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List of Abbreviations

AA	Severe Acute Allergic/Anaphylactic Reaction	HBV	Hepatitis B Virus
AABB	American Association of Blood Banks	HCV	Hepatitis C Virus
A&E	Accident and Emergency	HDN	Haemolytic Disease of the Newborn
AHOSTR	Acute Haemolytic or Other Severe Acute Transfusion Reaction	HIV	Human Immunodeficiency Virus
AHTR	Acute Haemolytic Transfusion Reaction	HLA	Human Leucocyte Antigen
ALI	Acute Lung Injury	HSE	Health Service Executive
ATR	Acute Transfusion Reactions	HVO	Haemovigilance Officer
BCSH	British Committee for Standards in Haematology	IBCT	Incorrect Blood Component Transfused
BNP	Brain-type Natriuretic Peptide	IBTS	Irish Blood Transfusion Service
CMV	Cytomegalovirus	ICU	Intensive Care Unit
CPAP	Continuous Positive Pressure Ventilation	ID	Identity
DAT	Direct Antiglobulin Test	ID band	Identity band
DCU	Dublin City University	IgA	Immunoglobulin A
DHTR	Delayed Haemolytic Transfusion Reaction	IMB	Irish Medicines Board
DNP	Did Not Progress	INAB	Irish National Accreditation Board
DOB	Date of Birth	INR	International Normalised Ratio
DOHC	Department of Health and Children	ISBT	International Society of Blood Transfusion
ECG	Electrocardiograph	ISO	International Standards Organisation
EHN	European Haemovigilance Network	IV	Intravenous
EU	European Union	MERS-TM	Medical Event Reporting System for Transfusion Medicine
FBC	Full Blood Count	MRN	Medical Record Number
FFP	Fresh Frozen Plasma	MRTC	Munster Regional Transfusion Centre
FMH	Fetomaternal Haemorrhage	NAT	Nucleic Acid Amplification Testing
FNHTR	Febrile Non-Haemolytic Transfusion Reaction	NBC	National Blood Centre
HAV	Hepatitis A Virus	NBUG	National Blood Users Group
Hb	Haemoglobin	NBS	National Blood Service
HBsAg	Hepatitis B surface antigen	NHO	National Haemovigilance Office

MWRH	Mid-Western Regional Hospital
NTproBNP	N terminal pro hormone brain-type natriuretic peptide
O ₂	Oxygen
OPD	Out Patient Department
PAD	Pre-deposit Autologous Donation
PCC	Prothrombin Complex Concentrate
PCR	Polymerase Chain Reaction
PTP	Post Transfusion Purpura
QA	Quality Assurance
QA/QC	Quality Assurance/Quality Control
RCOG	Royal College of Obstetricians and Gynaecologists
Rh	Rhesus
Rh D	Rhesus D
RTA	Road Traffic Accident
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SD	Solvent Detergent
SHOT	Serious Hazards of Transfusion, UK
SOP	Standard Operating Procedure
STTI	Suspected Transfusion Transmitted Infection
TACO	Transfusion Associated Circulatory Overload
TA-GvHD	Transfusion Associated Graft-versus-Host Disease
TRALI	Transfusion Related Acute Lung Injury
TRIP	Transfusion Reactions in Patients, The Netherlands
UK	United Kingdom
UTI	Urinary Tract Infection
vCJD	variant Creutzfeldt Jacob Disease
WNV	West Nile Virus

Introduction

We had an excellent response to the new format of the National Haemovigilance Office (NHO) Annual Report introduced last year and have decided to continue this format for the NHO Annual Report 2006, the seventh full year of NHO reporting.

Once again, the greatest number of reports received was in the Incorrect Blood Component Transfused (IBCT) category and again the number of unnecessary transfusions reported within that category continues to rise.

While the risk of transmission of the known viruses Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) are now extremely small due to rigorous screening measures, the emergence of other infectious diseases such as variant Creutzfeldt Jacob Disease (vCJD) and West Nile Virus (WNV) as new transfusion risks, emphasises the need to avoid unnecessary transfusions. As previously noted in June 2005, an Irish blood donor was subsequently diagnosed with vCJD, indicating that vCJD is potentially in the blood supply.

During 2006, European Union (EU) Directive 2002/98/EC followed by Commission Directive 2005/61/EC came fully into force. The NHO, therefore, focused on supporting hospitals to meet these requirements through an extensive hospital visit programme and education meetings. A new initiative to help ensure consistency of reporting, the Haemovigilance Handbook was presented at the NHO annual conference and following consultation will be circulated in draft format during 2007.

Dr. Paul Strengers, former president of the European Haemovigilance Network (EHN), carried out a review of haemovigilance in Ireland during a three day visit in July 2006. The visit included a full review of the operations of the NHO including an audit of NHO incident management and data input.

The educational initiative with Dublin City University (DCU) for individuals interested in haemovigilance practice continued with both professional development modules "Understanding and Management of Blood Transfusions in a Haemovigilance Context" and "Haemovigilance: Blood Transfusion Nursing" well

subscribed. We express thanks to NHO staff, lecturers from hospitals and the IBTS who continue to support this initiative

A paper based on the results of the Near Miss Project undertaken in 2003-2005 was accepted by Vox Sanguinis for publication in early 2007. The NHO thanks hospital staff in the ten participating hospital sites who contributed to the success of the project. The information on the causes of error obtained from this project can be used to support improvements in delivery of transfusion to patients. The experience gained with this project has also informed changes to the new NHO database, allowing a more detailed causal analysis of errors which is presented in a new section in this year's report (p22)

The NHO is grateful to HVOs, Medical Scientists, Consultant Haematologists/Pathologists and other hospital Consultants for their continued efforts and support of the overall haemovigilance programme.

The advice of the Medical Director and staff of the IMB – the Competent Authority, is also acknowledged as is the expertise of the staff of the IMB's Pharmacovigilance Department and the IMB Inspectorate.

I would also like to thank the IBTS Chief Executive, Mr. Andrew Kelly, National Medical Director, Dr. William Murphy and the staff of the IBTS. Their continued efforts in recruiting voluntary blood donors and maintaining high standards in processing and distribution of blood for transfusion are the backbone of the national haemovigilance scheme.

We hope that you find the NHO Annual Report 2006 useful in your practice. In compliance with the Official Languages Act 2003 copies of this report will also be available in the Irish language.

Your feedback will be welcome.

Dr. Emer Lawlor,
Director NHO

National Haemovigilance Office (NHO)

'Haemovigilance' shall mean a set of organised 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 at the IBTS was set up in 1999 to collect confidential anonymised reports of transfusion associated severe adverse reactions and events from healthcare professionals. The duty to report was based on professional responsibility.

From 8th November, 2005, EU Directive 2002/98/EC was transposed into Irish law by European Communities (Quality and Safety of Blood and Blood Components), Regulations 2005 SI 360/2005. 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. Details on reportable reactions and events and the format of reporting were set out in 2005/61/EC transposed as SI 547/2006. Reporting of non mandatory SAE (Incorrect Blood Component Transfused (IBCT)) to the NHO remains part of professional responsibility.

Further information on the reactions and events which are reportable and how to report is available in the draft Haemovigilance Handbook on the IBTS website. www.ibts.ie (Haemovigilance pages).

The remit of the NHO is to:

- Receive, collate and follow up reports from hospitals and general practitioners of adverse reactions/ events connected with transfusion of blood components/products and provide feedback information to those making the report as appropriate.
- Advise on the follow-up action necessary, particularly with regard to suspected hazards.
- Report adverse reactions to the IMB according to

an agreed procedure.

- Provide ongoing support to hospital-based HVOs and as appropriate to medical, nursing and technical staff.
- Provide medical, scientific and nursing analysis of reports of adverse reactions.
- Advise on improvements in safe transfusion practice based on the data supplied by hospitals.
- Support development of clinical guidelines for hospitals in relation to the use of blood components/ products.
- Support the audit function of hospitals in relation to transfusion practice.
- Promote the development of fully traceable transfusion records at hospital level.
- Report to the National Blood User's Group on a periodic basis with a view to developing national best transfusion practice.

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

Definition of Terms used in Haemovigilance

Serious Adverse Event:

Any untoward occurrence associated with the collecting, testing, processing, storage and distribution of blood and blood components that might lead to

- Death or
- Life-threatening, disabling or incapacitating conditions for patients or
- which results in, or prolongs, hospitalisation or morbidity (SI 360/2005)

Serious Adverse Reaction:

An unintended response in the patient associated with the collection or transfusion of blood and blood component that is

- Fatal
- Life-threatening, disabling or incapacitating or
- Which results in, or prolongs hospitalisation or morbidity(SI 360/2005)

Irish Medicines Board (IMB)

The IMB and NHO representatives had regular case review meetings during 2006 to discuss reported incidents. As and from 8th November 2005, the IMB has become the Competent Authority for implementation of all aspects of the EU Blood Directive, including haemovigilance.

Education, promotion & developments

The NHO continues to support the development of hospital in-service training programmes by working closely with hospital based HVOs. Support is also provided in transfusion education for nursing and laboratory science students.

All newly appointed hospital based HVOs attend an induction training programme at the National Blood Centre (NBC).

Hospital visits were a high priority for the NHO during 2006 because of the implementation of the EU Directive and a total of 54 hospitals were visited. In addition, staff from twelve hospitals attended two Open Days and staff from another seven attended special IBTS/NHO meetings for hospitals to whom the IBTS supplies crossmatched blood.

The first draft of the Haemovigilance Handbook designed to ensure consistency of reporting to comply with the Directive was presented at the NHO Annual Conference.

Audit of Haemovitalance in Ireland

Dr Paul Strengers, former president of the European Haemovigilance Network (EHN), carried out an audit of

haemovigilance in Ireland during a three day visit in July 2006. The Department of Health and Children (DOHC) had requested this review.

The terms of reference set by the DOHC included an assessment of;

- the haemovigilance reporting structures in Ireland
- whether the current reporting systems would meet the requirements of the EU Directive
- whether the National Haemovigilance Office achieved its remit
- how the Irish reporting system compared with those across Europe

The methodology included a review of both the National Haemovigilance Office and hospital based haemovigilance. Systems at the National Haemovigilance Office such as report management structures were reviewed. Dr Strengers met representatives from the Irish Blood Transfusion Service (IBTS) the Irish Medicines Board (IMB) and the DOHC. He visited hospitals, and met with hospital managers, consultant haematologists, haemovigilance officers and medical scientists. Submissions (oral and written) were made by the Irish Haemovigilance Association and the Academy of Medical Laboratory Scientists.

Scientific Meetings

The NHO Annual Conference entitled “**Haemovigilance – The Challenge of the EU Directive**” was held in Portlaoise in October 2006. The Irish Haemovigilance Association also held their annual meeting in conjunction with this event.

Presentations included:

- Haemovigilance Handbook Volume 1, its contents explained - Ms. Marcia Kirwan, HVO, NHO
- Reporting of Reactions - Ms. Mairead Sheahan, HVO, NHO
- Annual Notification of Serious Adverse Reactions – Ms. Jackie Sweeney, HVO, NHO
- The NHO Annual Report 2005 - Dr Emer Lawlor, Director, NHO.

- Donor Haemovigilance – Dr. Ellen McSweeney, Consultant Haematologist, IBTS.
- Education and spreading the word – How people gain their knowledge – Ms. Marina Cronin, HVO, NHO
- Training implications of the EU Blood Directive 2002/98/EU Kerry Partnership Group – Ms. Hazel Reid, Medical Scientist, Kerry General Hospital
- Cell Salvage and methods to reduce blood usage – Ms. Martina O'Connor, HVO, University College Hospital Galway
- Audit Results of Octaplas – Mr. John Sheehy, Regional Haemovigilance Co-ordinator, Cork University Hospital
- Blood Stock Management in the Health Service Executive (HSE) Mid-Western Area Hospital Blood Bank – Ms. Sheila Joyce, Chief Medical Scientist, Mid Western Regional Hospital (MWRH) Limerick

The presentations were followed by a chaired open forum discussion

The winning poster competition entry was submitted by Ms. Eilish Creamer, HVO, Royal Victoria Eye and Ear Hospital with a poster entitled "Updating Nurses' Knowledge of Blood Transfusion Management through use of a Questionnaire". Dr. Maeve Leahy, Consultant Haematologist, MWRH acted as adjudicator for the poster competition.

European Haemovigilance Network

In February 2006, the 8th European Haemovigilance Seminar, the annual meeting of the European Haemovigilance Network (EHN) was held in Porto, Portugal with an attendance of haemovigilance representatives from Europe and worldwide. The NHO had two posters on display, one covering Haemovigilance Reporting in Ireland (2000–2004) and the other featuring the Near Miss project.

Dublin was chosen as the location for the 9th European Haemovigilance Seminar to be held in February 2007. The organising committee made up of NHO and IBTS staff and the scientific committee of haematologists and

transfusion specialists together with the conference organisers worked hard during 2006 to ensure that the conference would be a success.

Serious Hazards Of Transfusion (SHOT) Near Miss Workshop

This workshop was held on 21st November 2006 in The Royal College of Pathologists, London. Speakers included Professor Harold Kaplan who had developed the Medical Event Reporting System in Transfusion Medicine (MERS-TM) used in the IBTS Near Miss Project, Dr Joanna Weirsum who presented Near Miss data from the Transfusion Reactions in Patients (TRIP) scheme in the Netherlands and Dorothy Stainsby presented the SHOT Near Miss data. Dr Lawlor presented the Irish experience with the Near Miss project.

Publications from NHO

In late 2006, Vox Sanguinis accepted an article based on the results of the Near Miss Project 2003–2005 entitled "Seven Hundred and Fifty Nine (759) Chances to learn: a 3-year pilot to analyse transfusion-related near-miss events in the Republic of Ireland" for publication.

The **NHO News**, an information newsletter circulated to all HVO, provides an informal forum for the reporting of work carried out within the NHO and individual hospitals, and includes local education and training initiatives and social events which may be of interest to other HVO. Details of events of national and international interest are also reported. During 2006, five editions of this newsletter were published.

Working Parties

IMB/INAB Working Group

During 2006, the NHO participated in the IMB/Irish National Accreditation Board (INAB) Working Group set up to develop requirements for Traceability and Haemovigilance requirements for ISO 15189 which is the quality standard to which all Irish hospital blood banks must adhere by 8th November 2008. The resulting document "*Minimum Requirements for Blood*

Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC" was issued in September 2006

Better Blood Transfusion Network UK and Ireland

This is a working group of United Kingdom (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. Lawlor and Ms. Kirwan represented the NHO and IBTS during 2006.

Information on haemovigilance can be directly accessed on the IBTS website @ www.ibts.ie. (Haemovigilance pages). The NHO is very grateful for the support of all involved.

Key Findings of Annual Report 2006

- The main feature of this year's report was the number of unnecessary transfusions (51), mainly due to errors in clinical decision making. This accounted for 33% of IBCT/Serious Adverse Events (SAE) and 17% of total reports.
- Eleven (11) cases involved unnecessary use of SD plasma for warfarin reversal in the absence of active bleeding (British Committee for Standards in Haematology (BCSH), 2004; Baglin et al 2006)
- In contrast, the number of ABO incompatible and wrong blood to patient events has decreased. Although it is too early to be confident of this, this may reflect an increased awareness of correct procedures at all stages of the transfusion chain.

SAE/IBCT Key Recommendations

Clinical SAE/IBCT Recommendations

- All hospitals should have systems in place to ensure that protected time is made available for medical staff to attend haemovigilance training so that doctors involved in the prescription of blood/blood components are aware of current guidelines in relation to prescription and appropriate use of blood/blood components.
- It is the responsibility of the prescribing doctor to ensure that the most recent laboratory results are checked prior to prescribing. This check should include verification of the patient's details and the date the sample was drawn. Particular care should be taken when reading results from the computer screen to ensure the correct result is read.
- The final checking procedures at the bedside need to be strictly followed. The final bedside check is complex, involving multiple documentation/patient checks which, if not done correctly by trained staff, can lead to error. Automated systems for bedside checking should be introduced where possible to reduce the risk of human error.
- Near patient testing can be a valuable aid in the decision when to transfuse particularly in the surgical setting. However ongoing training of staff using this equipment and validation and maintenance of the equipment is vital. Equipment such as blood gas analyser/Haemacue® machines should be subject to the same standards of testing and validation as equipment within the diagnostic laboratories (SHOT, 2006). Where possible, prescriptions should be based on results confirmed in the laboratory.
- Where patients are receiving shared care, systems must be in place so that special requirements such as the need for irradiated and/or cytomegalovirus (CMV) negative components can be communicated between centres.

Laboratory SAE/IBCT Recommendations

- The practice of staff who normally work in other laboratory disciplines performing cross-call cover in transfusion has been associated with increased risk of error. Training for all hospital blood bank staff is now mandatory under the provisions of EU Directive 2002/98/EC and formal ongoing training programmes for medical scientists of all grades providing cross-call cover in transfusion should be provided in every hospital transfusing blood. These systems should include regular evaluation and competency assessment of staff.
- Laboratories should have systems to ensure that units intended for disposal are labelled/marked appropriately. Units for disposal should be stored in a designated, quarantined area with controlled access by laboratory staff. Units returned for disposal should be disposed of as soon as possible to reduce the risk of re-issue/collection in error.
- The laboratory is responsible for controlling access to laboratory fridges. Automated systems that provide controlled access/audit trails of movement of units in and out of the laboratory would help to reduce error.

SAR Key Recommendations

- Appropriate transfusion of blood components is vital in reducing the incidence of complications of transfusion in particular of Transfusion Related Acute Lung Injury (TRALI) which has been identified as the most important cause of transfusion related mortality and morbidity in the UK SHOT scheme (Stainsby et al, 2006).
- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly and the patient observed closely for the first 15 minutes/50mls as severe reactions are most likely to occur within this time (BCSH, 1999; National Blood Users Group (NBUG), 2004).
- Each hospital must have a policy in place for the management of an acute transfusion reaction. This should include the medical and nursing management of the patient's symptoms and the investigations necessary to complete the transfusion reaction analysis.
- Even mild reactions should be reported to the HVO and hospital blood bank as subsequent reactions may be more severe.
- Patients who have experienced a severe allergic/anaphylactic reaction during a blood component transfusion should have a label placed on their chart alerting clinical staff to their history of transfusion reactions to ensure appropriate component selection and pre-medication is given prior to future transfusions.
- Where patients are receiving shared care, systems must be in place so that relevant details relating to transfusion such as history of reaction/allergy and/or pre-medication requirements can be communicated between centres effectively.
- All patients should be assessed pre-transfusion to assess their risk of developing Transfusion Associated Circulatory Overload (TACO). Particular attention should be paid to the identification and management of 'high-risk' patients such as small

elderly patients with a history of underlying cardiac disease or chronic anaemia.

- At risk patients should be transfused slowly on a unit by unit basis and close attention, where possible, should be paid to the patient's fluid balance status not only during the transfusion but also in the 24 hour period prior to transfusion. Single unit transfusions can result in TACO and therefore should be monitored as closely as multiple unit transfusions.
- The risk of TACO can be reduced by the administration of pre-transfusion diuretics. This may also be necessary for those on regular diuretic therapy.

Serious Adverse Reactions and Events 2006

Eighty five hospitals/facilities were issued with the 'Annual Notification of Serious Adverse Reaction and Events' form as set out in Annex II D and III C 2005/61/EC which has replaced the 'Nil to Report' form. Eighty four (99%) forms were returned for analysis. Twenty (24%) sites reported one or more SAR and 4 (5%) sites reported one or more SAE. Fifteen (18%) reported both SARs and SAEs and a further 45 (52%) indicated that they had not reported any SAR or SAE in 2006. This form does not collect non mandatory IBCT incidents

Denominator data

During 2006 a total of 188,154 (including Solvent Detergent (SD) plasma) components were issued by IBTS, (Table 1).

Table 1 Blood and Blood Components issued by IBTS 2006

Component	Number issued
Red Cells and Whole Blood	138,540
Platelets – Therapeutic Doses	20,355
Fresh Frozen Plasma	707
SD Plasma (Octaplas)	25,425
Cryoprecipitate	1,984
Cryo-depleted plasma	1,143
Total components issued	188,154

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

In total, 304 incidents were accepted for this report, up by 78 (26%) on 2005 figures. One hundred and eighty seven (187) were SAE/IBCT and the remaining 117 were SAR. An additional 40 reports did not fulfil the criteria for a Haemovigilance event, as on further investigation it was found that the reaction or adverse event was not related to transfusion. These reports were classified as 'Did Not Progress' (DNP).

The incidence of SAE/IBCT and SAR per unit transfused is listed in Table 2. The highest number of reports was, as in previous years, in the SAE/IBCT category followed by Febrile Non-Haemolytic Transfusion Reactions (FNHTR) and then TACO.

Table 2 Incidence of IBCT/SAE and SAR

IBCT/SAE and SAR per unit issued from IBTS-2006

Category	Red Cells & Whole Blood 138,540	Platelets 20,355	Plasma 27,275 ¹	Total components 188,154 ²
IBCT/SAE (155) ³	1 per 1,082	1 per 1,357	1 per 1,705	1 per 1,214
FNHTR (38)	1 per 4,777 ⁴	1 per 2,908	1 per 27,275	1 per 4,951 ⁵
Immunological Haemolysis (Acute) (2)	1 per 69,270	0	0	1 per 94,077
Anaphylaxis/Hypersensitivity (29)	1 per 15,393	1 per 1,131	1 per 13,638	1 per 6,488
Delayed Haemolytic Transfusion Reaction (Immunological Haemolysis) (4)	1 per 34,635	0	0	1 per 47,038
TACO (34)	1 per 4,329	0	0	1 per 5,534 ⁵
TRALI (2)	1 per 69,270	0	0	1 per 94,077
Confirmed Transfusion Transmitted Infection (TTI) (Viral) (0)	0	0	0	0
Possible STTI (Bacterial) (1)	0	1 per 20,355	0	1 per 188,154

¹ Solvent Detergent (SD) Plasma, Fresh Frozen Plasma (FFP) and Cryo Depleted Plasma

² Total components includes cryoprecipitate -1984 units

³ Excludes IBCT associated with Anti-D immunoglobulin and factor concentrates.

⁴ FNHTR: RCC-28; Whole Blood-1

⁵ Multiple Components: TACO- 2; FNHTR-1.

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

Introduction

The NHO collects both Serious Adverse Events (SAEs) which are mandatory under legislation (EU Blood Directive 2002/98/EC) and Incorrect Component Transfused (IBCT) which are non-mandatory but reportable under professional responsibility. This year the IBCT chapter has been renamed IBCT/SAE to reflect this.

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 1998)

A Serious Adverse Event (SAE), is defined within the directive as;

'any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs hospitalisation or morbidity'.

Summary of Findings

The total number of IBCT/SAEs reported in 2006 was 187. One hundred and fifty five (155) of these involved components and the remaining 32 events involved blood products.

The IBCT/SAE category accounted for 61% of incidents in 2006 (187 out of 304) which represents an increase of 14 (8%) from 2005. The incidence of IBCT/SAEs (involving components and SD plasma) is one per 1,214 units issued from the IBTS.

Risk Levels of Events

Level 1 (high risk events)

Events with real potential for permanent injury or to be life threatening

Ninety (90) out of 187 (48%) of events have been classified as level 1. This represents a 10% increase on the level 1 events reported in 2005. High risk events represented almost 50% of the total number of IBCT/SAEs reported in 2006. This may reflect both an increased awareness of reporting and improved systems for reporting from hospitals following the introduction of mandatory reporting in November 2005.

Level 2 (medium risk events)

Events which are very unlikely to cause permanent harm or have the potential for minimal or transient harm

Fifty-three (53) events have been classified as level 2. This event level has remained the same as 2005 at 28%.

Level 3 (low risk events)

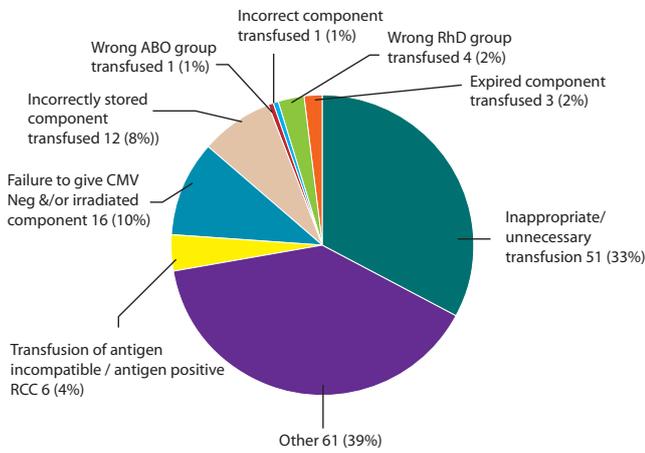
Events with no realistic potential for harm

The remaining 44 (24%) events have been classified as level 3, representing a 10% decrease in this event level from 2005. This reduction is due to the fact that the NHO no longer collects level 3 events. Low risk events, however, along with near-miss and non conformance data should be collected and analysed at local level.

Classification of IBCT/SAEs

In this year's report, we have classified each IBCT/SAE according to the nature of the event. Figure 1 gives a breakdown of IBCT/SAEs by nature of events (components and SD plasma only).

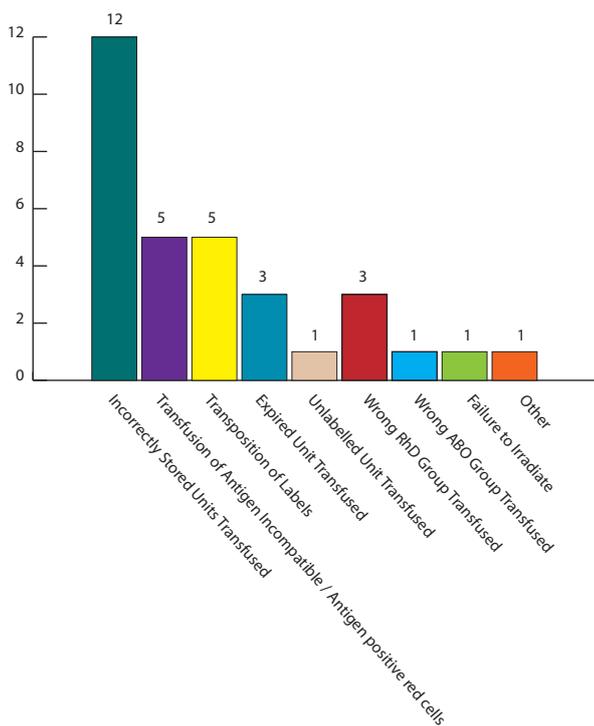
Figure 1 Breakdown of IBCT/SAE by Nature of Event (n=155)



Mandatory SAEs

Thirty-two of 187 (17%) events fitted the category of SAE reportable under EU Directive 2002/98/EC (i.e. events which effected the quality and/or safety of the blood supply). Figure 2 gives a breakdown of events reportable under the EU Directive.

Figure 2 - Breakdown of Mandatory SAE reportable under EU Directive (n=32)



IBCT/SAE Category - Main Findings

(See Figure 1)

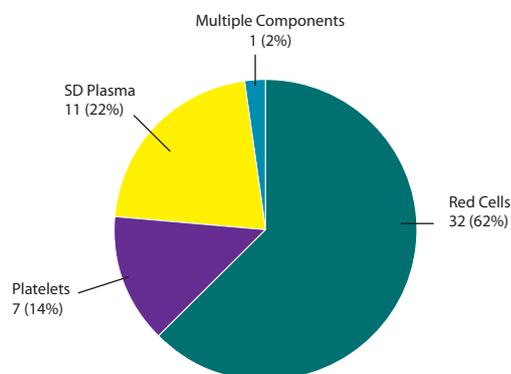
- Unnecessary transfusion was found to be the largest single category of error, accounting for 51 (33%) of the 155 events reported.
- There was one ABO incompatible transfusion (involving platelets)
- Wrong Rh D group transfused accounted for four (2%) events.
- Six (4%) events involved the transfusion of antigen incompatible / antigen positive red cells.
- Transfusion of incorrectly stored components accounted for 12 (8%) events.
- Failure to give CMV negative and / or irradiated components accounted for 16 (10%) events.
- Three (2%) events involved expired units being transfused.
- One event involved the wrong component being transfused (patient received SD plasma instead of the prescribed FFP).
- The remaining 61 (38%) events were categorised as 'Other' and are discussed on page 21 Figure 4.

Main Findings

Unnecessary Transfusions

The largest single IBCT/SAE event reported was unnecessary transfusion which accounted for 51 (33%) of events. Forty-eight (94%) events within this category involved errors outside the transfusion laboratory, six of which involved transfusions based on the wrong Hb results due to errors at pre transfusion sampling. The remaining three (6%) involved haematology laboratory errors.

A further breakdown of these events has been carried out to analyse this category of error in more detail.

Figure 3 Breakdown of Unnecessary Transfusion (n=51)

- Thirty two (62%) unnecessary transfusions involved red cells, seven (14%) involved platelets, 11 (22%) involved SD plasma and one (2%) involved multiple components.

Unnecessary Transfusion-Clinical Errors (n = 42)

- In nine (9) cases, red cells were given unnecessarily due to either failure to verify the patient's most recent laboratory Hb result or failure to verify the result of a check of Hb taken between units.
- Eleven (11) cases involved unnecessary red cell transfusions due to errors in clinical judgement. In one of these cases a breakdown of communication between medical teams contributed to the error.
- Eleven (11) cases involved inappropriate use of SD plasma for warfarin reversal. In two of these cases, SD plasma and Prothrombin Complex Concentrate (PCC) were given in addition to vitamin K. These cases demonstrate a lack of awareness of the appropriate treatment for warfarin reversal in the absence of active bleeding (BCSH, 2004; Baglin et al, 2006).
- Five (5) cases involved unnecessary platelet transfusions due to errors in clinical decision making. Communication problems between medical

teams was a contributing factor in two of these cases.

- One (1) case involved an unnecessary platelet transfusion due to a failure to check the patients platelet count between units.
- Five (5) unnecessary red cell transfusions were given as a result of errors made by nursing staff. Three cases involved failure to verify the prescription prior to commencing the transfusion. One case involved a nurse transcribing the wrong Hb result from the computer resulting in an unnecessary prescription (Case History 1). In a further case a patient who was only prescribed two units of RCC had three donor unit exposures. This occurred because 10–15 minutes into the transfusion the intravenous (IV) line was re-sited and following this, the original unit was discarded and a fresh unit of red cells was commenced by nursing staff.

Case History 1 Unnecessary Transfusion

This patient with a malignant condition was prescribed red cells for a haemoglobin (Hb) of 7.5g/dl. The transfusion was commenced but while it was in progress, the doctor checked the patient's results on the hospital computer system and found the actual Hb was 12.5g/dl. Nursing staff had earlier transcribed another patient's Hb result from the computer in error and the prescription had been based on this wrong result. The transfusion was discontinued immediately. The patient suffered no ill effects as a result of this unnecessary transfusion. As a result of this incident, local guidelines have been changed and all results must now be verified on the hospital computer system prior to prescribing.

Errors in Sampling (Clinical) (n=6)

- One (1) event involved an unnecessary red cell transfusion because the pre transfusion sample was taken from the wrong patient leading to a prescription based on another patient's Hb.
- Four (4) events involved unnecessary red cell transfusions due to haemodiluted samples being processed. In three (3) of these cases the samples were tested on either a blood-gas analyser or Haemacue® machine outside the laboratory.
- One (1) event involved an unnecessary transfusion of red cells but it is unclear if the sample was taken from the wrong patient or if the sample was haemodiluted. The pre transfusion Hb was 9.5g/dl, post transfusion of one unit of red cells, the Hb was 14.4g/dl.

Errors in Sample Processing (Laboratory) (n=3)

- In one (1) event, an unnecessary transfusion of red cells was given because the wrong Hb results were issued from the haematology laboratory. This was due to a mix up of specimen numbers on Hb samples in the laboratory leading to the results for another patient being issued for that patient.
- In one (1) event, an error in the laboratory analyser led to an unnecessary transfusion of SD plasma due to the wrong coagulation result being issued.
- In one (1) event, an unnecessary transfusion of platelets was given as the prescription was based on an inaccurate platelet count result. The FBC sample contained clots which were not detected when the laboratory tested the sample.

Recommendations

The following recommendations are based on the findings and the causal analysis of the administration errors presented on page 25.

- All hospitals should have systems in place to ensure that protected time is made available for medical staff to attend haemovigilance training so that doctors involved in the prescription of blood/blood components are aware of current guidelines in relation to prescription and appropriate use of blood/ blood components.
- It is the responsibility of the prescribing doctor to ensure that the most recent laboratory results are checked prior to prescribing. This check should include verification of the patient's details and the date the sample was drawn. Particular care should be taken when reading results from the computer screen to ensure the correct result is read.
- Near patient testing can be a valuable aid in deciding when to transfuse particularly in the surgical setting. However, ongoing training of staff using this equipment and validation and maintenance of the equipment is vital. Equipment such as blood gas analyser/Haemacue® machines should be subject to the same standards of testing and validation as equipment within the diagnostic laboratories (SHOT. 2006). Where possible prescriptions should be based on results confirmed in the laboratory.
- The final checking procedures at the bedside need to be strictly followed. The final bedside check is complex. It involves multiple documentation/patient checks, which, if not done correctly by trained staff, can lead to error. The introduction of automated systems for bedside checking should be introduced where possible to reduce the risk of human error.

Errors Involving Wrong ABO/Rhesus (Rh) D group, Wrong Blood Component or Blood to Wrong Patient (n=6)

- There were six (6) events involving wrong ABO/Rh D group, wrong blood component or blood to wrong patient in this reporting year. There were no sequelae as a result of these errors.

ABO Incompatible Transfusions

- There were no ABO incompatible transfusions involving red cells. There was one (1) ABO incompatible transfusion involving platelets. This error occurred due to the transposition of documentation for two units of platelets intended for two different patients in the laboratory and a failure of the bedside checking procedure.

Wrong Rh D Group Transfused

- There were four (4) events where the wrong Rh D group was transfused. Three of these events were due to errors within the transfusion laboratory.
- In the first case, the wrong Rh D group was selected by the medical scientist. A major contributing factor in this case was human error due to tiredness as the medical scientist involved had just spent the previous three hours carrying out a very complicated cross-match.
- In the second case, the patient was grouped correctly but the Rh D group was recorded incorrectly.
- In both cases, the medical scientist involved was on-call doing cross-call cover and in both cases, there was a failure of the bedside checking procedure so the errors were not detected.
- In the third event, it is unclear if the original sample was taken from the wrong patient or if there was a

grouping error. The discrepancy in Rh D groups was discovered during a subsequent grouping of the patient when it was noted in the patient's historical records that they had been grouped incorrectly one month previously.

- One further minor event involved the transfusion of two units of O Rh D negative red cells to an O Rh D positive patient. This event occurred as the initial reading of the test result was carried out using an immediate spin method. The result was reported as negative without waiting for the 30 minute incubation period as per Standard Operating Procedures (SOP). When the test result was re-read an hour later, a weak positive reaction was seen. This event involved a medical scientist who was doing cross-call cover.

Wrong Blood Component Transfused

- There was one (1) event involving the wrong component transfused, where the patient, with a rare disorder requiring treatment with Fresh Frozen Plasma (FFP) rather than SD plasma, received SD plasma instead of the prescribed FFP. This occurred due to multiple errors, mainly due to breakdown in communication between treatment centres, but also due to lack of clear guidelines relating prescription/issue of plasma and lack of adequate training for staff involved in cross-call cover in transfusion.

Blood to Wrong Patient

- There were no events involving the transfusion of a blood component to a wrong patient (blood to wrong patient) in this reporting year.

Errors Involving Transfusion of Antigen Incompatible/Antigen Positive Blood (n=6)

- There were six (6) events within this category in this reporting year, four of which occurred as a direct

result of errors within the hospital transfusion laboratory. One (1) event occurred due to an error in the blood supply centre and a further event occurred due to a clerical error on admission. There were no sequelae.

Laboratory Errors

- One (1) event involved the transfusion of blood which was not Kell negative to a woman of child bearing age in error. This event occurred as the medical scientist was just back from holidays and failed to recall that the blood centre had previously sent a memorandum recommending that all females of child bearing age should receive Kell negative RCC. This lady developed anti-K as a result of this error. The computer system in this laboratory has been amended as a result of this event and a warning flag has been added to alert staff to issue Kell negative units to all women under 60 years of age.
- One event involved the transfusion of C positive red cells to a patient with anti-C. This occurred as the medical scientist performing the crossmatch was inexperienced and overrode the computer alarm alerting her to the error as she thought that all Rh D negative units were C negative. This hospital operates a multidisciplinary laboratory system where staff rotate through all the disciplines and no one person is specifically allocated to transfusion on a permanent basis.
- One event involved a patient with a history of anti-E, anti-c and anti-Cw being transfused with red cells which were not antigen typed. The patient had low titre antibodies (detectable in enzyme only), the Quality Assurance (QA) flag was overridden by the medical scientist and incorrect units were selected for cross match. This event occurred during on-call hours.

- One further event involved a patient with a history of multiple antibodies which included anti-Fy^a, being transfused with one unit of red cells which were Fy^a positive. This event occurred due to a failure to ensure that the unit had been antigen typed prior to cross-match and issue.

Blood Centre Error

- This event involved the issue and transfusion of units which were typed incorrectly as Kell negative from the blood centre. The error occurred as the medical scientist performing the test and reading the controls was inexperienced and followed an SOP for this process which did not contain enough detail to determine the results correctly.

Admission Department Error

- This event involved a patient with a history of weak anti-Fy^a antibody receiving red cells which were not antigen negative. This error occurred due to a clerical error on admission involving the wrong medical record number (MRN) being entered onto the computer leading to a new patient record being created. This led to the patient's historical transfusion records, which were available in the laboratory, not being reviewed and the patient was thus transfused with blood which was Fy^a positive (Case History 2).

Case History 2

Transfusion of antigen incompatible blood

This elderly patient required transfusion of two units of red cells for chronic anaemia (Hb 8.6g/dl). This patient had been admitted to the same hospital previously and historical records in the transfusion laboratory had recorded the presence of a weak anti-Fy^a on antibody screen. Due to a clerical error on admission, the patient's surname was entered onto the computer incorrectly and a

new patient record, with a new MRN, was created. As a result of this, the patient's old notes and transfusion history in the laboratory were not available for staff to detect the antibody history. Two units red cells were cross matched, but the weak antibody was not detectable on this occasion so antigen negative blood was not selected. The error was discovered by chance after the transfusion when the medical scientist happened to use a different method to search for the patient's details. The scientist found that an error had been made in the spelling of the patients name on admission as the correct name for the patient came up on the system. The patient was very ill from their underlying condition and subsequently died, unrelated to transfusion. As a result of this error, the risk management and haemovigilance departments are addressing the training of clerical staff in relation to the importance of correct patient identification.

Recommendations

- The practice of staff who normally work in other laboratory disciplines performing cross-call cover in transfusion has been associated with increased risk of error (Lundy et al 2007). Training for all hospital blood bank staff is now mandatory under the provisions of EU Directive 2002/98/EC and formal ongoing training programmes for medical scientists of all grades providing cross-call cover in transfusion should be provided in every hospital transfusing blood. These systems should include regular evaluation and competency assessment of staff.

Errors Involving Transfusion of Incorrectly Stored Units (n=12)

- There were twelve (12) events within this category in this reporting year. All of the events involved red cells.

- In four events, units were returned to the laboratory for disposal but were placed back into either issue or stock fridges and not into quarantine. In two of the cases, there was a failure to mark/label the units for disposal. The units were subsequently re-collected in error and transfused.
- Two events involved units being stored in domestic fridges outside the laboratory prior to transfusion.
- In two separate events, units which had been out of controlled storage greater than 30 minutes were returned to the laboratory before the transfusion was commenced as the patient had either pyrexia or problems with IV access. The units were subsequently re-collected and transfused 6.5 and 24 hours later respectively.
- Two events involved units which were collected from the laboratory fridge and returned >30 minutes later. These units were subsequently re-collected and transfused so that the total transfusion time from initial collection to completion of transfusion exceeded the recommended four hours.
- Two events involved units being removed from and subsequently returned to controlled storage without logging the time of removal or return. In both events, the units were re-issued and subsequently transfused without confirmation of how long the units had been out of controlled storage.

Recommendations

- Verification of baseline observations and IV access should take place prior to collection of units from controlled storage.
- Laboratories should have systems to ensure that units intended for disposal are labelled and/or marked appropriately. Units for disposal should be stored in a designated, quarantined area with controlled access by laboratory staff. Units returned

for disposal should be disposed of as soon as possible to reduce the risk of re-issue/collection in error.

- The laboratory is responsible for controlling access to laboratory fridges (including satellite fridges). Automated systems that provide controlled access/audit trails of movement of units in and out of the laboratory would help to reduce error.

Errors Involving Transfusion of Expired Units (n=3)

- There were three (3) events involving expired units transfused in this reporting year.
- In the first case, a clinical decision was made by the patient's consultant to transfuse red cells that had expired 48 hours earlier and were due to be returned to the blood centre for disposal. This occurred in a massive transfusion setting where all available stock had been used for emergency transfusions for other critically ill patients and the hospital was awaiting delivery of additional stock from the blood centre.
- Two events involved expired red cells being transfused as units that had been crossmatched for patients but had subsequently expired, had not been removed from the blood fridge and were available for collection. Both events also involved failures in the final bedside checking procedures as the expiry date was not checked prior to commencing the transfusion. A further contributing factor in one of these events was that the laboratory is off-site. The HVO who is responsible for stock control and removing expired units from the available supply, was on holidays.

Recommendations

- The laboratory is responsible for stock control/management of expired units. There must be systems in place to ensure that expired units or units unsuitable for use are removed from blood fridges (including satellite fridges) on a daily basis. Any units near to expiry should be clearly marked to alert staff involved in collection/administration.
- Where transfusion laboratories are off-site, systems must be in place to enable the supplying laboratory to monitor the stock in satellite fridges and provisions must be in place to have cover when the person with responsibility for stock control is away on leave for any reason.
- Automated systems which would not allow release of expired blood from the laboratory/satellite fridges would reduce the risk of error.
- Hospitals should ensure that as far as possible they have adequate blood stocks to manage massive bleeding episodes in patients. A review of the adequacy of stock and the speed of response should be undertaken after every episode to ensure that lessons may be learned and applied in future.

Errors Involving Failure to Give CMV negative/Irradiated Components (n=16)

- There were 16 events involving failure to give CMV negative and/or irradiated components, three of which involved paediatric patients (<18years of age).
- In 14 out of the 16 (88%) events, CMV negative and/or irradiated components were not prescribed.
- One event involved an error at the blood centre where a non-irradiated unit of red cells was issued with a label stating it had been irradiated. (See errors involving paediatric patients on page 27 for further details on this event)

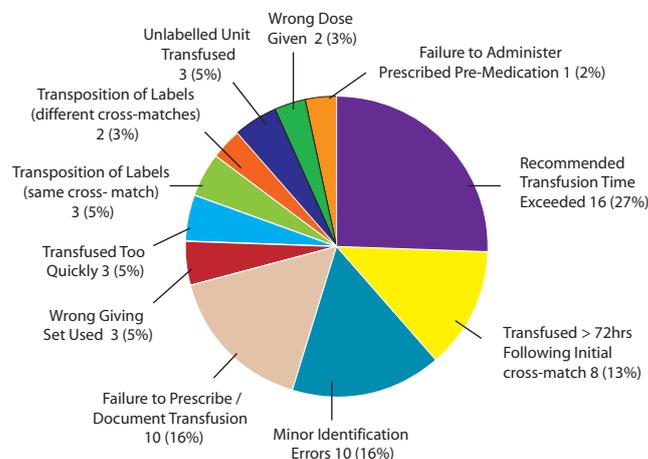
- One further event involved a laboratory error where the medical scientist failed to issue the requested special requirements as s/he overrode the computer warning in error.

Recommendations

- Medical staff involved in the prescription/request of components for patients with special transfusion requirements such as CMV negative and/or irradiated components should receive education and training in the management of these types of patients.
- All hospitals should have policies and procedures in place to manage patients with special requirements and ensure that where special requirements are required, they are received.
- Where patients are receiving shared care, systems must be in place so that special requirements such as need for irradiated and/or CMV negative product can be communicated between centres.
- Laboratory computer systems should have audible and visual alarms to alert staff to patients with a history of special transfusion requirements. Particular care should be taken by laboratory staff not to override these types of alarms inadvertently.

IBCT/SAE in the 'Other' Category

Figure 4 Breakdown of 'Other' SAEs/IBCT (n=61)



Findings

- Apart from the events involving transposition of labels between different cross-matches and unlabelled units being transfused, the majority of events within the 'other' category involved minor low risk (level 3) events.
- Five (8%) events involved transposition of labels (two cases involved transposition between cross-matches for different patients).
- Three (5%) events involved unlabelled units being transfused (two SD plasma units and one red cell unit).
- Sixteen (27%) events involved transfusions which exceeded the recommended transfusion time of four hours following removal from controlled storage.
- Failure to prescribe/document transfusion and minor identification errors accounted for ten (16%) events each.
- The remaining events are identified in figure 4 above.

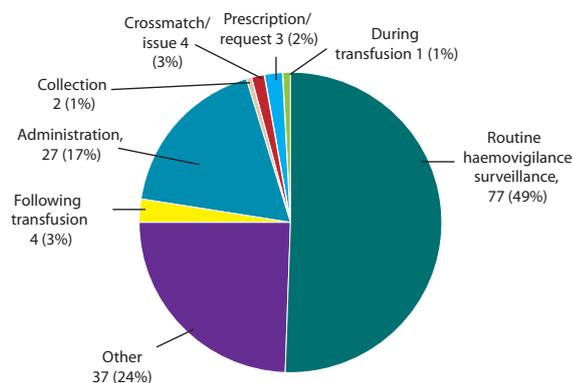
Where, Who, What, Why? Analysis of IBCT/SAE Data

As a result of experience gained during the NHO three year Near-Miss pilot research project, the NHO have analysed this year's data using methodology adapted from the Mers-TM system. Mers-TM is a web-based event reporting system designed specifically to collect, classify and analyse events that could compromise the safety of transfused blood (Kaplan et al, 2002).

This section of this year's report presents data relating to error discovery and error occurrence. It examines the steps in the work process where events are being discovered and who is discovering the errors. It also examines where errors are occurring and who is involved. The highest risk steps in the work process have been identified and analysed and the most significant causal factors are presented where possible. The majority of events involved more than one root cause. Only the most significant causal factor for each event has been included in the analysis.

Discovery Data

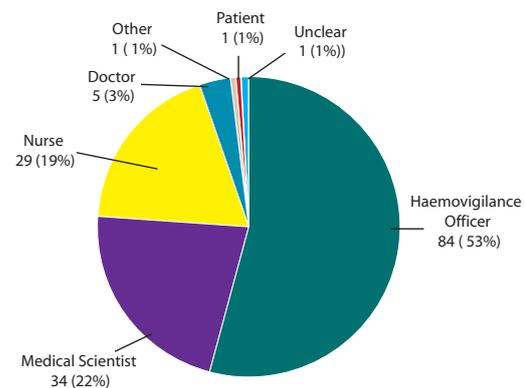
Figure 5 - Step in the work process where errors were discovered (n=155)



Findings

- The majority of errors 77 (49%), were discovered during routine haemovigilance surveillance or audit. This reinforces the need for continual haemovigilance surveillance and ongoing audit within each hospital involved in transfusion.
- This was followed by 'other' miscellaneous steps in the work process where 37 (24%) events were discovered.
- The administration process has also been highlighted as an important step for error discovery with 27 (17%) of errors being detected at some point in this process.

Figure 6 - Who Discovered the Errors (n=155)

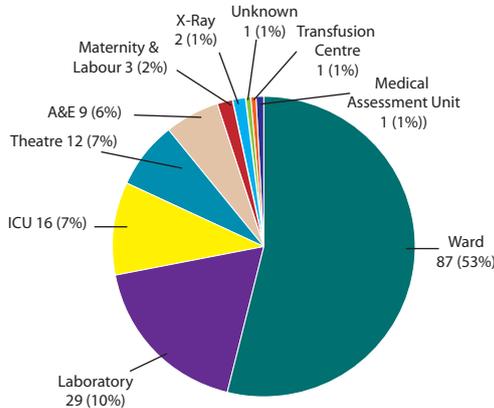


Findings

- The majority of errors 84 (53%) were discovered by the HVO demonstrating the vital role the HVO play in error detection and reporting.
- This was followed by medical scientists who discovered 34 (22%) of events and nursing staff who discovered 29 (19%) of events.

Occurrence Data

Figure 7 - Where Errors are Occurring (by Department/Clinical area) (n=161*)



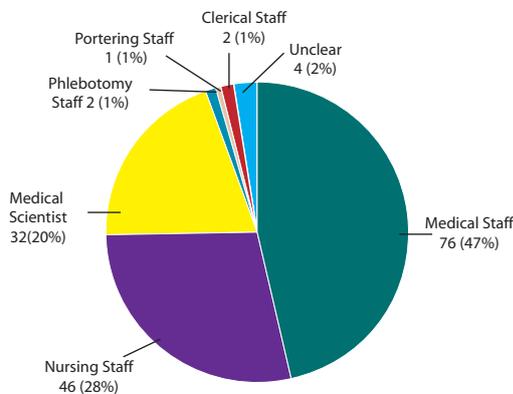
*Some events involved errors in more than one area

Findings

- The majority of errors 87 (53%) occurred on the wards (including haematology/oncology wards).
- This is followed by the transfusion laboratory where 29 (18%) of errors occurred and the Intensive Care Unit (ICU) where 16 (10%) of errors occurred.

Who was Involved

Figure 8 - Who was involved in Errors (n=163)*



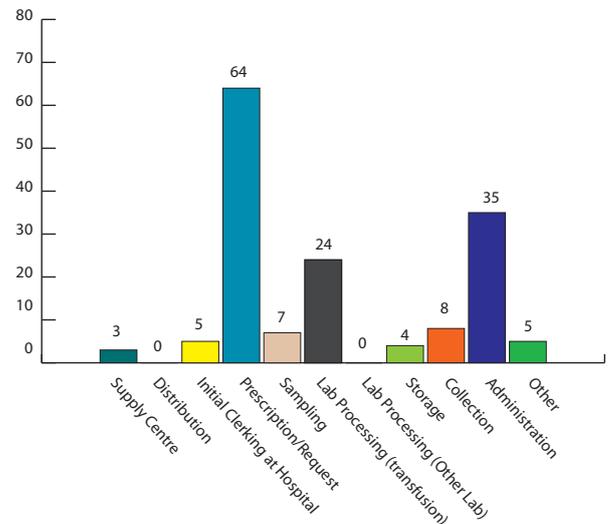
*Some errors involved more than one grade of staff

Findings

- Medical staff were most frequently involved in error with 76 (47%) events involving doctors. While many of these events involved errors by junior doctors, a number of events involved senior medical staff. In one event, a consultant instructed that a unit of red cells be given unnecessarily to a patient with a Hb of 15.2g/dl because it had been crossmatched and was available for the patient.
- Nursing staff were involved in 46 (28%) events and laboratory staff were involved in 32 (20%) events.

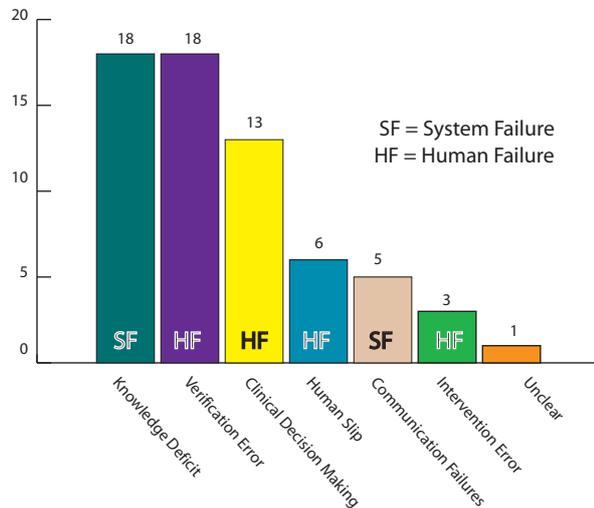
High Risk Steps in the Work Process

Figure 9 - Steps in the work process where errors first occur (1st site of error n=155)



- This data reflects findings from 'first site of error' (Figure 9) which found that prescription/request (which involves medical staff), administration (which involves nursing staff) and laboratory processing in blood transfusion (which involves medical scientists) were the three highest risk steps in the work process.

Figure 10 - Breakdown of Errors First Occurring at Prescription/Request (by causal factors n=64)



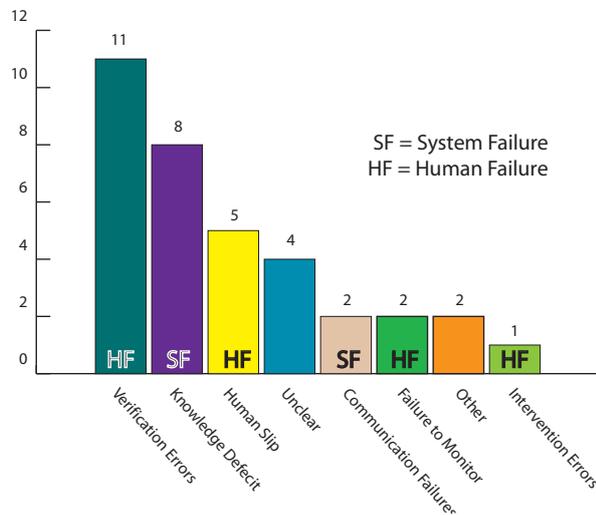
Analysis of Errors that first occurred at Prescription/Request (n=64)

- Forty (62%) errors occurring at prescription/request involved human failures, twenty-three (36%) involved system failures and in one event (2%), it is unclear if system or human failure was the cause of error.
- Eighteen of the 64 (28%) errors involved a knowledge deficit of the prescribing doctor i.e. the prescribing doctor was unaware of the guidelines relating to prescription/appropriate use of components or the need for special requirements. This led to patients having components prescribed unnecessarily or not receiving CMV negative/irradiated components when they were indicated.
- A further 18 (28%) events involved verification errors, i.e. failure to verify or wait for the most recent laboratory results prior to prescribing or failure to verify the prescription prior to requesting/administering the unit. This resulted in prescriptions based on the wrong blood results and missed

changes to prescriptions/requests leading to unnecessary transfusions.

- Thirteen (20%) events involved errors in clinical decision making i.e. the clinical decision to prescribe the blood/blood component was not within best practice guidelines leading to unnecessary transfusions.
- Six (9%) events involved human errors i.e. slips or oversights while writing the prescription that led to patients with special requirements not receiving CMV negative and/or irradiated components.
- Five (8%) events involved communication failures i.e. a breakdown of communication and/or difference of opinion between medical teams treating the patient. This led to confusion in the treatment plan resulting in patients having components prescribed unnecessarily.
- Three (5%) minor events involved intervention errors i.e. the prescribing doctor was aware of, but failed to adhere to the hospital policy for prescription. These minor errors relate to events where the patient received components (in the theatre setting) which were not prescribed in writing, but were required.
- In a further event, the cause of the error is unclear.

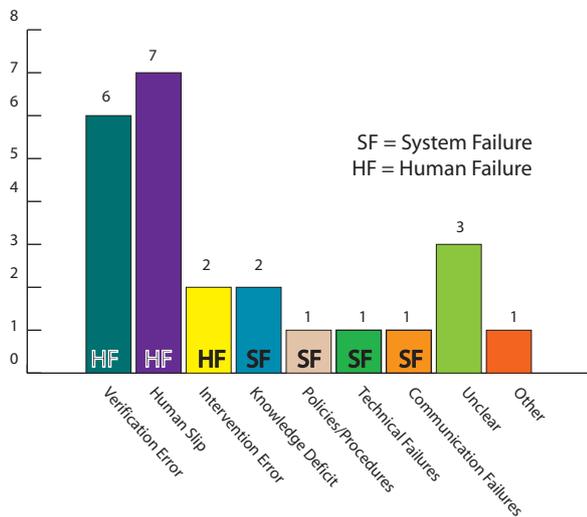
Figure 11 - Breakdown of Errors that First Occurred at Administration (by causal factors n=35)



Analysis of Errors First Occurring at Administration (n=35)

- The majority, 19 (54%) events first occurring at administration involved human failures, ten (29%) involved system failures and in the remaining six (17%) events, the root cause was unclear.
- Eleven (31%) events involved verification errors i.e. failure of the bedside checking procedure or failure to check the patient's IV access/observations prior to collection of units. This led to patients receiving unnecessary/incorrectly stored/expired units.
- Eight (23%) events involved a knowledge deficit, i.e. staff being unaware of the guidelines relating to transfusion procedures. This resulted in patients receiving units that had been incorrectly stored, units being transfused outside the recommended timeframe and unnecessary transfusions.
- Five (14%) events involved human slips, i.e. where staff appeared to have a 'mind-slip' and simply forgot to carry out a task or procedure or omitted a step from a procedure. Three of these relate to staff simply picking up the wrong giving set prior to going to the patients bedside as the blood giving sets were stored next to the regular giving sets. One event involved the rate on an infusion pump being incorrectly set, resulting in a unit of red cells being transfused over 2.5 hours instead of the prescribed 4 hours. One further event involved a human slip due to distraction caused by a busy workload. This resulted in a unit that had been out of controlled storage >30 minutes being returned, recollected and transfused to a different patient.
- Two events involved communication failures i.e. failures in the handover procedures where units had been commenced in one clinical area and the patient was then transferred to another clinical area. This resulted in units being transfused outside the recommended time frame of four hours following removal from controlled storage.
- Two events involved failure to monitor the transfusion/patient appropriately. This led to units being transfused too quickly. In both cases the units were transfused in just over one hour instead of the recommended four hours.
- One event involved an intervention error, i.e. where the nursing staff were aware of, but failed to adhere to the correct procedures for transfusion. This led to a patient being transfused, with an incorrect transfusion number on their ID band.
- In two further low-risk events, patients were transfused outside the recommended four hour time frame. In the first event, a clinical decision was made to slow the rate of transfusion due to pyrexia and in the second event the patient was being assisted to the bathroom very frequently during the transfusion and this unavoidably slowed the rate of transfusion.
- In four events, the cause of the error remains unclear.

Figure 12 - Breakdown of Errors First Occurring During Laboratory Processing (Blood Transfusion Laboratory) (by causal factors n=24)



Analysis of errors first occurring in the Blood Transfusion Laboratory (n=24)

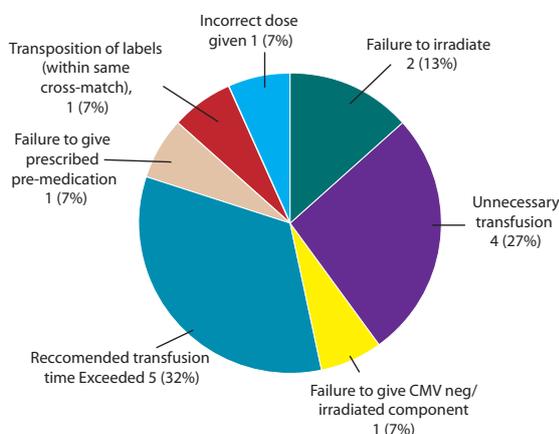
- Fifteen (62%) of the errors first occurring in the blood transfusion laboratory involved human failures and five (21%) involved system failures. In three events, the causes of error remain unclear and one further event involved a clinical decision that led to laboratory staff being involved in a reportable error.
- Seven (29%) events involved errors made by staff on-call or providing cross-call cover.
- Six (25%) events involved verification errors i.e. failure to carry out final crosschecks of units or documentation prior to issue. This resulted in patients receiving units with labelling errors such as wrong unit labels, incorrect details on unit labels and unlabelled units. In one event, platelets which were ABO incompatible were issued due to a failure in documentation checking prior to issue. The bedside checking procedure failed in all of the above events, as none of the errors were detected at the final bedside check.
- Seven (29%) events involved human slips. Reasons cited include staff being just back from holidays, rushing to issue units in emergency settings and distractions caused by busy workloads. These errors resulted in the wrong Rh D group being issued in two events, antigen incompatible units being issued in two events, transposition of labels in one event, blood which was not antigen typed being issued in one event and one further event involved blood being crossmatched on a sample that was >72 hours old.
- One event, involved a failure in policies/procedures, i.e. laboratory policies or procedures were absent, unclear or outdated. In this event, a unit that was intended for disposal was issued in error as the SOP relating to disposal of units was unclear.
- One event involved a communication failure where SD plasma instead of the prescribed FFP was issued in error. The medical staff in this site often requested FFP when they meant SD plasma and the medical scientist involved assumed the request was an error. Another contributing factor was that this patient was on holidays and was not being treated in her usual treatment centre. Faxed details of the correct treatment for the patient were not received until after the patient had been transfused with SD plasma.
- Two events involved knowledge deficits, i.e. where staff were inexperienced or unaware of the correct procedures to follow. Both events resulted in the issue of antigen incompatible blood to patients. In both cases the medical scientists involved were carrying out cross call cover and /or had not received appropriate training.
- Two events involved intervention errors, i.e. where laboratory staff were aware of, but failed to adhere to laboratory SOPs. In the first event, specimen numbers became mixed up during processing in the haematology laboratory resulting in the wrong Hb results being issued for the patient leading to an

unnecessary transfusion. The medical scientist involved failed to adhere to the reporting guidelines which stated that s/he should have asked for a repeat sample to confirm the drop in Hb. In the second event (described in page 17; Wrong Rh D group transfused), the medical scientist failed to adhere to the laboratory SOP on reading a test result. This culminated in the issue of Rh D negative red cells to an Rh D positive patient.

- One event involved a technical error and occurred due to a failure in the laboratory analyser. This resulted in the wrong results being issued leading to the patient receiving an unnecessary transfusion.
- In three (13%) events, the cause of error remains unclear due to insufficient data relating to the event being provided. In one further event, compatible unlabelled blood was issued due to a clinical decision by the patient's consultant. This patient required urgent transfer by ambulance to another centre and the patient's consultant ordered that the blood be issued immediately without waiting for laboratory staff to label the units.

Errors Involving Paediatric Patients 0-18years (n=15)

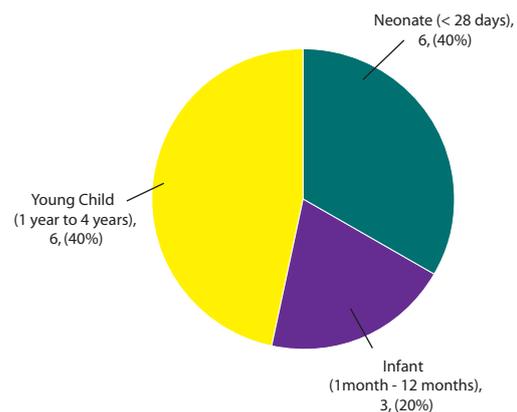
Figure 13 - Breakdown of paediatric events by nature of event (n=15)



Findings

- There were fifteen (15) events within the SAE/IBCT category involving paediatric patients. This represents almost 10% of the total number of SAE/IBCT events reported (excluding Anti-D and factor concentrates). Thirteen (13) events relate to errors involving red cells and the remaining two (2) errors involved platelets.
- Six reports involved neonates, six involved young children and a further three reports occurred in infants.

Figure 14 - Breakdown of paediatric errors by age (n=15)



- Unnecessary transfusion occurred in four (27%) events. Two cases involved prescriptions based on the wrong blood results. In the first case, the sample was incorrectly read on a blood gas analyser machine (Case History 3) page 28, and in the second case, the prescribing doctor read the wrong Hb result on the computer. In the third case, an inexperienced junior doctor prescribed red cells unnecessarily and the fourth case, involved an error in dosage calculation leading to a child being over transfused and requiring venesection to reduce the Hb. (Case History 4 page 28).

- Three (20%) events involved failure to give CMV negative or irradiated components. One of these cases involved a labelling error in the blood centre. The unit issued to the hospital was marked CMV negative/irradiated on the unit label, but the irradiation sticker which should have changed colour when irradiated had not done so, indicating the unit had not been irradiated. The error was not detected at checking procedures in the hospital. The remaining two events involved prescription errors where special requirements were not prescribed.
- The most common failure relating to paediatric patients was exceeding the recommended transfusion time. This occurred in five (32%) events. The timing ranged from 4 hours 30 minutes to 6 hours and 35 minutes. In four of these cases the transfusion was commenced, then stopped but not disconnected and was subsequently recommenced at a later stage. In the remaining case, a clinical decision was made to transfuse the blood over six hours as the patient had experienced previous reactions.
- One event involved a failure to administer the prescribed pre-medication prior to transfusion of red cells to a patient who had a history of previous reactions. This error led to the patient experiencing an urticarial reaction.
- One event involved the wrong dose of platelets being given. This occurred due to another patient's prescription being brought to the bedside and failure to check the patient's identification (ID).
- One further event involved an error in the transfusion laboratory resulting in transposition of the labels on the units. This error occurred as the medical scientist was rushing to issue the red cells following an urgent telephone request for blood. The labels for the two units (within the same cross-match) were transposed in error and this was not detected at the bedside check.

Case Histories Involving Paediatric Patients

Case History 3

A transfusion of red cells was ordered for this baby in ICU based on a Hb reading of 9.2g/dl. The sample was analysed using a blood gas analyser. Following transfusion of 30mls of the unit, the Hb result from the haematology laboratory was reviewed which showed that the actual Hb level was 14g/dl. The laboratory result had not been consulted prior to commencing the transfusion although it was available. The transfusion was discontinued immediately on discovery of the error. As a result of this event, the policy in this site has been changed so that Hb results from blood gas analysers may no longer be used for transfusion purposes.

Case History 4

This baby required a transfusion for an underlying chronic medical condition. The Hb was 4.9g/dl and because of the underlying condition, the aim was to keep the Hb at 8g/dl. The amount of red cells required was calculated incorrectly by the prescribing doctor leading to the baby being over-transfused. The error was discovered post-transfusion following review of the post transfusion Hb which was found to be 12 g/dl. This baby required two venosections to reduce the Hb down to an appropriate level.

- In addition, five events involving paediatric patients are described in the SAE/IBCT Factor Concentrate section (p 29).

Recommendations

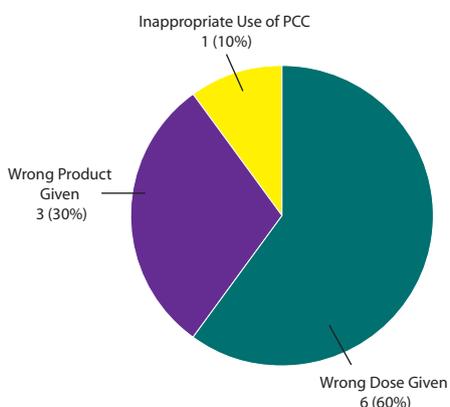
- Neonates and infants have specialised blood requirements and errors can be associated with serious sequelae. Medical staff require specific education and ongoing training in relation to the prescribing needs of neonates and infants.

- All hospitals involved in transfusing children should have specific paediatric policies in place including systems for ensuring that children with special transfusion requirements receive the appropriate component/product.
- Where patients are being transferred from theatre to clinical areas with transfusions in progress, the time of commencing the transfusion must be verified as part of the handover procedure. Transfusions should not be turned off and left connected to patients, even if the child may require a top-up transfusion on return to the ward. There is the risk of the blood becoming bacterially contaminated where the unit is recommenced and transfused outside the recommended transfusion time.

IBCT/SAE Involving Factor Concentrates/Blood Products

The NHO collect errors involving factor concentrates (reactions are reportable to Pharmacovigilance within the IMB). There were ten IBCT/SAE involving products in this reporting year, five (50%) of which involved paediatric patients (<18 years). Two events involved prescription errors relating to albumin which are not normally collected but which are included as they are of concern, particularly since they involved paediatric patients.

Figure 15 - Breakdown of the errors involving products (n=10)



Findings - Wrong Dose Given (n=6)

- Six (60%) errors involved the wrong dose being given.
- In three events, the error was due to dosage miscalculation. (One involved recombinant factor VIIa, one recombinant factor VIII and one, albumin). In the first event, the wrong formula was used to calculate the dose. In the second event, the dose was miscalculated resulting in the patient receiving too much product. The third event involved confusion when converting grams to millilitres during the calculation of 20% albumin dosage, resulting in the patient receiving three times the dose of albumin that was prescribed. In spite of last year's NHO recommendation of a two-person check for calculations of factor concentrates, this practice does not always prevent miscalculations occurring, as in all three events, a double check of the calculation failed to detect the error.
- In one event, the laboratory documentation issued with the vial of product and not the prescription was used to check the dosage resulting in double the dose of product being given. Contributing factors in this event were that it occurred during a weekend when both the medical and nursing staff on duty were unfamiliar with administering factor concentrates and were unaware that there was both a prescription sheet and laboratory issue form for the product. Remote checking away from the bedside was also involved.
- Two events involved errors in infusion rates. In the first event, the infusion pump used was faulty, but this was not detected due to a failure to monitor the patient correctly. In the second event, the rate of transfusion was increased by staff in response to an instruction received the previous day stating that albumin should be transfused within three hours. This resulted in the child receiving double the

prescribed dose of albumin and developing respiratory symptoms that required treatment with diuretics.

Wrong Product Given (n=3)

- Three (30%) events involved the wrong product being given.
- The first event involved a patient with factor VIII deficiency receiving recombinant factor IX resulting in no therapeutic benefit to the patient. In the second event, the patient's ongoing treatment requirements had been changed from one recombinant factor VIII product to another type. This was not detected at administration resulting in the patient receiving the wrong product. Both of these errors occurred as the staff failed to check the patients' treatment records prior to administration.
- The third event involved the prescription of the incorrect form of PCC for warfarin reversal. This event occurred as two forms of PCC were available for use in this site, only one of which was licensed for warfarin reversal and the prescribing doctor was unaware of this.

Inappropriate Use of PCC (n=1)

- One event involved the inappropriate use of PCC for warfarin reversal in a non-bleeding patient where Vitamin K is the treatment of choice.

Recommendations

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

Hospital, Dublin 8.

- The same precautions and identification procedures need to be followed for factor concentrates and blood products as for blood components.
- All staff involved in the prescription, issue and administration of factor concentrates should receive appropriate training.
- It is important that where patients are receiving a particular recombinant product, that this is not changed inadvertently, as there is a danger of developing inhibitors when the patient's products are switched.

Adverse Events associated with Anti-D immunoglobulin

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

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

There were 22 reports of serious adverse events associated with Anti-D administration.

Table 3 Errors Associated with Anti-D Immunoglobulin (n=22)

Type of Error	Number
Omission/Delay of Anti-D Ig	13
Failure to adhere to/lack of understanding of guidelines	3
Errors in clinical judgement	3
Human error (clinical)	4
Patient related error	1
Laboratory error	2
Unnecessary Treatment with Anti-D	8
Immune Anti-D present	4
Anti-D given outside the guidelines	1
Unnecessary extra dose Anti-D	1
Anti-D given to RhD positive mother (clinical error)	2
Other	1
Human error (clinical)	1
Total Cases	22

Omission of Anti-D (n=8)

Findings

In eight (8) cases, Anti-D should have been given but was omitted. In two cases the patients subsequently produced Anti-D (Case histories 5 and 6).

- Two of the cases were associated with a lack of understanding of guidelines for Anti-D prophylaxis/failure to adhere to hospital guidelines in relation to antenatal use of Anti-D and misunderstanding of the role of the Kleihauer test. In one of these cases, where Anti-D was omitted, this resulted in the patient becoming sensitised (Case History 5).
- In three further cases, the patients were not given Anti-D after sensitizing events due to errors in clinical judgement. In one of these cases, sensitization of the patient would also appear to have occurred (Case History 6).
- A further case involved human error where there was a failure to prescribe Anti-D at the time of receipt of the cord blood result.

Case History 5

Omission of Anti-D due to lack of understanding guidelines

This young Rh D negative female presented to the hospital following a fall onto her abdomen at 31 weeks gestation during her first pregnancy. A Kleihauer test was used to estimate the foetomaternal blood loss following the event. The result of the Kleihauer test was negative and the doctor incorrectly presumed that Anti-D was not required and discharged the patient. The error was discovered eight weeks later following delivery when laboratory staff were processing the cord blood and maternal samples. The DAT was positive on the cord blood sample and the mother, who had previously a negative antibody screen, had

been sensitised and now had Anti-D present in her plasma. The baby suffered no sequelae as a result of the omission; however, the omission will have implications for the mother in future pregnancies. As a result of this incident there has been an increased emphasis on Anti-D administration and the management of sensitising events in local education sessions, in addition to a local review and update of the Anti -D guidelines.

Case History 6 Omission of Anti-D due to error in clinical judgement

This Rh D negative mother presented with vaginal spotting at 28 weeks. Due to an error in clinical judgement, the consultant felt Anti-D was not required as the bleed was so minor. At delivery, a group and hold was requested on this patient. Anti-D and E were detected which had not previously been present. As a result of this event, new Anti-D guidelines have been drafted in the hospital.

Delay in administering Anti-D (n=5)

In a further five cases Anti-D administration was delayed beyond the recommended outer limit of 72 hours post exposure.

One case involved a patient who took early discharge but was subsequently contacted and Anti-D was given 86 hours later.

A further event occurred due to system error within the laboratory. (Case History 7)

Case History 7 Delay in administration of Anti-D due to an error in the laboratory

This Rh D negative mother delivered a Rh D positive baby. The mother was discharged home. The hospital policy was to contact the community midwife and inform them that Anti-D was required for the patient but the hospital laboratory forgot to telephone the community midwife. The error was discovered by the medical scientist. The mother was advised to return to the hospital 75 hours post delivery for product administration. As a result of this error, the hospital policy has changed and now it is the responsibility of the community midwife to contact the hospital and follow up all Rh D negative mothers who deliver.

In a further case there was a delay in Anti-D administration due to failure to adhere to guidelines (Case History 8).

Case History 8 Delay in administration due to failure to adhere to guidelines.

This Rh D negative patient presented with an ectopic pregnancy at eight weeks. She was medically managed with methotrexate. The clinician initially believed Anti-D was not indicated in view of early gestation. However following review of Royal College of Obstetricians and Gynaecologists (2002) / BCSH (2006) guidelines, the decision was reversed and Anti-D was administered 91 hours post the event.

Unnecessary Treatment with Anti-D (n = 8)

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

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

Findings (n=6)

- Four cases involved giving Anti-D to women already sensitized (with immune Anti-D) due to failure to verify results prior to prescribing/administering Anti-D. Although none of these cases resulted in any adverse effects for the mothers or the babies, failure to appreciate the significance of immune Anti-D in these cases could result in lack of appropriate monitoring of pregnancies at risk of Haemolytic Disease of the Newborn (Case History 9).
- In a further case, a patient received two unnecessary extra doses due to an error in clinical laboratory assessment concerning Kleihauer results.
- In a further case, an unnecessary dose was given after a spontaneous abortion in the first trimester – against hospital guidelines.

Case History 9

Anti-D administered to mother with immune Anti-D due to failure to verify results

This patient had a vaginal bleed at 36 weeks gestation. The patient stated that she was Rh negative. She presented to the consultant's out patient department (OPD), was reviewed and prescribed Anti-D immunoglobulin and asked to present to the hospital for administration of Anti-D. It is unclear whether

the patient had her antenatal medical record with her. The consultant and administering nurses could not recall if the patients' medical record was requested, was available or was checked to confirm the patient's antibody and Rh D group status prior to administration and there was no documentation in the medical record. The patient was Rh D negative but had anti-D and anti-C antibodies. A medical scientist who was aware of the patient's Rh group status identified the error when performing stock checks and noticed that the patient had incorrectly received Anti-D. As a result of this case the OPD policy was reviewed. A medical record and MRN is generated or retrieved for each out-patient.

Unnecessary treatment with Anti-D Immunoglobulin to Rh positive mothers

Findings (n=2)

- Both cases were associated with failure to verify the patients Rh D group prior to prescribing or administering Anti-D.
- In the first case due to a transcription error, a test result was incorrectly recorded in the patient's medical notes resulting in the patient receiving Anti-D unnecessarily (Case History 10).
- In the second case, due to human error, the doctor prescribed and administered Anti-D even though the laboratory report indicating the patient was Rh D positive was available.

Case History 10

Unnecessary treatment with Anti-D immunoglobulin to Rh D positive mother

This patient presented with vaginal bleeding at 39 weeks gestation. A midwife recorded in error that the patient was Rh D negative in the medical notes. A doctor then thought that the patient was Rh D negative and prescribed and administered Anti-D immunoglobulin. The laboratory report in the medical record was not referred to or checked. The error was discovered two days later when the patient represented with bleeding and a midwife noticed her Rh status and that she had incorrectly received Anti-D. The hospital guidelines are being reviewed as a result of this incident.

Other Anti-D incident (n=1)

This incident involved two patients with the same first name on the same ward. Both required Anti-D. Anti-D was issued for patient A. The doctor did not perform an identity check and the Anti-D which was issued and prescribed for patient A was administered to patient B. The event was discovered when Anti-D was requested again for Patient A.

Discussion/Recommendations

- It is evident that a number of hospitals still lack guidelines for Anti-D administration. Each hospital should have clear written protocols in place for when and how to administer Anti-D.
- There is also evidence of failure to adhere to or understand the guidelines for Anti-D prophylaxis. In particular there appears to be a general misconception regarding the role of the Kleihauer test estimation of fetomaternal haemorrhage (FMH) in antenatal sensitising events. The Kleihauer must not be used to determine if Anti-D is required. **Its role is to guide what dose of Anti-D is required. If a sensitising event (e.g. abdominal trauma) after 20 weeks occurs, Anti-D should be given and the dose adjusted for the size of bleed.**
- Specific education on the management of Anti-D prophylaxis should be provided to all clinical and laboratory staff involved with issuing or administration of Anti-D. This will be particularly important if routine antenatal Anti-D prophylaxis is introduced as the number of pregnant women presenting with Anti-D in their serum due to passive immunisation will increase.
- Hospital protocols should specify the criteria for Anti-D administration and require that the patient's blood group and antibody screen results be checked prior to Anti-D prescription.
- The hospital transfusion laboratory should have a clear policy on how they report the results of patients with variant D types (weak D or partial D) and whether Anti-D prophylaxis is indicated.
- Laboratory reports on blood group serology should be clear and provide unambiguous advice on the need for repeat testing and Anti-D prophylaxis in patients with Anti-D detected in their serum.
- Patient identification procedures for the administration of Anti-D should mirror those for blood administration.

Serious Adverse Reactions

There were 149 initial SAR reports during the reporting year 2006. After review, 117 SAR reports were accepted by the NHO. As in previous years there were no reports of SAR in the Transfusion Associated Graft versus Host Disease (TvGHD) or Post Transfusion Purpura (PTP) categories. There were no reports of donor adverse events related to Predeposit Autologous Transfusion (PAD).

Acute Transfusion Reactions (ATR)

Acute Transfusion Reactions are defined as those occurring within 24 hours of transfusion. During the reporting year 2006, 69 reports of Acute Transfusion Reactions were reported.

Acute reactions include:

- Acute Haemolytic Transfusion Reactions,*
- Febrile Non-Haemolytic Transfusion Reactions,*
- Acute Allergic and Anaphylactic Transfusion Reactions.

*Reactions within these two categories were reported to the NHO up to the end of 2006 as Acute Haemolytic and Other Severe Acute Transfusion Reactions (AHOSTR) and the reactions submitted as AHOSTR have been reclassified by the NHO for this year's report. This brings the reports in line with the recent

International Society of Blood Transfusion (ISBT)/EHN definitions (Draft NHO Haemovigilance Handbook) and with the new EU reporting categories being developed.

Acute Haemolytic Transfusion Reactions (AHTR)

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

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

Acute Haemolytic Transfusion Reactions (Immunological haemolysis due to other alloantibody-Acute)

There were two (2) acute haemolytic reactions associated with red cell antibodies. In one case, a patient who was transfused ten days previously received a red cell transfusion crossmatched against a sample which was eight days old instead of against a fresh sample taken within 24 hours of transfusion in line with BCSH guidelines (2004) or within 72 hours as allowed by American Association of Blood Banks (AABB) guidelines (2005). The patient had developed multiple antibodies as a result of the initial transfusions, which were not detected on the old sample (Case History 11).

In the second case, the reaction was associated with a weak anti-E in a patient which was not detected at the time of antibody screen and crossmatch because of use of an insufficiently sensitive technique.

Case History 11 Acute Haemolytic Transfusion Reaction

This elderly man on anti-platelet agents received six units of blood for gastrointestinal haemorrhage. At that time he had anti-E and anti-C^w antibodies and was given E/C^w negative red cells. Ten days later, his Hb had fallen again and he was recrossmatched on call and started on a unit of blood. About two hours into the transfusion, when about 150mls had been transfused, he developed hypertension, tachycardia and a temperature rise of 1.7°C and rigors. His bilirubin and lactate dehydrogenase (LDH) were raised. Serological investigations on the post transfusion sample showed that the Direct Antiglobulin Test (DAT) was positive and that, in addition to the anti-E and anti-C^w, he had developed anti-Fy^a, anti-K, anti-Jk^b and anti-S. The phenotype of the transfused unit was Fya, Jkb positive. Further investigations found that the patient had been crossmatched through human error on a sample which was eight days old instead of a fresh sample and the patient had developed multiple red cell antibodies since his initial transfusion leading to acute haemolysis.

Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

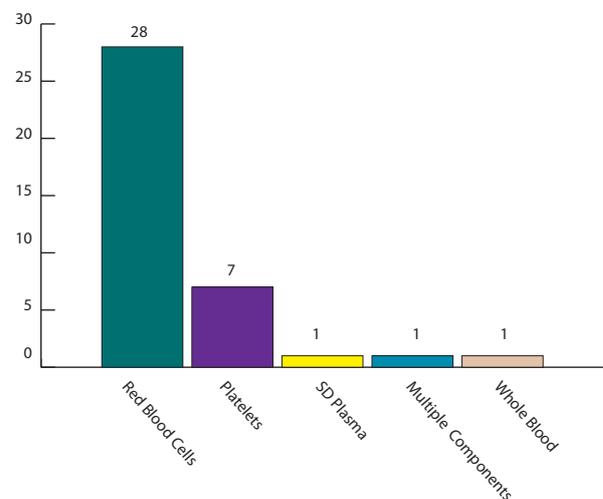
A FNHTR is defined as a rise in temperature of >1.5°C above the patient's (pre-transfusion) baseline value together with rigors or chills, occurring during or within four hours following transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or the patient's underlying condition and where symptoms lead to increased morbidity (NHO 2007). The major concern in evaluating these reactions is to exclude bacterial contamination of the unit or haemolysis due to incompatible red cells (Heddle & Kelton, 2001).

Findings

There were 38 reports which fulfilled the criteria for a FNHTR reaction which, although considered not serious, can be uncomfortable for the patient and may recur on further transfusions. Thirty four of the patients experiencing FNHTR reactions were adults, the majority of these being elderly (>70 years). Four FNHTR reactions occurred in paediatric patients.

Twenty eight reports involved red cells only, seven involved platelets, (three involved pooled platelets, three involved apheresis platelets and in one case, both pooled and apheresis platelets were implicated). One report involved both red cells and platelets. One reaction was reported with SD plasma and there was one report of FNHTR to whole blood.

Figure 16 - Components (incl SD plasma) implicated in FNHTR N= 38



Blood cultures from the patient were undertaken in 17 cases and from the pack in 24 cases. Cultures of both pack and patient were performed in only 14 cases. In six cases, initial cultures of patient showed bacterial growth but there was no growth from the pack in any case. Contamination during culturing was suspected in some of these cases.

While in many of the cases the patient was acutely

unwell, in the 14 cases where time to recovery information was provided, 11 recovered fully within 12 hours. A further patient recovered within 24 hours, but two patients took over 24 hours to recover. On review of these two cases, it is likely that these reactions were due to the patient's underlying condition rather than related to transfusion.

Acute Allergic and Anaphylactic Transfusion Reactions (AA)

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

Clinical Signs & Symptoms and Laboratory Findings

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

- The symptoms encompass mild allergic-type reactions such as urticaria/pruritis associated with or without gastrointestinal discomfort, to major reactions with stridor, wheeze, angioedema, bronchospasm and hypotension occurring during or within four hours of transfusion (ISBT, 2006).
- An anaphylactic reaction or anaphylaxis is characterized by severe hypotension and collapse which may be accompanied by laryngeal oedema and respiratory obstruction (Vamvakas and Pineda, 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

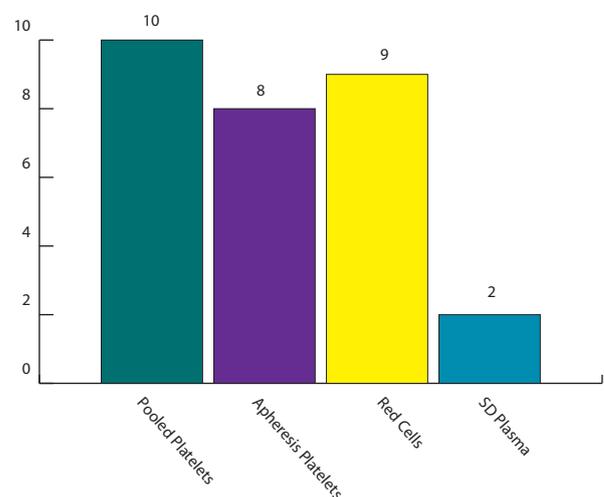
should be submitted to the NHO.

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

Findings

There were 29 AA reactions reported as follows: nine were associated with red cells, ten with pooled platelets (one patient had also received the blood product PCC) and eight with apheresis platelets. There were two reports of AA associated with SD plasma both associated with patients undergoing cardiac surgery and on review these were considered unlikely to be due to transfusion. Twenty-two of the patients were adults and seven were paediatric patients. No cases of AA due to IgA deficiency with antibodies were reported but IgA levels were reported in only eight cases.

Figure 17 - Components (incl SD plasma) implicated in AA (n=29)



Because of the increased numbers of ATR reported with red cells, we reviewed the red cell FNHTR and AA reactions by the type of blood bag into which the unit had been bled. As previously noted in 2005, analysis showed an increased incidence of reactions, particularly AA reactions, with one type of blood bag used to collect whole blood. This may reflect the slightly increased amount of plasma left in the Saline Adenine Glucose Mannitol (SAGM) units after processing compared to those prepared from other types of collection bag.

Recommendations

Clinical management of Acute Transfusion Reactions including Acute Severe Allergic and Anaphylactic Reactions

- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly and the patient observed closely for the first 15 minutes/50mls as severe reactions are most likely to occur within this time. (BCSH, 1999; NBUG, 2004).
- Each hospital must have a policy in place for the identification and management of an acute transfusion reaction. This should include the medical and nursing management of the patient's symptoms and the investigations necessary to complete the transfusion reaction analysis. Following a severe transfusion reaction involving red cells, the transfusion should be discontinued completely and no further units from this crossmatch should be transfused until an ABO incompatible transfusion has been excluded and the blood has been re-crossmatched. The NBUG has produced recommendations for the Management of an Acute Transfusion Reaction (NBUG, 2004) (Appendix 1).
- Even mild reactions should be reported to the HVO and hospital blood bank as subsequent reactions may be more severe.
- Most allergic transfusion reactions respond to chlorpheniramine. Steroids should be reserved for the more severe reactions.
- Prophylaxis with antihistamines should be considered if there is a previous history of allergy or repeated transfusion reactions.
- Protocols and training for the management of anaphylaxis should be in place in each hospital and all staff involved in transfusion should be familiar with them.
- Patients who have experienced a severe allergic/anaphylactic reaction during a blood component transfusion should have a label placed on their chart alerting clinical staff to their history of transfusion reactions to ensure that appropriate pre-medication is given prior to future transfusions.
- Where patients are receiving shared care, systems must be in place so that relevant details relating to transfusion such as history of reaction/allergy and/or pre-medication requirements can be communicated between centres effectively.
- IgA deficiency (<0.05mg/dl) with anti-IgA antibodies can cause severe allergic /anaphylactic reactions. IgA levels should be checked in patients with severe or repeated allergic/anaphylactic reactions. Since the transfused component may contain appreciable quantities of IgA, where possible, samples taken pre-transfusion should be used to check IgA levels.
- If anti-IgA antibodies are present, these patients will require special transfusion management including the use of washed cellular components for future transfusions

- With the recent introduction by IBTS of pooled platelets in platelet additive solution, washed platelets should only be necessary for the prevention of AA reactions in patients with a history of IgA deficiency with antibodies or in patients with severe AA reactions to platelets which are not managed by pooled platelets in additive solution and premedication.

Serological investigations

- Where patients have been recently transfused (within 14 days) a fresh sample should be used for the crossmatch, as antibodies developing after transfusion may not be detected on earlier samples. The BCSH guidelines (2004) require that the sample should be less than 24 hours whereas the AABB guidelines (2005) accept a sample that is less than 72 hours old.
- It is essential to carry out adequate serological investigations in patients with multiple antibodies who present with an acute reaction.
- If possible, further transfusions should be delayed until completion of the transfusion reaction work-up. However in a massive haemorrhage, the designated emergency stock of O Rh D Negative blood may be used while the investigations are ongoing.

Bacterial Culture

- Both the patient and the transfused unit(s) should be cultured to exclude bacterial contamination of the unit where the reaction is associated with fever and chills/rigors. This is particularly important when the reaction occurs with a platelet transfusion as platelet concentrates are stored at room temperature and the incidence of bacterial contamination is highest in platelet concentrates.
- A protocol for culturing of the blood component i.e. pack and segment line is available by writing to the Quality Assurance/Quality Control Department of

the IBTS. This protocol outlines the procedure to be followed when culturing a unit implicated in a febrile transfusion reaction which can be modified for hospital use. Culturing the outside of the blood pack is unnecessary.

- Specimens e.g. urine, sputum necessary to exclude other possible sources of infection should also be cultured if indicated.
- Classical allergic or anaphylactic reactions do not routinely require culture of the unit/pack or serological investigations. However, where atypical symptoms such as fever are present in a suspected AA reaction, or where skin manifestations are absent, it is important to culture both the implicated unit(s) and the patient, to rule out underlying sepsis and/or bacterial infection in the unit and in the case of red cells to undertake serological tests to exclude incompatibility.

Delayed Haemolytic Transfusion Reactions (DHTR)

Definition

Delayed haemolytic transfusion reactions (DHTR) are defined as evidence of clinical or laboratory features of haemolysis occurring more than 24 hours and up to 28 days following the transfusion of a blood component and associated with serological evidence of antibodies. (ISBT Working Party, Capetown, 2006; NHO Haemovigilance Handbook 2007)

Clinical Symptoms and Laboratory Findings

Clinical signs of delayed haemolysis can be similar to those described for acute haemolytic transfusion reactions but are usually less severe and the diagnosis may be missed if not suspected. Clinical symptoms may be absent and the only sign may be a falling haemoglobin.

For the purpose of analysis, the NHO grades such reactions by severity using the Serious Hazards of Transfusion criteria (SHOT, 1999).

- Group 1: Asymptomatic with 'antibody only' detected, with or without a positive DAT level.
- Group 2: Demonstrates evidence of haemolysis measured by falling haemoglobin levels and a positive DAT level.
- 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.

DHTR are reportable to the EU as Immunological haemolysis due to other alloantibody – Delayed.

Findings

Four incidents were reported in this category accounting for 1% of all incidents reported and 3.4% of all serious adverse reactions reported.

One case showed no evidence of haemolysis and was classified as a Group 1. Two reactions were classified as a Group 2. One case showed evidence of haemolysis and jaundice and was classified as Group 3. The antibodies involved were Anti-E, Anti-e, Anti-s, Anti-K and Anti-Jk^a. All patients recovered without sequelae.

Recommendations

- It is likely that DHTR is under-diagnosed. It is essential that any patient presenting with any signs of haemolysis or a positive DAT, some days after a transfusion should be investigated for a DHTR. The successful diagnosis depends also on accurate history taking and the eliciting of a history of recent transfusion.
- Consideration should be given to issuing antibody cards to patients with clinically significant antibodies (NBUG, 2004) and the possibility of a national patient antibody register for patients with red cell antibodies should also be evaluated (Lariat and Fisher, 2005; O'Brien, 2008, personal communication).

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

SHOT Group	Age & Gender	Interval between transfusion and onset of symptoms/ signs	Findings	Antibody	Outcome
Group 1	Elderly Male	2 weeks	No evidence of haemolysis	Anti-K	Recovered with no ill effects
Group 2	Adult Female	2 weeks	Positive DAT Fall in Hb	Anti-Jk ^a	Recovered with no ill effects
Group 2	Elderly Female	7-10 days	Positive DAT Raised LDH	Anti-E & Anti-s	Recovered with no ill effects
Group 3	Elderly Female	2 weeks	Jaundice, fall in Hb, lowered haptoglobins, haemoglobinuria	Anti-Jk ^a & Anti-e	Recovered with no ill effects

Respiratory Complications of Transfusion

Transfusion Related Acute Lung Injury (TRALI)

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

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

TRALI is characterised by the following

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

Possible TRALI

- ALI as above
- No pre-existing ALI before transfusion or during or

within six hours of transfusion

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

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 Human Leucocyte Antigen (HLA) Class I or II or granulocyte antibodies as a result of pregnancies or transfusion which react with antigens present on the patient's white cells. (Kopko and Popovsky, 2007). HLA and granulocyte antibody testing is undertaken on female donors and male donors with a history of transfusion implicated in TRALI. Where the antibody in the donor has a specificity which reacts with an antigen present on the patient's cells, this is consistent with a diagnosis of TRALI. Donors involved in a TRALI investigation who are found to have HLA or granulocyte antibodies are permanently deferred.

Table 5: Reports received as possible TRALI 2006 (n=7)

Component	No of donors	Gender	Investigations	Comment
Red Cells	1	F	Donor HLA antibodies detected against patient HLA antigens	Classified as TRALI
Red Cells	3	2 M ,1 F	Female Donor HLA antibodies detected against patient HLA antigens	Classified as possible TRALI
Red Cells	2	2 M	Not investigated	Reclassified as TACO Case
Red Cells	2	1 M,1F	Female donor negative for HLA and granulocyte antibodies	Reclassified as TACO Case
Red Cells	4	2M, 2F	Female donors negative for HLA and granulocyte antibodies	Reclassified as TACO Case
Red Cells				DNP Unrelated to transfusion
Pooled platelets				DNP unrelated to transfusion

Findings

Seven cases were initially reported to the NHO as possible TRALI. On review of clinical presentation and donor investigations in three of the cases, TACO was considered the most likely diagnosis and these cases were transferred to the TACO category. Two cases were reviewed and considered to relate to the patient's underlying condition and were classified as a DNP. The remaining two cases, (Case Histories 12 and 13) both associated with red cells were considered as TRALI or possible TRALI. Both are described in detail below.

Case History 12 - TRALI

This elderly female patient with a history of ischaemic heart disease had vascular surgery complicated by massive bleeding requiring transfusion of red cells, SD plasma and recombinant factor VIIa. She subsequently developed pneumonia and a large left sided pleural effusion. Six days after surgery she received a transfusion of a unit of red cells for a haemoglobin of 7.2 g/dl. One hour into the transfusion she developed hypotension, tachycardia, falling O₂ saturations and chest x-ray changes compatible with ALI and required ventilation. The patient typed as A*01, B*08 B*5, DRB1*03, 07.

Donor investigations: Investigation of the donor, who was female, showed the presence of anti HLA Class I antibodies with multiple specificities including anti-A1, as well as Class II antibodies. Class I antibodies were also detected in the recipient. Granulocyte antibodies were not detected in either the donor or recipient at the Platelet and Granulocyte Immunology Laboratory, National Blood Service (NBS), Bristol. The donor has been permanently deferred. The patient remained ventilated for a number of days and then recovered, but remained ill from underlying disease.

Case History 13 below illustrates the complexity of evaluating transfusion reactions with respiratory symptoms. The definition of TRALI is a clinical one: acute onset, hypoxemia with bilateral infiltrates on chest x-ray and absence of circulatory overload occurring within six hours of transfusion. The reaction was within the time frame for TRALI (<six hours of transfusion) and the falling O₂ sats and x-ray appearance were consistent with a diagnosis of TRALI or possible TRALI.

The presence of a raised NTpro-BNP¹ level post transfusion together with the considerable volume of parenteral fluid administered in the preceding two days made Transfusion Associated Circulatory Overload (TACO) also a possibility. While a recent article (Gajic et al, 2006) reviews evidence that BNP levels can be raised in ICU patients with ALI without evidence of ventricular dysfunction, a ratio greater than 1.5 from the pre-transfusion to the post transfusion sample is consistent with transfusion overload (Zhou et al 2005.) Gajic et al (2006) suggest that TRALI and fluid overload may co-exist in spite of the assumption of the Canadian Consensus conference that this is rare. The patient also had evidence of pulmonary emboli on pulmonary angiogram.

The presence of HLA antibodies in the female donor of the second unit reactive with the B*07 in the recipient was also supportive of TRALI although B*07 is a common antigen being found in over 30% of the population. The donor was permanently deferred on the basis of the HLA antibody results and involvement in a case of possible TRALI.

Case History 13 - Possible TRALI

A female patient was transferred to a tertiary care hospital from another hospital for ventilatory support following an episode of acute respiratory distress and falling O₂ sats, an hour and a half after the commencement of a third unit of red cells. The patient had

¹ N terminal prohormone brain type natriuretic peptide

undergone a subtotal hysterectomy three days previously for severe menorrhagia. The Hb pretransfusion was 7.6g/dl.

The chest x-ray showed bilateral pulmonary infiltrates and CT showed bibasal consolidation. The patient required 80% O₂ therapy for 10 hours. Two doses of frusemide were given 6 hours apart. The diuretic response was recorded as 1,755ml over a 10 hour period. A CT pulmonary angiogram later on the day of transfer showed consolidation and pulmonary emboli in the right upper lobe and possibly in the left lower lobe. The patient recovered completely within four days and was discharged.

On review of the records, it appears the patient had received considerable volumes of fluid on the day of surgery and the following day (total intake 9000mls, total recorded output 1550mls although the fluid balance was incomplete and the patient was vomiting). On the day of transfusion, she was still vomiting with a low fever and had been started on antibiotics for a suspected urinary tract infection (UTI). Because of this, she had been given 2000mls of IV fluid (output not recorded) before she received the first unit of blood at 18.30pm. NTproBNP level on the day of the reaction was 1702mg/L. The pre transfusion specimen for NTproBNP from the day before surgery was 34mg/L.

Donor investigations

Two of the units (the first and the third unit) were from male donors with no history of transfusion, and were not further investigated. The second unit transfused was from a female donor. This donor was recalled and investigated for granulocyte and HLA

Class I and II antibodies. The patient's HLA Class I type was A*01, B*57, B*07. Strong Class I antibodies with multiple HLA specificities including anti-B7 reactive with the HLA B 7 antigen on the patient's white cells were detected in the donor. Granulocyte antibodies and lymphocyte antibodies were negative on the donor sample referred to the Platelet and Granulocyte Immunology Laboratory NBS Bristol. The donor was deferred.

Recommendations

- Appropriate transfusion of blood components is vital in reducing the incidence of this serious and potentially fatal complication of transfusion which has been identified as the most important cause of transfusion related mortality and morbidity in the UK SHOT scheme (Stainsby et al 2006).
- The IBTS has put in place a number of measures with a view to minimising the risk from TRALI, namely avoiding the use of plasma from female donors both for suspension of pooled platelets and as FFP and in early 2004 deferring new and lapsed female plateletpheresis donors with a history of pregnancy. Moreover, as part of the vCJD Policy, SD plasma has become the standard plasma product. To date, SD treated plasma has not been convincingly implicated in TRALI.
- It can often be difficult to differentiate between TRALI and TACO. Clinical evaluation of pre and post transfusion fluid balance and pre and post transfusion BNP levels may be helpful in differentiating TACO from TRALI (Zhou et al 2005).

Transfusion Associated Circulatory Overload (TACO)

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

There were 34 reports of TACO, up by nine (9) reports from 2005, an increase of 36%. Three reports were initially submitted as TRALI but after investigation were reclassified as TACO. Thirty two reports were associated with red cell transfusion; the two remaining cases involved red cells and platelets in one case and red cells and SD plasma in the second. Fifteen patients developed TACO after a single unit of red cells.

Seventeen of the patients were males and 17 were female. Nineteen of the patients were over 70 years of age and 27 had underlying cardiac disease or respiratory disease, while nine of these patients had both.

The patient's weight was available in only 18 cases, and in five cases, the patient's weight was less than 50 kgs. One of the latter cases involved a child with a history of chronic renal failure. Fluid balance information was available in only 13 cases. Time of onset of symptoms was given in 26 cases and was between 20 minutes after starting the transfusion to 16 hours later.

Diagnosis was based on symptoms and clinical findings in 24 cases. A chest x-ray was performed in only nine cases. The commonest symptoms and signs were dyspnoea (24 cases) hypertension (15 cases) and falling O₂ (12 cases) saturations. Tachycardia was present in eight cases. Five patients also complained of sub-sternal discomfort.

Nine of the patients had been on regular diuretics. Only four patients received a diuretic immediately pre-transfusion; two of these were patients on regular diuretics. Five patients received a diuretic during the transfusion and 25 received diuretics post transfusion.

Outcome data was available in 33 cases. Twenty seven patients recovered fully. Time to recovery was given in 17 patients and recovery was complete by 24 hours in 13 patients. Two patients required ongoing cardiac support. Three patients died later of their underlying condition unrelated to transfusion and the fourth case, mentioned below where the diagnosis of TACO was uncertain, the cause of death was likely to have been due to a cardiac event.

Delayed onset of TACO

TACO usually occurs within six hours of transfusion but seven cases (21%) had an onset of symptoms over six hours with a mean onset of ten hours.

Two of these cases with onset over six hours after transfusion were originally submitted as TRALI and were re-categorised as TACO following clinical and/or laboratory follow-up.

In the first case, a small patient (44 kgs) received four units of red cells over 20 hours, and subsequently was commenced on IV fluids. She developed symptoms almost eight hours post transfusion. In this case, there was clinical and chest x-ray evidence of overload, and a response to diuretics.

In the second case, the patient who had an underlying haematological malignancy developed symptoms which required admission to hospital approximately 12 hours post transfusion as an outpatient. On further review of the clinical details, the diagnosis of TACO was difficult to substantiate as there was no response to diuretics and other possibilities were pulmonary emboli or a cardiac event. While ECG and troponin levels (mildly elevated) were not remarkable, the BNP levels which were done retrospectively on stored samples were very

high both pre and post transfusion. Such high levels have been shown to be a predictor of cardiovascular events particularly incipient heart failure and death (Bibbins-Domingo et al, 2007).

TACO and Bleeding Patients

Three patients had TACO in the context of transfusion for bleeding. Two of these patients had hypotension.

In one case, it is possible that both the transfusion and underlying cardiac ischemia may have contributed to the overload.

In the second case, a critically ill patient with significant co-morbidity had an uncontrolled haemorrhage. This patient had massive fluid resuscitation, along with both red cells and plasma. At six hours into resuscitation, fluid intake was approximately seven litres. The patient was administered diuretics and required ventilation.

In the final case, initially submitted as TRALI, a previously healthy young female patient with severe anaemia and intra-abdominal bleeding received two units of red cells in one hour followed by 2.5 litres of fluids over a short time and developed respiratory symptoms. While pulmonary oedema was initially deemed unlikely, it was later confirmed on x-ray, and the patient recovered following diuretics and Continuous Positive Pressure Ventilation (CPAP). Donor investigations were negative.

These cases illustrate clearly the potential for TACO associated with replacement therapy for severe bleeding. This can occur even in healthy young individuals.

Recommendations

- All patients should be assessed pre-transfusion to assess their risk of developing TACO. Particular attention should be paid to the identification and management of 'high-risk' patients which include:
 - Patients of low body weight
 - Elderly

- Infants and children
 - Physiologically compromised patients, especially with a history of cardiac, respiratory or renal insufficiency or chronic anaemia.
- At risk patients should be transfused slowly at a rate of 1ml/kg/hour (Popovsky 2001) and close attention, where possible, should be paid to the patient's fluid balance status not only during the transfusion but also in the 24 hour period prior to transfusion. Single unit transfusions can result in TACO and therefore should be monitored as closely as multiple unit transfusions.
 - Transfusion should be on a unit-by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component. This assessment should include:
 - A careful estimation of the patient's hydration and cardiac status prior to transfusion
 - Thorough review of the patient's fluid balance during transfusion of any blood component
 - The possible need for 'prophylactic' diuretic therapy
 - The risk of TACO can be reduced by the administration of pre-transfusion diuretics. This may also be necessary for those on regular diuretic therapy.
 - In very low weight/at-risk patients, it may be advisable to transfuse units with an interval of 24 hours between each unit, in combination with pre-transfusion diuretics. Some patients take as long as 24 hours to readjust blood volume particularly in those patients whose venous pressure is raised pre-transfusion (Mollison et al 1997).
 - Clinical evaluation of pre and post transfusion fluid balance and pre and post transfusion NTproBNP/BNP levels may be helpful in differentiating TACO from TRALI (Zhou et al 2005).

Suspected Transfusion Transmitted infection

The NHO collects and investigates reports of

- All suspected transfusion-transmitted viral infections relating to blood components which have been transfused after the introduction of mandatory testing for that virus.
- Viral infections which are not covered by mandatory testing, e.g. Hepatitis A virus, (HAV), CMV and Parvovirus, but which are suspected to be associated with a blood transfusion.
- The NHO also collects and investigates reports of transfusion-transmitted bacterial and parasitic infections.

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

These reports of suspected transfusion transmitted infection may indeed be due to the transfusion of an infected or contaminated unit, but equally, infection may have been acquired from another source. Investigation of markers of infection in an implicated donation, or in subsequent samples from the donors of implicated donations, can confirm transfusion as the probable cause of infection, or identify the need to investigate other possible sources (SHOT, 1998). 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, 1998):

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

and, either

- A donor who had evidence of the same

transmissible infection donated at least one component received by the infected recipient

or

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

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

The current estimated risk for HIV and HCV is less than 1 per 4 million components transfused (O'Riordan, 2002, personal communication). These residual risk estimates are based on serological testing and nucleic acid amplification testing (NAT) for HCV and HIV.

Even prior to the introduction of NAT testing the risk for Hepatitis C for screened blood was 1:500,000 which is estimated to be less than the risk of infection from nosocomial sources. (Ross et al, 2000; Gerberding et al, 2003)

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

Hepatitis B infection is not uncommon in the community and in up to 40% of cases, no risk such as sexual exposure, intravenous drug abuse or transfusion is present. Evidence of past cleared infection in blood donors, a highly selected population, was found in 0.17% i.e. 17 in 10,000 donors in the first year of testing. In many of these cases, nosocomial risks in the past may be responsible. Such cleared infection does not pose a risk to recipients and in a number of countries such individuals are acceptable as donors. In Ireland, we introduced core antibody testing to reduce the possible risk of donors donating before HBV

infection was fully cleared i.e. in the second window period when HbsAg is no longer detectable in blood but before an adequate (>100miu/l) antiHbs antibody is found. Because hepatitis B core antibody is a mandatory test, donors with cleared infection found reactive for the marker are also deferred.

Bacterial infection remains a rare but serious complication of transfusion, particularly associated with platelets which are stored at 22°C (Stainsby et al, 2006). The IBTS has introduced bacterial screening of all platelets before issue and the diversion of the first aliquot of the blood donation into the blood testing pouch which are measures which have been shown to reduce the risk of bacterial contamination (McDonald, 2006)

The risk of receiving an incorrect blood component is in fact much greater than the risk of receiving a

transfusion-transmitted infection. Over the eight year period since UK SHOT began reporting, confirmed reports of TTI accounted for 1.8% of incidents in comparison to reports in the IBCT category, which accounted for 70% (Stainsby et al 2006).

Findings

Ten initial reports of STTI were received. Two reports were not progressed. One of these was a case of possible hepatitis, where no infectious markers were identified and where the abnormal liver function tests on investigation were considered due to the patient's underlying condition. The second case was a case of a possible unspecified viral infection. On investigation, this was considered due to the patient's underlying condition. The remaining eight cases, three hepatitis C infection, one hepatitis B infection, one hepatitis A infection, and three suspected bacterial infection cases

Table 6 Suspected Transfusion Transmitted Infection (n=8)

Case Number	Date of Incident	Gender & Age	Infectious Agent	Components	Donors Implicated	Comments
Case 1	1997	M Adult	Hepatitis C	Red cells, Platelets, FFP	53	47 donors returned and retested HCV negative. 6 donors tested HCV negative on archive samples. Transfusion transmitted infection considered unlikely.
Case 2	2004/2005	F Adult	Hepatitis C	Red cells	5	Transfusion transmitted infection excluded.
Case 3	2002	F Adult	Hepatitis C	Red cells	2	1 donor retested negative. Other donor not available to retest but PCR testing of donation archive negative. Transfusion transmitted infection considered unlikely.
Case 4	2005	M Adult	Hepatitis B	Red cells	3	Transfusion transmitted infection excluded.
Case 5	2004	F Adult	Hepatitis A	Red cells	4	Transfusion transmitted infection excluded.
Case 6	2006	F Adult	Micrococcus and coagulase negative staphylococcus grew at 3.3 days	Pooled platelets	4	4 red cell units cultured negative. 1 plasma available cultured negative. Transfusion transmitted infection considered possible.
Case 7	2006	M Adult	Acinetobacter baumannii/ Staphylococcus hominis grew in residual platelet pack	Pooled platelets	8	8 red cell units cultured negative. 1 residual platelet content grew Acinetobacter baumannii - commonly isolated from hospital environment. Other platelet pack no growth. Transfusion transmitted infection considered unlikely.
Case 8	2006	M Adult	Klebsiella	SD Plasma	Pooled product	Aliquots of SD plasma batch cultured negative. Transfusion transmitted infection excluded.

were accepted for further evaluation. After evaluation, transfusion transmitted infection was excluded or considered unlikely in seven cases and possible in one case of bacterial contamination.

Suspected Viral Infections

Three cases of hepatitis C involved transfusions in 1997, 2002 and 2004-2005 respectively. All the donors had been tested by serology at the time of donation and by Polymerase Chain Reaction (PCR) on any donations made from late 1999 onwards. In case 1, 53 donors were involved; 47 returned to donate and retested HCV negative, and a further six donors tested negative on archive samples from the original donation by PCR and serology. In case 2 from 2004-5, all five donors retested negative. In case 3, involving two donors, one donor retested negative, and HCV PCR and serology testing of the archive sample from the second donor who was not available for retesting, was negative.

In the Hepatitis B case, (case 4), investigated, all three donors had tested negative for hepatitis B at the time of donation (HBsAg and anti-hepatitis B core antibodies) and two of the three donors had returned to donate and tested negative over six months after the implicated transfusion. The third donor was recalled and also tested negative over six months after the implicated donation. The patient came from an ethnic group with a high rate of endemic HBV infection. Transfusion was excluded as the source.

One case of hepatitis A (HAV), case 5, in an elderly woman who had received four units of blood was investigated. Three donors tested negative on the archive sample of the donations and one donor was found to have HAV IgG antibodies indicating past infection. The three negative donors were recalled and again tested negative for HAV antibodies. Public health assessment suggested an alternative source for the hepatitis.

Bacterial Infections

Three cases of possible bacterial infection were reported. Two cases were associated with platelets and a further case with SD plasma (case 8).

In the first case associated with platelets, (case 6) routine bacterial screening of an aliquot from a pooled platelet unit undertaken in the IBTS showed a mixed growth of micrococcus and coagulase negative staphylococcus after three days in culture. As is standard practice, the platelets had been issued after a negative bacterial culture at 24 hours and had been transfused to a post operative patient who had not had any reaction but who was put on antibiotics as a precaution. Further investigation of other components from the four donations to the positive platelet pool cultured negative. The NHO does not routinely collect these unconfirmed positive culture reports but in this case as the patient had been kept on antibiotics for some days before the issue was resolved, the NHO decided to collect the incident as a possible bacterial infection.

In the second platelet case (case 7), where the investigation was triggered by a febrile reaction with rigors, the patient's blood culture showed mixed growth. Bacterial screening by the IBTS of the residual contents of one of the platelet bags showed a growth of *Acinetobacter baumannii*, an aerobic gram negative bacillus commonly isolated from the hospital environment and hospitalised patients and *Staphylococcus hominis* which was also most likely to be a contaminant. No growth was observed in the other platelet bag or the eight associated red cell units. Bacterial contamination was considered unlikely.

In the case reported with SD plasma, (case 8) clinical and laboratory investigations including cultures of the batch of SD plasma ruled out infection of the product. The reaction was considered due to underlying sepsis in the patient.

Recommendations

- Investigations into suspected transfusion transmitted viral infections are difficult. They can involve considerable upset to donors who often have to be recalled and offered testing and they are resource intensive.
- Where pre-transfusion samples are available, these samples can provide significant help in investigation. Patients such as haematology patients undergoing chemotherapy who will require ongoing transfusion should be offered testing before therapy and at regular intervals with storage of samples wherever possible for further testing if necessary. In these patients, virology screening for hepatitis B should include anti-hepatitis B core and surface antibodies in addition to hepatitis B surface antigen as reactivation of hepatitis B may occur as a result of chemotherapy leading to a possible poorer outcome for the patient (Lalazar et al, 2007), nosocomial infection risks and unnecessary donor investigations.

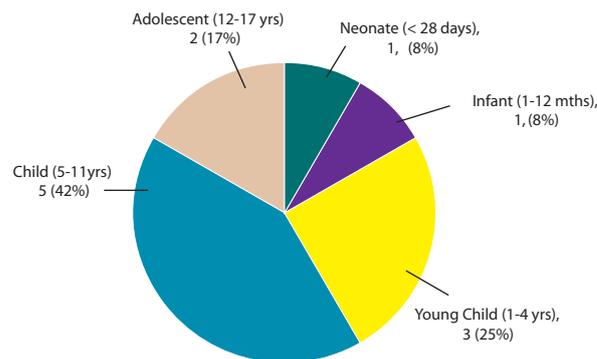
Paediatric Serious Adverse Reaction (n = 12)

Twelve of 117 (10%) SAR reports occurred in paediatric patients. Some of these have already been highlighted in the separate reaction categories but for ease of reference have been summarised in this section. Seven involved platelets, four involved red cells and there was one case reported associated with SD plasma where the reaction was considered to be unlikely to be due to the transfusion.

There were four FNTHR and seven AA reactions and one case of TACO (case 14). Five of the reactions

were in children (5–11 years), three in young children (1-4 years), two in adolescents (12-17 years) and one each in a neonate (<28 days) and an infant (1-12 months).

Figure 18 Breakdown of Paediatric Reactions by age (n=12)



Case History 14

This young child with severe anemia due to renal disease weighing 16.5kgs was prescribed 243 mls of red cells over four hours. The child developed tachycardia, dyspnoea, cyanosis, restlessness/anxiety and crepitations and the unit was discontinued after three hours although symptoms had begun to develop 30 minutes into the unit. There was no fluid balance record. The child was treated with O₂, diuretics, steroids and anti-histamine. The child recovered with no sequelae. The recovery period was not specified.

Table 7 Breakdown of Paediatric SAR by Category
(n= 12)

AA	SD Plasma	Neonate (<28 days)
AA	Red Blood Cells	Young child (1-4 years)
AA	Platelets	Child (5 -11 years)
AA	Platelets	Child (5 -11 years)
AA	Platelets	Child (5 -11 years)
AA	Platelets	Child (5 -11 years)
AA	Platelets	Adolescent (12 -17 years)
FNHTR	Platelets	Infant (1 -12 months)
FNHTR	Red Blood Cells	Young child (1 - 4 years)
FNHTR	Platelets	Child (5 -11 years)
FNHTR	Red Blood Cell	Adolescent (12 -18 years)
TACO	Red Blood Cells	Young child (1 -4 years)

Recommendations

- Paediatric patients with chronic anemia, respiratory, cardiovascular or renal disease should be transfused slowly and close attention should be paid to the patient's fluid balance. The onset of symptoms suggestive of overload should lead to the transfusion being slowed or discontinued until symptoms have resolved.

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Appendix 1

Management of an Acute Transfusion reaction

