a failure to monitor a process or patient status. Examples include failure to monitor rate of transfusion leading to patient being transfused too quickly/slowly or a trained medical scientist operating an automated instrument and not realising that the pipette dispensing the reagent is clogged.
Slip	Errors occur where there is a failure in the performance of highly developed skills for example computer entry error or simple mind slip leading to failure to complete a task.
Trip	Failures in whole body movement, for example dropping a blood bag which splits and is wasted.
Patient Related	Errors which occur directly as a result of actions or characteristics of patients, and which are not within the control of the health care team. Examples include where a patient gives wrong information about their patient details or where patients remove their own ID band.
Unclassifiable	Errors which arise and cannot be classified in any of the current categories.

## SYSTEM FAILURE

CONTRIBUTING FACTORS	DESCRIPTION
Design	Errors which arise due to inadequate design of equipment, software or materials e.g. design of workspace, software packages, or label design.
Materials	Errors which arise due to deficits in materials e.g. defects in label adhesive, or ink smears on pre-printed labels or forms.
Construction	Errors which occur following poor construction e.g. incorrect set-up of blood pumps/laboratory equipment or installation of equipment in an inaccessible area.
Management Priorities	Errors which occur as result of organisational management prioritisation of other issues over safety e.g. decisions on staffing levels, limited or absent phlebotomy services, no provision for medical record numbers out of hours (Lundy et al, 2007)
Policies and Procedures	Errors which occur due to unclear/outdated or absent Standard Operating Procedures (SOP) Policies/procedures should be current, understandable well presented and accessible to all staff.
Culture	Errors which arise from a collective approach to safety and risk. Groups may establish their own modes of function as opposed to following prescribed methods e.g. not paging a manager/doctor out of hours to review a result /decision, as it is not usual practice.

(Available at <http://www.mers-tm.org/>, Accessed on 21/12/2009)









