

National Haemovigilance Office

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Annual Report
2000

Foreword

The National Haemovigilance Office (NHO) is now firmly established in its role of collecting and analysing voluntary confidential information relating to adverse clinical reports from blood transfusion. The first Annual Report of the NHO covered the relatively short period from 1 October 1999 to 31 December 1999, but illustrated that transfusion of a blood component to the wrong patient was the most frequent problem, (44% of reports). This year, the first complete year of reporting, the category of Incorrect blood component transfused (IBCT) again exceeds all others.

The Report's findings illustrate that while blood transfusion therapy is a safe procedure, there is still a need to develop and perfect systems at hospital level to ensure safety and elimination of errors at all stages of the transfusion chain.

A considerable number of recommendations have ensued from the analysis of the reports received and these are summarised at the beginning of this report and expanded upon within each appropriate chapter. Primary areas of concern are those incidents in the categories of IBCT and transfusion associated circulatory overload (TACO) as these incidents provide opportunities for improved practice.

In order to achieve improvements in transfusion safety - which is the ultimate goal of the National Haemovigilance programme - the office has continued to extend its involvement with hospital based Transfusion Surveillance Officers (TSO) in a pro-active way. Extensive educational visits, together with the development of in-service education programmes have continued. This aspect of the programme has been most rewarding, with a steady building of mutual trust and networking between the NHO staff, hospital based TSOs and others working in the area of transfusion throughout the country.

The NHO again wishes to acknowledge the support of Consultant Haematologists, Hospital based TSOs, Hospital Laboratory Technologists and Hospital Consultants in the many hospitals who have participated and supported this programme. The continued feedback from the wider 'transfusion community' is most encouraging. Thanks are also due to the Minister for Health and Children and his Department, Directors of Nursing, Chief Executive Officers and Hospital Administrative staff.

At this point I would like to mention the contribution of the Serious Hazards of Transfusion (SHOT), the UK haemovigilance reporting system. The structure and development of this report is based on that of SHOT and by using published SHOT reports as references, the NHO has established a framework for our own report, and this has proved invaluable.

A number of people have been involved in the continued development of the National Haemovigilance Programme. A multi-disciplinary National Steering Committee was established to oversee and monitor the initial implementation of the scheme. The advice and support of the Medical Director and staff of the Pharmacovigilance Department of the Irish Medicines Board (IMB) has also been invaluable.

The work of the National Blood Users Group in researching best transfusion practice and in the preparation of national guidelines for the use of blood components must be recognised as a significant contribution to patient safety. Appreciation should also be extended to the Consultant Haematologists and the Management and Staff of the Irish Blood Transfusion Service (IBTS).

On a personal level, I wish to mention Mr. Peter McDonnell and Mr. Gary Keany of the Training Department at the IBTS who developed the induction-training sessions for newly

appointed TSOs. I also personally acknowledge, in a special way, the patience and efforts of the Staff of the NHO in compiling and drafting this report.

In the interest of improving the care and safety of patients requiring transfusion throughout the country, the NHO will continue to promote Haemovigilance in the year ahead by initiating regional seminars and study days. The existing education programme will also be developed further.

The excellent progress made in the first fifteen months of this programme has provided a firm foundation for these developments and augers well for the future.

Dr Emer Lawlor
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Table of Contents

	<i>Page Number</i>
Foreword	3
Table of Contents	5
Recommendations	7
Haemovigilance – an Overview	11
<i>Hospital Transfusion Committees</i>	11
<i>National Blood Users Group</i>	12
<i>Education, Promotions and Developments</i>	12
<i>NHO News</i>	12
<i>NHO Audit Tool</i>	12
<i>"Near Miss" Pilot Scheme</i>	13
<i>Definition of an Adverse Event/Reaction</i>	13
<i>Reporting Forms</i>	13
<i>'Did not Progress'</i>	14
<i>'Nil to Report'</i>	14
<i>Denominator</i>	14
<i>Incidents January – December 2000</i>	15
Incorrect Blood Components Transfused	17
<i>Findings</i>	18
<i>Recommendations</i>	19
<i>Table 3 IBCT</i>	20
<i>Table 4 IBCT Minor Incidents</i>	25
<i>IBCT Detailed Case Histories</i>	27
Severe Acute Anaphylaxis/Anaphylactoid Reactions	33
Acute Haemolytic and Other Severe Acute Transfusion Reactions	41
Transfusion Association Circulatory Overload	49
Suspected Transfusion Transmitted Infection	53
Delayed Haemolytic Transfusion Reaction	57
Unusual Transfusion Reactions	61
References	63
Appendix 1	67
Appendix 2	69

Recommendations

- ◆ The importance of positive patient identification at the bedside using three minimum identifiers, i.e. full name, date of birth and unique hospital number, both at the time of sampling and administration is highlighted.
- ◆ Should there be a discrepancy in any of the three minimum identifiers on the patient's identity bracelet, the compatibility report form, the component issue label, the prescription or the clinical notes, the transfusion must not proceed and the laboratory must be contacted.
- ◆ All stages of the transfusion process, from prescription, sample taking, cross matching in the laboratory to bedside administration require an uninterrupted working environment, with adequate space.
- ◆ Whether using manual or a semi-automated systems, the laboratory must develop procedures to build in checks for all critical points in transfusion testing, e.g. preserving the identity of samples during separation and processing.
- ◆ Computer software should be validated to ensure that it does not permit the allocation or release of ABO incompatible Red Cell Concentrate (RCC) units.
- ◆ It is recommended that hospitals put in place automated transfer systems of laboratory information to clinical areas to avoid communication errors.
- ◆ Computerised identification systems are available to ensure safe transfusion at the bedside. These systems must now be evaluated further with a view to their development within transfusion practice. Their potential value in areas other than the transfusion setting, for example in reducing drug administration errors, should also be evaluated, as this will improve their cost effectiveness.
- ◆ Satisfactory thawing of Fresh Frozen Plasma (FFP) is the responsibility of the hospital blood bank¹. If frozen plasma is to be thawed outside the laboratory, staff carrying out this procedure must be competent in doing so and a register of individual training records should be maintained.
- ◆ Immunocompromised patients have special transfusion requirements. The transfusion prescription and the request form must be accurately completed to include these special requirements, i.e. cytomegalovirus (CMV) antibody negative and irradiated cellular components. Through the provision of additional information such as diagnosis, provisional or otherwise, and past medical history on the transfusion prescription, Laboratory and Nursing staff may be prompted to intercept errors leading to omission of special requirements for this patient group.
 - ❖ Sharing care with tertiary care centres is becoming increasingly more common, especially in the Haematology/Oncology setting. A secure system to ensure that patients in shared care receive the appropriate blood components in the participating hospitals is recommended.
- ◆ It is recommended that vital signs relating to transfusion be recorded separately from routine vital signs and clearly dated to enable the information to be retrieved at a later date where necessary².
- ◆ It is recommended that where a severe reaction occurs, the transfusion should be discontinued and not recommenced until a full documentation check, serological investigation and medical review has been undertaken.

- ◆ The causes of anaphylactoid/anaphylactic transfusion reactions are not always clear and may be linked to an allergy to plasma proteins. In some rare cases IgA deficiencies with anti-IgA antibodies have been described, therefore it is recommended that IgA levels be checked when symptoms of anaphylactoid transfusion reactions develop, as these reactions can be life threatening in patients with IgA deficiency.
 - ❖ In cases of suspected allergic/anaphylactoid reactions, or in patients who have had difficulties with previous transfusions, it may be necessary to pre-medicate with an antihistamine before each transfusion episode³.
 - ❖ If a patient has a history of **repeated** anaphylactic or severe anaphylactoid transfusion reactions and IgA level is normal, the patient should receive washed cellular components if further transfusions are needed. Plasma transfusions should be given cautiously after appropriate pre-medication⁴.
 - ❖ Patients with IgA deficiency (<0.05mg/dL) should have anti-IgA antibodies checked and if positive will require special management, including the use of washed cellular components, for future transfusions⁴.
- ◆ It is particularly important to fully investigate any severe acute symptoms occurring during the transfusion in an effort to identify the cause of the symptoms. In a number of cases reported of anaphylactoid reactions, the diagnosis was not clear and full serological/bacterial culture of patient and packs was not undertaken. A protocol for blood pack culture is available on request from the Quality Assurance/Quality Control Department of the Irish Blood Transfusion Service (IBTS).
- ◆ Reports received indicate that transfusion associated circulatory overload (TACO) is associated with considerable morbidity. In one reported case with underlying cardiac disease, it may have contributed to mortality. In response to these reports, particularly associated with the administration of FFP, the National Haemovigilance Office (NHO) issued an information leaflet on the use of FFP. (see Appendix 1) This included:
 - ❖ Firm indications for the use of FFP
 - ❖ Suggested infusion rates
 - ❖ Management of anticoagulation in the preoperative period
 - ❖ Conditional uses of FFP
- ◆ Careful attention should be paid to the patient's fluid balance prior to transfusion of any blood component. In those patients considered to be at greater risk of developing circulatory overload, the very small, elderly, cardiac or respiratory compromised patient, the transfusion should be administered slowly and the patient must be closely monitored for early signs and symptoms⁵. In addition, the use of diuretic therapy should be considered as a prophylactic measure in those patients considered to be at risk.
- ◆ The symptoms suffered during any transfusion reaction reinforce the need to **transfuse only** where an alternative therapy does not exist.
- ◆ Because of the need to conserve supplies of Rhesus D negative blood for females of child bearing age, hospitals should have policies to cover switching patients from Rhesus D negative to Rhesus D positive blood when stocks are low or when massive bleeding is anticipated.
- ◆ Careful history taking in relation to transfusion and pregnancies by the requesting physician is important. However, up to 12% of patients do not realise that they have had a transfusion⁶, so access to and checking of previous transfusion records are essential. Inter hospital computer access to laboratory transfusion records may need to be evaluated for use in the future.

- ◆ As antibodies can develop rapidly, patients being repeatedly transfused, depending on the interval between transfusions, should have a fresh sample submitted within 24-72hrs of a planned transfusion in accordance with British Committee for Standards in Haematology (BCSH) Guidelines⁷.

Haemovigilance – an overview

Haemovigilance has been defined as:

" A set of surveillance procedures, from the collection of blood and its components to the follow-up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence"

The Scheme is an anonymised system similar to that in place for monitoring drug safety (Pharmacovigilance) and is dedicated to the improvement of practice within the transfusion chain at all stages from donor to recipient. Reporting of incidents is seen as part of the professional responsibility of all Health Care Professionals.

The remit of the National Haemovigilance Office (NHO) is to:

- ◆ Receive, collate and follow up reports from hospitals and general practitioners of adverse reactions/events to transfusion of blood components/products and provide feedback information to reporters as appropriate.
- ◆ Advise on the follow-up action necessary, particularly with regard to suspected hazards.
- ◆ Report adverse reactions to the Irish Medicines Board (IMB) according to an agreed procedure.
- ◆ Provide ongoing support to hospital-based Transfusion Surveillance Officers (TSO) and as appropriate to medical, nursing and technical staff.
- ◆ Provide medical, scientific and nursing analysis of reports of adverse reactions.
- ◆ Advise on improvements in safe transfusion practice based on the data supplied by hospitals.
- ◆ Support the 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 Users Group on a periodic basis with a view to developing national best transfusion practice.

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

The NHO is located at the National Blood Centre, James's St., Dublin 8 and functions under the directorship of a Consultant Haematologist with two Transfusion Surveillance Officers (TSO), an Office Administrator and Assistant Administrator.

Hospital Transfusion Committees

The NHO actively encourages and supports the development of multi-disciplinary Hospital Transfusion Committees to provide a forum for discussion and exchange of views at local level. It is also necessary to avoid assigning blame when an error is identified, but rather to find the root causes of the error. Without an adequate understanding of the causes of error, there is little likelihood the error can be corrected and prevented in the future. It is essential to look for and to eliminate situations that set up humans for failure⁸. An environment that encourages organisations to identify errors, evaluate causes and take appropriate actions to improve performance in the future can be developed through the establishment of a Hospital

Transfusion Committee⁹. The concept of local 'ownership' of issues in a 'no blame culture' is a fundamental element in supporting the role of the Hospital based TSO and also to the overall success of the National Haemovigilance Programme.

National Blood Users Group

The National Blood Users Group was established by the Minister for Health and Children for the purpose of preparing and disseminating guidelines for the use of blood products in Ireland

"A Guideline for Transfusion of Red Blood Cells in Surgical Patients" is the first in a series of planned National Blood Users Group publications, produced according to the principles of evidence-based medicine. This document provides a valuable tool against which actual practice may be audited and measured. Copies of this publication have been widely distributed during 2001. Copies may also be downloaded and directly accessed on the Irish Blood Transfusion Service (IBTS) Website @ www.ibts.ie (Publications page).

Education, Promotion and Developments

Improvements in hospital transfusion practices have been promoted and supported by a number of different means. A vital part of the support structures for the NHO are the training and education programmes for nursing, medical and laboratory students. All newly appointed Hospital based TSOs attend an induction programme, which includes an introduction to Good Manufacturing Practice and an overview of the IBTS manufacturing processes in the National Blood Centre.

The NHO has established an extensive network of contacts by personal visits, regular correspondence and telephone communication. The NHO Staff continue to take part in interview panels when requested. Upon the appointment of the hospital based TSO, information packs, correspondence and induction days are arranged to encourage uniformity of practice and a free, open exchange of information.

As the majority of TSO appointments were confined to the centres with a sizeable blood usage, the NHO developed and provided a number of 'in-service' education sessions within smaller centres in an attempt to standardise care before, during and upon completion of transfusions.

Information on Haemovigilance can be directly accessed on the IBTS Website @ www.ibts.ie.

NHO News

The first edition of ***NHO News***, a quarterly newsletter for TSOs, was launched in June 2000. The aim of this newsletter is to provide news and helpful information in an informal fashion to TSOs around the country. TSOs are encouraged to forward details of events that may be of national interest, including results of audit trails, local education and training initiatives, study days or incidents of interest that arise and may be of assistance or relevance to work carried out by other TSOs. The newsletter also provides a forum for TSOs to promote their efforts within their own hospital community.

NHO Audit Tool

Included in the remit of the NHO is the development of the audit function at hospital level in relation to transfusion practice. As a result of feedback from TSOs around the country, NHO staff designed an audit tool to assist in identifying areas of transfusion practice where difficulties frequently arise. The document is loosely based on the NHO detailed questionnaires and was designed for ease of completion both from observing practice and archived patient records.

The initial audit trial permitted an overall assessment of the strength of the audit tool and allowed for modifications in future reviews. Re-audits will be carried out using the improved audit tool, to evaluate the efficacy of current guidelines in achieving quality care.

Resulting recommendations will be used to promote improvements in transfusion practice by identifying areas of educational need and using the collated information for educational purposes. All participants in this project will receive feedback and analysis.

'Near Miss' Pilot Scheme

It is recognised that for every transfusion of wrong blood, despite there having been an error at some point during the process, many other incidents are prevented by careful checking procedures. Adequate understanding of the causes of error is essential if the error is to be corrected and prevented in the future. It is vital to search for and eliminate faults within a system that allow humans to make a mistake⁸.

In an effort to assess any problem areas that may be contributing factors to reportable incidents, a 'Near Miss' pilot scheme will be undertaken in the near future. The goal of this project will be:

- a) to raise the level of awareness of error detection and
- b) to evaluate, and put in place, systems which reduce the frequency of human failure.

The Near Miss scheme will have its own set of reporting forms, and it is anticipated that evaluation of near miss incidents would greatly enhance the safety of transfusion and prevent such incidents occurring in the future.

Definition of Adverse Event/Reaction

Reported incidents are considered as adverse events if they fulfill the following criteria:

Adverse Event:

Definition: An undesirable experience occurring following administration of a blood component/product.

Adverse Reaction:

Definition: A reaction which is harmful and unintended and which occurs following transfusion of therapeutic volume of a blood component/product.

Serious Adverse Reaction:

These include adverse reactions, which fall into one or more of the following categories

- ◆ Fatal
- ◆ Life-threatening
- ◆ Require or prolong hospitalisation
- ◆ Permanently disabling or requiring treatment to prevent permanent damage or disability
- ◆ Potential to cause foetal harm

Reporting Forms

The NHO has the following set of forms in operation for the reporting of various types of incidents, reactions and events:

1. Initial Report Form
2. Incorrect Blood Component/Blood Product Transfused
3. Acute Haemolytic or Other Severe Acute Transfusion Reaction
4. Delayed Haemolytic Transfusion Reaction
5. Transfusion-Related Acute Lung Injury

6. Severe Acute Anaphylaxis/Anaphylactoid Reactions
7. Transfusion Associated Circulatory Overload
8. Post Transfusion Purpura
9. Transfusion Associated Graft versus Host Disease
10. Unusual Transfusion Reactions

Reports received by the NHO are also monitored for increased frequency of adverse events/reactions to detect any problems which might be caused by changes in the collecting and processing of blood components, e.g. increased incidences of anaphylactoid or unusual reactions. As this was the first full year of the scheme, the data collected this year may be useful as a baseline in future years, although it is recognised that increased reporting may also reflect increased vigilance and awareness at hospital level.

'Did Not Progress'

A total of 102 transfusion 'incidents' were reported to the NHO. Of these, 17 incidents did not fulfill the criteria for a haemovigilance event. It was apparent upon further investigation that these incidents were simple febrile or urticarial reactions or could be attributed to the patient's underlying condition, e.g. sepsis or malignancy.

In one case, an initial report of suspected Transfusion Related Acute Lung Injury (TRALI) was determined to be due to pulmonary haemorrhage on investigation and has been excluded from further evaluation. Anonymised information regarding all these reported incidents was retained, thus providing an important source of learning for the future.

'Nil to Report'

To ascertain the percentage of hospitals participating in the NHO reporting scheme, a 'Nil to Report' form (see appendix 2) was sent through the TSO to all hospitals where blood is transfused (n=75). In the absence of a TSO at hospital level, the form was sent to the Pathologist, Senior Laboratory Technologist or Senior Nursing staff. The receiver of the form was asked if he/she had already reported incident(s) to the NHO during the period 1 January – 31 December 2000. If no adverse event had been seen, he/she was asked to return the form as 'nothing to report'.

Of the 75 hospitals eligible to participate, 28 (37.3%) submitted incident reports during the reporting year, 27 (96.4%) of which confirmed they had previously submitted a report by returning the 'Nil to Report' form. A further 23 (30.6%) returned the form stating they had 'nothing to report'. Combining these 23 hospitals with the 28 hospitals which contributed incident reports, participation in the scheme can be said to be 68% (51 of 75 hospitals). These hospitals are responsible for transfusing approximately 70% of all blood components transfused.

The 'Nil to Report' form was also used to ascertain the number of units transfused in each hospital in an effort to provide an accurate denominator against which transfusion risk can be assessed. For this reason it was necessary to identify the returning hospitals and when data was collated, reports were anonymised by removing all identifiers. Since 32% of hospitals did not respond, it was decided that the number of units issued from the IBTS during the reporting period would more accurately reflect the denominator.

Denominator:

In an effort to put the following data in context, an analysis of the number of units issued in this period was also carried out. These figures do not account for units discarded or wasted. See Table 1 over:

Table 1: Number of units issued by IBTS January – December 2000

Component	Total Issues
Red Cells	124,291
Platelets	41,207
Fresh Frozen Plasma	24,811
Cryoprecipitate	1,848
Whole Blood	506
Combined total	192,663

Incidents January – December 2000

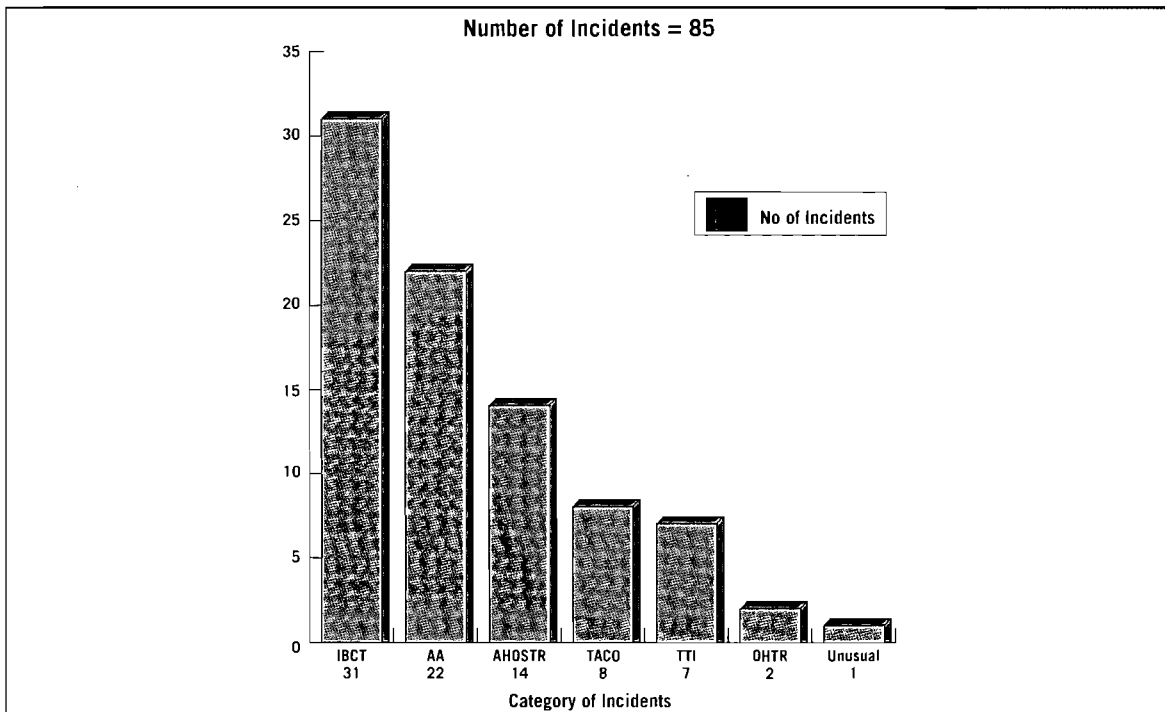
During the one-year period 1 January to 31 December 2000, there were 85 confirmed reports received and reviewed by the NHO which have been categorised as follows:

Table 2 NHO-Confirmed Reports by Category

IBCT	A/A	AHOSTR	TACO	TTI	DHTR	Unusual	Total Incidents
31	22	14	8	7	2	1	85
37%	26%	17%	9%	8%	2%	1%	100%

- IBCT* Incorrect Blood Component/Product Transfused.
- A/A* Severe Acute Anaphylactoid or Anaphylactic Reaction.
- AHOSTR* Acute Haemolytic or Other Severe Acute Transfusion Reaction.
- TACO* Transfusion Associated Circulatory Overload.
- TTI* Transfusion Transmitted Infection.
- DHTR* Delayed Haemolytic Transfusion Reaction

Graph 1 NHO Incidents by Category



There were no reports received in the categories of:

- ◆ Post Transfusion Purpura, (PTP)
- ◆ Transfusion Related Acute Lung Injury (TRALI)
- ◆ Transfusion Associated Graft versus Host Disease (TAGvHD).

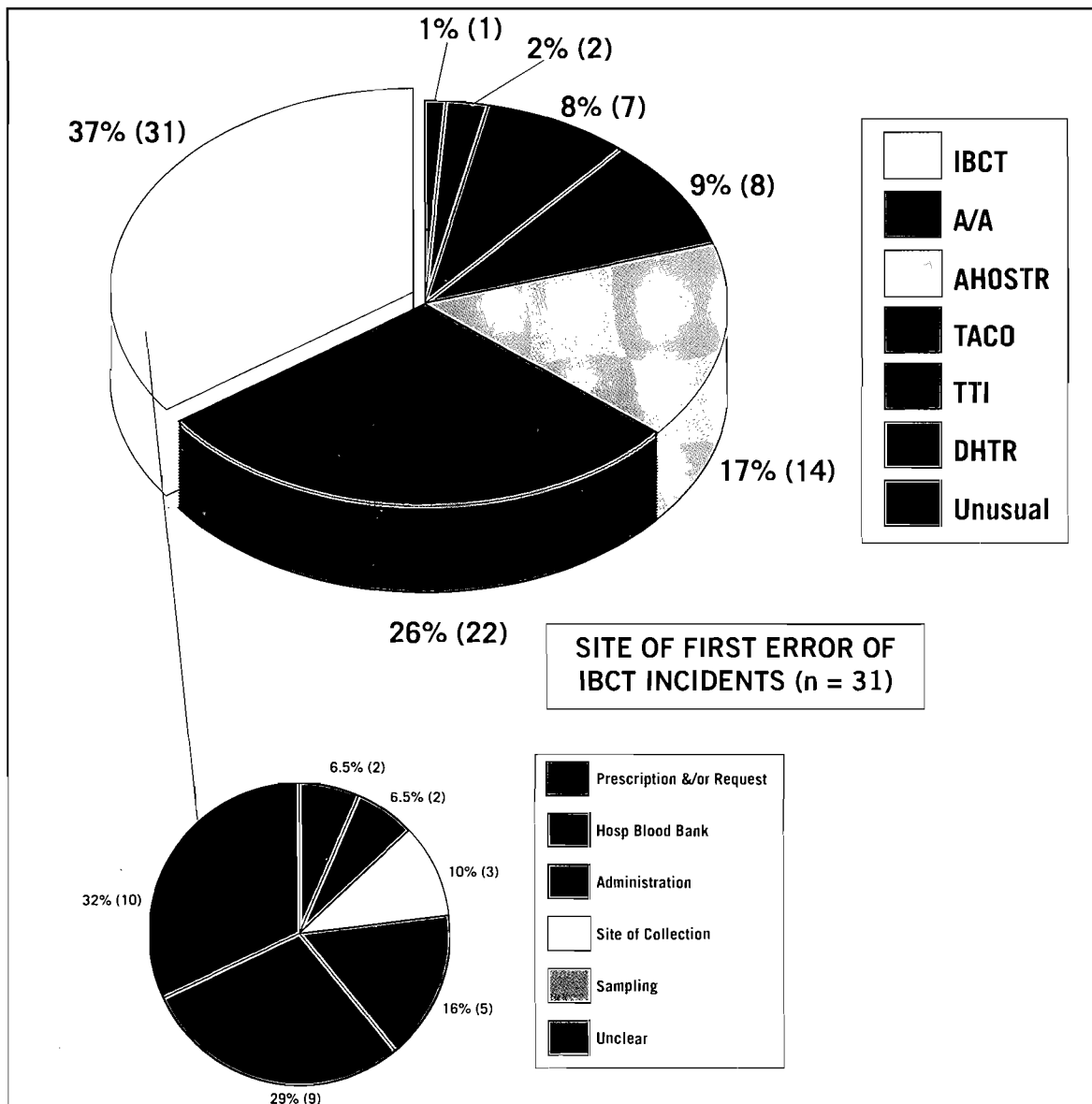
Incorrect Blood Component/Product Transfused

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

This category accounted for 37% of incidents reported (31 of 85).

**Graph 2 - National Haemovigilance Office (NHO)
Incidents January-December 2000 (n= 85)**

- IBCT *Incorrect Blood Component/Product Transfused.*
- A/A *Severe Acute Anaphylactoid or Anaphylactic Reaction.*
- AHOSTR *Acute Haemolytic or Other Severe Transfusion Reaction.*
- TACO *Transfusion Associated Circulatory Overload.*
- TTI *Transfusion Transmitted Infection.*
- DHTR *Delayed Haemolytic Transfusion Reaction*



FINDINGS

- ◆ The frequency of reports in this category highlights the need for attention to guidelines and extreme care when sampling blood pre-transfusion and issuing/administering blood components/products.
- ◆ In three cases, patients received the wrong ABO/Rhesus group (IBCT Cases 1, 2 & 3).
 - ❖ In one of these cases incorrect details were given to the porter and subsequently the incorrect pack was collected from storage. Bedside checking was inadequate and failed to detect the error (IBCT Case 1).
 - ❖ Due to distraction of the operator the computer warning was overridden and patient's blood group was changed (IBCT Case 2).
 - ❖ Rhesus D negative patient incorrectly transfused with Rhesus D positive blood due to incorrect blood grouping and failure to check historical records. (IBCT Case 3).
- ◆ In a further two cases involving transposition of ABO groups, no component was actually transfused, but as all checking procedures had been passed, it was decided to include these as actual incidents rather than 'near misses' (IBCT Cases 4 & 5).
- ◆ In one case, a Rhesus D negative female received Rhesus D positive Fresh Frozen Plasma (FFP) when due to a transcription error she was incorrectly grouped as Rhesus D positive. (IBCT Case 16).
- ◆ In four cases, patients were transfused unnecessarily due to failure to communicate the correct results between laboratory and clinical staff (IBCT Cases 7, 8, 9 & 10).
 - ❖ In one of these cases, the incorrect transfusion led to circulatory overload with major and continuing morbidity (IBCT Case 8).
- ◆ In one case it was unclear as to the site of first error where either the wrong component was ordered or the request was misinterpreted. However the error was not identified at the bedside checking procedure pre-transfusion (IBCT Case 14).
- ◆ In two cases the error occurred at hospital blood bank site of collection and proceeded through to transfusion (IBCT Cases 17 & 18).
- ◆ In one case the error occurred at pre-transfusion sampling, the hospital number and date of birth were incorrectly transcribed. This error proceeded through to transfusion despite multiple checking procedures (IBCT Case 12).
- ◆ In a further four cases, the original error occurred in the laboratory (IBCT Cases 6, 11, 13 & 15).
 - ❖ In one of these cases the error was detected during the bedside checking procedure pre-transfusion. However, no action was taken and the unit was transfused (IBCT Case 13).
- ◆ In five cases there was a failure to request cytomegalovirus (CMV) antibody negative &/or Irradiated cellular components for immunocompromised patients. There were no clinical sequelae. (IBCT Cases 19-23).
- ◆ In one case FFP was thawed outside the laboratory by nursing staff. Following transfusion, deposits were seen in the pack, which may have been due to inadequate defrosting. The reaction that occurred in the patient may or may not have been linked to this. (IBCT Case 24).
- ◆ Seven incidents (IBCT Cases 25-31) could be classified as minor but were collected by the NHO as they reflect the necessity for careful monitoring of the transfusion process. These incidents covered units expired, undetected changes in hospital digits and bedside administration errors - in some cases a series of errors.

- ◆ The bedside checking procedure is vital in preventing transfusion error and is the last opportunity to detect an identification error. In twenty of the thirty-one IBCT cases (i.e. 64.5%) the bedside checking procedure failed. It is also important to note that this final check will not necessarily detect errors of sampling or other errors, such as those occurring in the transfusion laboratory¹⁰.

RECOMMENDATIONS

- ◆ The importance of positive patient identification at the bedside using three minimum identifiers, i.e. full name, date of birth and unique hospital number, both at the time of sampling and administration is highlighted.
- ◆ Should there be a discrepancy in any of the three minimum identifiers on the patient's identity bracelet, the compatibility report form, the component issue label, the prescription or the clinical notes, the transfusion must not proceed and the laboratory must be contacted.
- ◆ All stages of the transfusion process, from prescription, sample taking, cross matching in the laboratory to bedside administration require an uninterrupted working environment, with adequate space.
- ◆ Whether using a manual or a semi-automated system, the laboratory must develop procedures to build in checks for all critical points in transfusion testing, e.g. preserving the identity of samples during separation and processing.
- ◆ Computer software should be validated to ensure that it does not permit the allocation or release of red cell ABO incompatible units.
- ◆ It is recommended that hospitals put in place automated transfer systems of laboratory information to clinical areas to avoid communication errors.
- ◆ Computerised identification systems are available to ensure safe transfusion at the bedside. These systems must now be evaluated further with a view to their development within transfusion practice. Their potential value in areas other than the transfusion setting, for example in reducing drug administration errors, should also be evaluated, as this will improve their cost effectiveness.
- ◆ Satisfactory thawing of FFP is the responsibility of the hospital blood bank¹. If frozen plasma is to be thawed outside the laboratory, staff carrying out this procedure must be competent in doing so and a register of individual training records should be maintained.
- ◆ Immunocompromised patients have special transfusion requirements. The transfusion prescription and the request form must be accurately completed to include these special requirements, eg. CMV antibody negative and irradiated cellular components. Through the provision of additional information such as diagnosis, provisional or otherwise, and past medical history on the transfusion prescription, Laboratory and Nursing staff may be prompted to intercept errors leading to omission of special requirements for this patient group.
 - ❖ Sharing care with tertiary care centres is becoming increasingly more common, especially in the Haematology/Oncology setting. A secure system to ensure that patients in shared care receive the appropriate blood components in the participating hospitals is recommended.
- ◆ It is recommended that vital signs relating to transfusion be recorded separately from routine vital signs and clearly dated to enable the information to be retrieved at a later date where necessary².

Table 3. Incorrect Blood Component Transfused (IBCT)

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/ Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 1	Group O Rhesus D positive	Group B Rhesus D positive	50-100 mls of Red Cell Concentrate (RCC)	Symptoms of vomiting, fever and rigors developed. Patient recovered within 24 hours with no sequelae.	Incorrect details given to porter when collecting RCC. Unit checked in office. Incorrect unit hung without positive patient identification.
IBCT Case 2	Group A Rhesus D positive	Group B Rhesus D positive	2 units of RCC	No features of haemolysis developed. No sequelae.	Laboratory staff overrode computer warning, although alerted, and changed patient's blood group on screen from group A to group B. Error discovered one week later.
IBCT Case 3	Group O Rhesus D negative	Group O Rhesus D positive	2 units of RCC	No features of haemolysis. Patient died from underlying problems.	Elderly male patient requiring large volume transfusion intraoperatively, changed from group O Rhesus D negative to group O Rhesus D positive to maintain supply. Two weeks later grouped as O Rhesus D positive (mixed field), historical records were not checked, two units of group O Rhesus D positive RCC were issued and transfused.
IBCT Case 4	Group O Rhesus D positive	Group A Rhesus D positive	Nil	Not transfused.	Remote checking of unit in the Nurses' Station. Positive patient identification not confirmed. Error detected as unit was about to be transfused.
IBCT Case 5	Group A Rhesus D positive	Group O Rhesus D positive	Nil	Not transfused	Remote checking of unit in the Nurses' Station. Positive patient identification not confirmed. Error detected as unit was about to be transfused.

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 6	Group A Rhesus D positive	Group A Rhesus D positive	4 units of RCC	No symptoms developed. No sequelae.	Antibody screen reported incorrectly as negative. Antigen negative blood not selected.
IBCT Case 7	Group O Rhesus D positive	Group O Rhesus D positive	2 units of RCC	No symptoms developed. No sequelae.	Error in verbal communication resulting in unnecessary transfusion.
IBCT Case 8	Group O Rhesus D positive	Group O Rhesus D positive	2 units of RCC	Elderly patient with underlying renal impairment developed symptoms of cardiac failure, dyspnoea, tachycardia and circulatory overload during transfusion. The patient subsequently developed renal failure, which requires ongoing management. This patient had a significant medication history, which included long-term use of non-steroidal anti-inflammatories and analgesics - known to be associated with renal dysfunction.	Incorrect haemoglobin result given verbally leading to inappropriate transfusion. Computer generated report discovered following the transfusion.
IBCT Case 9	Group O Rhesus D positive	Group O Rhesus D positive	1 unit of RCC	No symptoms developed. No sequelae.	Transfusion based on incorrect verbal report of haemoglobin result.
IBCT Case 10	Group O Rhesus D positive	Group O Rhesus D positive	1 unit of RCC	No symptoms developed. No sequelae.	Transfusion based on incorrect verbal report of haemoglobin result.

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 11	Group O Rhesus D negative	Group O Rhesus D negative	1 unit of RCC	No symptoms developed. No sequelae.	Due to distraction, staff member placed issue label for blood component pack on incorrect pack.
IBCT Case 12	Group O Rhesus D positive	Group O Rhesus D positive	5 units of RCC	No symptoms developed. No sequelae.	Pre-transfusion sample was incorrectly labelled using incorrect surname but correct hospital number and date of birth. The error continued through the transfusion chain without being identified by nursing/medical staff during the bedside checking procedure.
IBCT Case 13	Group A Rhesus D negative	Group O Rhesus D negative	2 units of RCC.	No symptoms developed. No sequelae.	Pre-transfusion sample correctly labelled. Name and date of birth on separated serum tube was incorrectly transcribed in the laboratory, hence incorrect patient name and date of birth on issue label. Although noted by nurses, transfusion proceeded.
IBCT Case 14	Group A Rhesus D positive	Group A Rhesus D positive	4 units FFP	Patient died from underlying disease. Circulatory overload may have contributed to mortality.	6 units of platelets were prescribed. It is unclear whether platelets or plasma were verbally requested by telephone. 6 units of plasma were issued. Bedside check failed to recognise the error.
IBCT Case 15	Group O Rhesus D negative	Group O Rhesus D negative	4 units FFP	No symptoms developed. No sequelae.	Unique hospital number temporarily unavailable, incorrect patient selected from computer screen and component issued with wrong patient details. Component administered to correct patient.

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 16	Group O Rhesus D negative	Group O Rhesus D positive	7 units FFP	No symptoms developed. No sequelae	Incorrect Rhesus group issued due to transcription error. Historical records not found. Error detected 2 months later when re-grouped in the same laboratory.
IBCT Case 17	Group A Rhesus D positive	Group O Rhesus D positive	1 Platelet Concentrate pooled	No symptoms developed. No sequelae	Group A Rhesus D positive platelets were labelled and ready for transfusion, however unlabelled group O Rhesus D positive platelets were collected and transfused in error.
IBCT Case 18	Group A Rhesus D positive	Group O Rhesus D negative	1 Platelet Concentrate pooled	No symptoms developed. No sequelae	Platelets intended for another patient transfused in error. Patient conscious and not asked to identify self. Identity bracelet missing.
IBCT Case 19	Data not available	Data not available	4 units RCC	No symptoms developed. No sequelae.	Failure to prescribe and request CMV antibody negative and irradiated blood for an immunocompromised patient.
IBCT Case 20	Data not available	Data not available	1 aliquot of Paedipack (RCC).	No symptoms developed. No sequelae	Failure to prescribe and request CMV antibody negative and irradiated blood for immunocompromised patient, verbal request to laboratory was made later. However, component issued and transfused was not irradiated.
IBCT Case 21	Group O Rhesus D positive	Group O Rhesus D positive	1 unit of Platelet Concentrate Apheresis	No symptoms developed. No sequelae	Failure to request CMV antibody negative and irradiated component for immunocompromised patient. Correct component prescribed. Bedside check did not detect the error.

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 22	Group O Rhesus D positive	Group O Rhesus D positive	1 unit of Platelet Concentrate pooled.	No symptoms developed. No sequelae	Failure to request CMV antibody negative and irradiated component for immunocompromised patient. Correct component prescribed. Bedside check did not detect the error.
IBCT Case 23	Group O Rhesus D positive	Group O Rhesus D positive	1 unit of Platelet Concentrate Apheresis	No symptoms developed. No sequelae.	Failure to request CMV antibody negative and irradiated component for immunocompromised patient. Correct component prescribed. Bedside check did not detect the error.
IBCT Case 24	Group O Rhesus D positive.	Group O Rhesus D positive	300 ml FFP	'Nettle sting' type body rash.	Deposits seen in pack after transfusion. May have been due to inadequate defrosting.

Table 4 Incorrect Blood Component Transfused (IBCT) - Minor Incidents

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 25	Group B Rhesus D negative	Group O Rhesus D negative	1 unit of RCC	No symptoms developed. No sequelae	Unit, which was due to expire at midnight, was issued. Transfusion took place 8 hours after midnight. Bedside check failed to identify the error.
IBCT Case 26	Group AB Rhesus D positive	Group AB Rhesus D positive	1 unit of RCC	No symptoms developed. No sequelae	Hospital blood bank issued two expired units. Error not noted during bedside check of first unit. During bedside check of second unit error was identified and Laboratory notified.
IBCT Case 27	Group O Rhesus D positive	Group O Rhesus D positive	1 unit of RCC	No symptoms developed. No sequelae	Digit discrepancy in hospital number at phlebotomy. The error continued through the transfusion chain without being identified despite multiple checking procedures. No bedside check carried out, identification bracelet missing.
IBCT Case 28	Data not available	Data not available	Platelet Concentrate pooled 1 unit	No symptoms developed. No sequelae.	One unit of Platelet concentrate pooled was delivered outside normal working hours. No facility available in this hospital for storage of platelets. Nursing staff decided to defer transfusion and store platelets overnight in satellite fridge without contacting the on-call medical or laboratory staff for advice. Platelets transfused the next morning.
IBCT Case 29	Group A Rhesus D positive	Group A Rhesus D positive	1 unit of FFP	No symptoms developed. No sequelae.	The hospital blood bank issued two units of FFP one of which had expired at midnight. The bedside check failed to identify the error.

Case No.	ABO & Rhesus Group of Patient	ABO & Rhesus Group of IBCT	Volume of Incorrect Blood Component/Product Transfused	Symptoms & Outcome	Cause of Error
IBCT Case 30	Group A Rhesus D negative	Group A Rhesus D negative	1 unit of RCC	No symptoms developed. No sequelae.	Unit, which was due to expire at midnight, was issued. The near expiry date was highlighted by the Laboratory. Transfusion took place 9½ hours after midnight. Bedside check failed to identify the error.
IBCT Case 31	Group O Rhesus D negative	Group O Rhesus D positive	1 vial of Anti-D immunoglobulin	No symptoms developed. No sequelae.	Due to failing blood supply, group O Rhesus D positive RCC was issued to a group O Rhesus D negative male patient. Anti-D was then given inappropriately.

Incorrect Blood Component Transfused – Detailed Case Histories

IBCT Case 1

This was a non-emergency transfusion of RCC outside normal working hours to a patient for anaemia of malignancy. Patient X was grouped as group O Rhesus D positive. Patient Y had a similar name and was on the same ward. Both patients had blood available for them. The porter who had been asked to collect the blood for Patient X, was given Patient Y's addressograph label by ward staff and so collected the incorrect unit for this patient. Two qualified nurses checked the unit in the office – not at the bedside - against Patient Y's chart and documentation. At the bedside, Patient X – although conscious - was not asked to state his name or date of birth, neither was his identity bracelet checked –which was legible and correct. The error was noted when laboratory staff recognised that the incorrect unit had been removed from storage, by which time 50-100 mls. of group B Rhesus D positive blood had been transfused. Patient X developed symptoms of fever, rigors and vomiting and the transfusion was discontinued completely. The patient recovered within 24 hours with no ill effects.

IBCT Case 2

This young patient had received a non-emergency transfusion of two units of RCC for anaemia of malignancy in an in-patient setting. Patient details on the sample were hand-written, correct and labelled at the bedside. Due to distraction, a laboratory technician overrode a warning on the computer system, and in error, changed patient's blood group from A to B and the patient received a unit of group B Rhesus D positive blood. This error was identified one week later when cross-matching was repeated. Due to underlying condition, the patient had no anti-B detectable. There was no observable morbidity.

IBCT Case 3

An elderly male patient grouped as O Rhesus D negative and required multiple transfusions perioperatively. A decision was made to change over from negative to positive components to maintain Rhesus D negative supply. Two weeks later a further transfusion of two units of RCC was prescribed. The cross-match was performed outside normal working hours and the patient grouped as O Rhesus D positive with mixed field. No Rhesus D antibodies were detected on pre-transfusion antibody screen. Historical records were not checked so two units of group O Rhesus D positive RCC were issued and transfused. The error was recognised the following day in the laboratory during routine checking and retrospective antibody screen showed anti D in enzyme only. There were no features of haemolysis. The patient developed no adverse effects as a result of this transfusion, but died 24 hours later from underlying disease.

IBCT Case 4

A transfusion of RCC was to be administered to a patient in a day care setting. Two nurses checked the unit in the nurses' station – not at the bedside - and one nurse then proceeded to the bedside, where the identity bracelet was not checked. Positive identification was not sought from the patient. A unit of RCC group A Rhesus D positive was placed on the intravenous stand at the patient's bedside to be commenced when a platelet transfusion was completed. The error was detected when the staff nurse was informed that the patient's blood group was O Rhesus D positive. The unit had not been connected to the patient.

IBCT Case 5

A transfusion of RCC was to be administered to a patient in a day care setting. The patient's blood group was A Rhesus D positive. Two nurses checked the unit in the nurses' station – not at the bedside - and one nurse then proceeded to the bedside, where the identity band was not checked. Positive identification was not sought from the patient. The nurse connected a unit of O Rhesus D positive RCC to the patient's central venous line. The error was detected when the transposition error in another transfusion on the same ward was

made known to the nurse involved. (see IBCT 4 above) The roller clamp on the blood administration set had not been unclamped and so no blood was infused.

IBCT Case 6

Four units of RCC were transfused following an intraoperative bleed. No transfusion history was recorded on the transfusion request forms. This patient had previously been transfused and had an anti Jk^a. Pre-transfusion antibody screen performed but due to an inconclusive result, was to be repeated. However, staff changeover due to illness led to the issue of four units of RCC without confirming the result. The patient was asymptomatic and suffered no sequelae. Laboratory staff detected this error when extra units were requested post-operatively.

IBCT Case 7

An error occurred in communication between medical staff regarding this transfusion which resulted in the patient being transfused unnecessarily with two units of RCC. The patient developed no adverse effects as a result of this transfusion.

IBCT Case 8

An elderly patient was transfused with two units of RCC following elective surgery. This incident occurred following a change of staff who assumed that the verbal report of a haemoglobin of 7.5 gm/dl referred to a post transfusion sample result and a further two units were transfused (actual haemoglobin 9.5gm/dl). The patient had an underlying chronic renal impairment with associated cardiac problems. During transfusion symptoms of circulatory overload developed with no response to intravenous diuretics. This patient required renal dialysis, and continues on maintenance dialysis. There was a significant medication history, which included long-term use of non-steroidal anti-inflammatories and analgesics – known to be associated with renal dysfunction. The error was discovered when the computer-generated report stating the correct haemoglobin result was found following the transfusion.

IBCT Case 9

This non-emergency transfusion took place in an in-patient setting. One unit of RCC was prescribed for an elderly patient with a haemoglobin of 8.1 gm/dl, which had been reported verbally and recorded as such in the medical notes. Error was identified by the Transfusion Surveillance Officer (TSO) during routine auditing of transfusions when the haemoglobin was found in fact to be 9.6 gm/dl. The patient developed no adverse effects as a result of this transfusion.

IBCT Case 10

This elderly patient had suspected gastro-intestinal bleed with associated anaemia. Laboratory staff telephoned a haemoglobin result of 6.7 g/dl. This result was however two days old and the anaemia had been appropriately treated. The ward staff assumed that this result was the most recent haemoglobin and based on this inaccurate information, four units of RCC were requested and issued. As the first unit was completed the computer-generated result was then viewed and the actual haemoglobin was found to be 10.8gm/dl. No further units were transfused. The patient developed no adverse effects as a result of this transfusion.

IBCT Case 11

This elderly patient was transfused for anaemia in a non-emergency setting. In the laboratory, due to distraction, the computer-generated issue label with patient details was placed inadvertently on a unit of RCC, which was of the correct group, but had not been cross-matched for this patient. The pre-transfusion bedside check failed to recognise that the donation number on the issue label on the back of the pack did not match the donation number on the Irish Blood Transfusion Service (IBTS) label on the front of the pack. The patient developed no adverse effects as a result of this transfusion. The error was discovered the following day by laboratory staff during a routine stock check.

IBCT Case 12

An elderly patient requiring five units of RCC following elective surgery was transfused between the Operating Theatre, Recovery Unit and the ward. The pre-transfusion sample was hand-written but incorrectly labelled by the phlebotomist – the surname was incorrectly spelled which in effect created a new surname. This error continued throughout the transfusion chain process. Subsequently the surname on the pack issue label was also incorrect. Two nurses and an anesthetist checked the units as correct, without reference to the patient, who was conscious and able to identify him/herself. The identity bracelet was correct in all details, but was not included in the checking process. There were no complications relating to this transfusion. The error was discovered by laboratory staff one week later when repeat cross matching was requested with correct details written on sample tube and on request form.

IBCT Case 13

This patient was group A Rhesus D negative and was transfused during the night with two units of group O Rhesus D negative RCC. The pre-transfusion sample was labelled using only two patient identifiers, as the Hospital Number was not available because the Admissions Office was closed. Two units of RCC were issued and transfused uneventfully. During the night, two further units were requested over the telephone for an emergency transfusion. The laboratory staff generated the request form using patient details from the separated serum sample tube but transcribed these details incorrectly. A further transcription error arose when inputting data into the computer and the surname was incorrectly spelled. Hence two units of RCC were issued with the incorrect date of birth and incorrect surname. The discrepancy in date of birth was noted, however, the incorrect surname was not noted and the unit was transfused without consulting laboratory staff. The patient developed no adverse effects as a result of this transfusion. The TSO noted the error during routine surveillance.

IBCT Case 14

A patient was prescribed 6 units of single donor platelets (1 adult dose) prior to an invasive procedure, but 6 units of FFP were issued instead, based on a telephone request where either the wrong component was ordered or the order was misinterpreted. The bedside checking process did not detect the error. During the 4th unit the patient arrested. This patient died of underlying disease, but an element of circulatory overload cannot be ruled out and may have been a contributing factor, as the volume of four units of plasma (approximately 880 mls) is considerably greater than that of platelets (approximately 300mls). The event was reported to the TSO as a reaction to platelets and the error was identified during the investigation.

IBCT Case 15

FFP was administered in an emergency to the intended patient but ascribed on hospital computer for another patient of the same name. This arose because the chart was unavailable immediately and only name and date of birth were recorded on the pre-transfusion sample tube label. The unique hospital number was not recorded. The laboratory selected another patient of same name but different date of birth from computer screen, changed the details on the sample tube to match and issued four units of FFP to that patient. The discrepancies were noted at the bedside but the transfusion proceeded without contacting laboratory staff. The patient developed no adverse effects as a result of this transfusion. The TSO was informed of the event some days later.

IBCT Case 16

An elderly Rhesus D negative woman was incorrectly grouped as Rhesus D positive due to transcription error. Historical records were not found as she had been transfused under a different medical record number previously. Seven units of Rhesus D positive FFP were issued and transfused. Subsequent transfusion two months later identified error, showing incorrect group had been issued on this occasion. The patient developed no adverse effects as a result of this transfusion.

IBCT Case 17

One pool of unlabelled group O Rhesus D positive platelets were collected in error and transfused to a group A Rhesus D positive patient, while group A Rhesus D positive platelets were already labelled and available in the hospital blood bank for this patient. The bedside checking procedure failed to identify the error. Laboratory staff detected the error during a routine stock check. The patient developed no adverse effects as a result of this transfusion.

IBCT Case 18

This patient was transfused with one unit of apheresed platelets for acute haemorrhage associated with coagulopathy in Intensive Therapy Unit (ITU). He was group A Rhesus D positive. One pack of apheresed platelet concentrate group O Rhesus D negative, intended for another patient in ITU was collected from the blood bank and placed at the bedside of this patient. Two people checked the component at the bedside but the patient, although conscious was not asked to confirm positive identification. There was no patient identity bracelet in place. The error was detected when the empty pack with the other patient details on it was found at the bedside of this patient. The patient developed no adverse effects as a result of this transfusion.

Failure to administer CMV antibody negative and irradiated products

IBCT Case 19

A new patient with an underlying haematological disorder requiring CMV antibody negative and irradiated cellular blood components received 4 units of RCC which were not CMV antibody negative or irradiated when transfused in a general hospital before transfer to a specialist Haematology centre. The patient suffered no sequelae. The TSO identified this error during routine surveillance.

IBCT Case 20

An anaemic baby required emergency transfusion as an in-patient. Care was being shared with a tertiary centre and patient required CMV antibody negative and irradiated cellular components as per tertiary centre's instructions. Request form was hand-written omitting this detail. Prescribing doctor later verbally requested CMV antibody negative and irradiated component but did not change the prescription accordingly. The component issued was not irradiated. Two nurses checked unit and patient identity at bedside. This case highlights the need to prescribe components needing special requirements on prescription sheet. The patient suffered no sequelae.

IBCT Case 21

Patient scheduled for peripheral blood stem cell (PBSC) collection was transfused with non-irradiated, non-CMV antibody negative platelets twenty-four hours prior to procedure. The component had been requested verbally when the laboratory already knew the patient's group, but the requesting doctor failed to mention the special requirements needed for this transfusion. The component had been correctly prescribed on the transfusion prescription form, but the bedside check failed to identify that special requirements were not met. Laboratory staff discovered the error when subsequent transfusion of CMV antibody negative and irradiated component was ordered. The patient suffered no sequelae.

IBCT Case 22

A potential bone marrow transplant patient was transfused with non-irradiated, non-CMV antibody negative pooled platelet concentrate in a day ward setting. The component had been requested verbally when the laboratory already knew the patient's group, but the requesting doctor failed to mention the special requirements needed for this transfusion. The component had been correctly prescribed on the transfusion prescription form but the bedside check failed to identify that special requirements were not met. Laboratory staff discovered the error when subsequent transfusion of CMV antibody negative and irradiated component was ordered. The patient suffered no sequelae.

IBCT Case 23

A patient due to undergo PBSC harvest received non-irradiated, non-CMV antibody negative unit of platelet concentrate apheresis. Component had been requested verbally when the laboratory already knew the patient's group, but requesting doctor failed to mention the special requirements for this transfusion. The component had been correctly prescribed on the transfusion prescription form but the bedside check failed to identify that special requirements were not met. The TSO discovered error when reviewing pre bone marrow/PBSC transplant patients. The patient suffered no sequelae.

Failure to defrost Plasma correctly

IBCT Case 24

FFP was collected from laboratory freezer and defrosted at ward level by nursing staff. The patient, who already had an underlying petechial rash due to meningococcal sepsis, developed an urticarial 'nettle sting' type rash during transfusion. On examination, following transfusion, deposits were seen in remaining plasma, which may have been due to inadequate defrosting. The patient recovered without sequelae.

Incorrect Blood Component Transfused - Minor Incidents

Seven incidents (IBCT 25-31) could be classified as minor but were collected by the NHO as they reflect the necessity for careful monitoring of the transfusion process. These incidents covered units expired, undetected changes in hospital digits and bedside administration errors, - in some cases a series of errors. As there are a number of similarities in all of these cases, for reporting purposes, one case is included in detail.

IBCT Case 27

This elderly patient was transfused for anaemia with one unit of RCC, as an in-patient in a non-emergency setting. The hospital number was transcribed onto the sample tube incorrectly at time of sampling. In the laboratory, transfusion records were not checked and the discrepancy was not detected. This incorrect number was transcribed onto the issue label and the issue report form. The name and date of birth were correct on all documentation but the hospital number had a digit discrepancy. The unit was not formally checked for identity at time of collection from storage. Remote checking of the unit in the Nurses' Station failed to identify the error prior to transfusing the first unit. The patient's identity bracelet was missing, thus positive patient identification was not confirmed. Staff checking the second unit discovered the error and contacted the laboratory. The patient developed no adverse effects as a result of this transfusion.

Severe Acute Anaphylactoid or Anaphylactic Reaction

Definition: Allergic, anaphylactoid and anaphylactic transfusion reactions span a range of symptoms of varying severity. The symptoms encompass simple allergic-type reactions such as urticaria/pruritis or urticaria/pruritis associated with gastrointestinal discomfort, to more severe reactions such as stridor, wheeze, bronchospasm, laryngeal oedema and hypotension. The onset of intractable hypotension or shock with loss of consciousness is commonly designated as an anaphylactic reaction. In its severest form anaphylaxis can be life threatening⁴.

This category accounted for 26% of incidents reported (i.e. 22 of 85).

In most cases symptoms described were not severe and patients recovered without sequelae. All incidents were included in the overall review for the purposes of this Report and where recommendations re future transfusions were given by the reporting hospitals, these have also been included. A number of cases with more severe symptoms or those that illustrate the requirement of pre-medication have been described in more detail.

FINDINGS AND RECOMMENDATIONS:

- ◆ The occurrence of anaphylactoid reactions particularly with Fresh Frozen Plasma (FFP) emphasises the need to only use FFP when clinically indicated. The National Haemovigilance Office (NHO) issued an information leaflet to hospitals drawing particular attention to this, a copy of which is attached (see Appendix 1)
- ◆ It is particularly important to fully investigate any severe acute symptoms occurring during the transfusion in an effort to identify the cause of the symptoms. In a number of anaphylactoid reactions reported the diagnosis was not clear and full serological/bacterial culture of patient and packs was not undertaken. A protocol for blood pack culture is available on request from the Quality Assurance/Quality Control Department of the Irish Blood Transfusion Service (IBTS).
- ◆ The causes of anaphylactoid/anaphylactic transfusion reactions are not always clear and may be linked to an allergy to plasma proteins. In some rare cases IgA deficiencies with anti-IgA antibodies have been described, therefore it is recommended that IgA levels are checked when symptoms of anaphylactoid transfusion reactions develop, as these reactions can be life threatening in patients with IgA deficiency.
 - ❖ In cases of suspected allergic/anaphylactoid reactions or in patients who have had difficulties with previous transfusions, it may be necessary to pre-medicate with an antihistamine before each transfusion episode³.
 - ❖ If a patient has a history of **repeated** anaphylactic or severe anaphylactoid transfusion reactions and IgA level is normal, the patient should receive washed cellular components if further transfusions are needed. Plasma transfusions should be given cautiously after appropriate pre-medication⁴.
 - ❖ Patients with IgA deficiency (<0.05mg/dL) should have anti-IgA antibodies checked and if positive will require special management, including the use of washed cellular components for future transfusions⁴.

Table 5 Severe Acute Anaphylaxis/Anaphylactoid Reaction (AA) -

*Included in this report as a full case review

Case No.	Component	Reason for transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/ Recommendations for future transfusions
AA Case 1	Red Cell Concentrate (RCC)	Anaemic post elective orthopaedic surgery.	Hypotension, tachycardia, pyrexia and confusion.	IgA level not checked. Patient cultured-no growth. Pack not cultured.	50 mls. transfused.	Paracetamol orally.	Recovered with no ill effects.
AA Case 2	Pooled Platelet Concentrate.	Low platelet count following chemotherapy.	Wheeze and watery eyes.	IgA level normal.	Immediately following completion of transfusion.	Hydrocortisone and Piriton given intravenously (IV).	Recovered with no ill effects.
AA Case 3*	RCC	Anaemia secondary to bleeding.	Dyspnoea, anxiety, restlessness and flushed colour.	IgA deficient <0.05 mg/dL. Pack cultured-no growth. Patient not cultured.	100 mls transfused.	Hydrocortisone and Piriton given IV.	Recovered with no ill effects. Subsequent transfusion of washed cellular components with premedication was uneventful.
AA Case 4	Pooled Platelet Concentrate	Malignant haematological disorder	Urticaria and periorbital oedema.	IgA level normal.	Immediately following completion of transfusion.	Hydrocortisone and Piriton given IV.	Recovered no ill effects. Pre-medication to be given prior to future transfusions.

Case No.	Component	Reason for transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/ Recommendations for future transfusions
AA Case 5	RCC	Anaemia secondary to malignancy	Hypotension, dyspnoea and tachycardia	IgA level normal. Patient cultured-no growth. Pack not cultured.	100 mls transfused.	No medication prescribed.	Recovered with no ill effects
AA Case 6	Pooled Platelet Concentrate	Malignant haematological disorder.	Substernal discomfort, dyspnoea, restlessness and anxiety.	IgA level normal.	5 – 10 mls.	Hydrocortisone IV.	Recovered with no ill effects.
AA Case 7	Fresh Frozen Plasma (FFP)	Melena, INR 4.1 on oral anticoagulant.	Urticaria on upper body, face flushed and felt hot but apyrexial	IgA level normal.	Following completion of 2nd unit.	Hydrocortisone IV. and Piriton orally	Recovered with no ill effects.
AA Case 8	FFP	Meningococcal septicaemia with coagulopathy.	Urticaria and pyrexia.	IgA level not checked.	150 mls transfused.	Paracetamol only	Recovered with no ill effects.
AA Case 9	FFP	Haematuria and melena, INR 4.5 on oral anticoagulant.	Urticaria, periorbital oedema and cyanosis.	IgA level normal.	Following completion of 4th unit.	Piriton IV.	Recovered with no ill effects.
AA Case 10	Pooled Platelet Concentrate.	Malignant haematological disorder.	Urticaria, pruritic rash on lower limbs.	IgA level normal.	Following completion of transfusion.	Hydrocortisone and Piriton IV.	Recovered with no ill effects.

Case No.	Component	Reason for transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/ Recommendations for future transfusions
AA Case 11*	Saline washed Platelet Concentrate	Malignant haematological disorder	Urticaria and chest pain.	IgA level normal.	After 200 mls of 2nd unit had been transfused.	Dexamethasone IV. Piriton already given pre-transfusion.	Recovered with no ill effects. Pre-medication to be given prior to future saline washed platelet transfusions.
AA Case 12	Apheresis Platelet Concentrate	Malignant haematological disorder.	General pruritis, anxiety, dyspnoea, hypotension, substernal discomfort and periorbital oedema.	IgA level not checked.	During first 15 minutes of 1st unit.	Hydrocortisone and Piriton IV.	Recovered with no ill effects after 4 hours.
AA Case 13	FFP	Raised INR on oral anticoagulant. For angiogram.	Hypotension, substernal discomfort, anxiety, urticaria and facial flushing.	IgA level not checked.	Upon completion of 3rd unit.	Hydrocortisone and Piriton IV. Glyceril Trinitrate spray and nasal oxygen.	Recovered with no ill effects within 2 hours.
AA Case 14	RCC	Anaemia due to Myelodysplasia	Progression of fever, rigors, dyspnoea, discolouration and loss of sensation and on right side of body.	IgA level normal. Pack cultured-no growth. Patient not cultured.	30-40 mls of first unit.	Hydrocortisone and Piriton IV.	Recovered with no ill effects.

Case No.	Component	Reason for transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/ Recommendations for future transfusions
AA Case 15*	FFP	Coagulopathy due to liver disease. INR 3 prior to elective procedure.	Dyspnoea, urticaria and hypertension.	IgA level normal.	During 3rd unit.	Hydrocortisone and Piriton IV. and nebulised Salbutamol.	Recovered with no ill effects. Antihistamine cover prior to future transfusions.
AA Case 16*	Pooled Platelet Concentrate	Malignant haematological disorder.	Dyspnoea, falling Oxygen saturation, anxiety, pyrexia of 40°C and hypertension.	Patient cultured-no growth. Pack discarded in error. Chest X-Ray not performed. IgA level not checked.	200 mls transfused.	Hydrocortisone and Piriton IV. Paracetamol orally and 40% nasal oxygen.	Recovered with no ill effects.
AA Case 17	Pooled Platelet Concentrate	Malignant haematological disorder.	Hypotension, dyspnoea, urticaria, facial flushing and generally feeling unwell.	IgA level not checked.	During 2nd unit.	Hydrocortisone and Piriton IV. Nasal Oxygen and Salbutamol nebuliser.	Recovered with no ill effects.
AA Case 18	FFP	Coagulopathy secondary to underlying illness.	Hypotension, urticaria and tachycardia.	IgA levels normal.	Upon completion of 2nd unit.	Vitamin K, Piriton and Hydrocortisone all given IV.	Already in Intensive Care Unit (ICU) unrelated to transfusion reaction. Patient has since recovered.

Case No.	Component	Reason for transfusion	Symptoms	Investigations	Stage Transfusion Reaction developed	Treatment	Sequelae/ Recommendations for future transfusions
AA Case 19*	Pooled Platelet Concentrate	Low platelet count post chemotherapy.	Hypotension, urticaria, unresponsive to verbal command for 40 seconds.	IgA level normal.	140 mls transfused.	Hydrocortisone and Piriton given IV.	Recovered with no ill effects
AA Case 20	RCC	Anaemia post operatively.	Hypotension, nausea and facial flushing.	IgA level normal. Patient and pack cultured- no growth.	During 3rd unit.	Synthetic colloid given.	Recovered with no ill effects.
AA Case 21	Pooled Platelet Concentrate	Low platelet count due to Myelodysplasia	Dyspnoea, chest tightness, periorbital oedema, rash and blisters.	IgA level normal.	Following completion of transfusion.	Hydrocortisone and Piriton IV. Nebulised Salbutamol.	Recovered with no ill effects.
AA Case 22*	FFP	Coagulopathy pre-operatively.	Dyspnoea, bronchospasm, rash, shivering, backpain and headache.	IgA levels not checked.	Following completion of 6th unit.	Hydrocortisone and Piriton IV.	Transferred to ICU post operatively. Recovered subsequently with no ill effects

Severe Acute Anaphylactoid or Anaphylactic Reaction – Detailed Case Histories

Six cases displaying more severe symptoms are described in greater detail.

AA Case 3

This elderly patient had a history of flushing, weakness and breathlessness when previously transfused. During the first 15 minutes (100 mls) of 1 unit of RCC, symptoms of dyspnoea, restlessness and flushing again developed. The transfusion was discontinued and Hydrocortisone, Piriton and nasal oxygen were administered. The pack cultured negative. IgA levels were checked and found to be deficient (<0.05mg/dL) but anti IgA antibodies were not performed. This patient recovered with no sequelae but subsequently died from unrelated causes.

AA Case 11

This patient with an underlying malignancy was receiving transfusions as supportive therapy in a non-emergency setting and had been premedicated with Piriton. This patient also had asthma and was taking a Ventolin inhaler as needed. During the second unit of saline washed platelet concentrate, the patient developed urticaria and chest pain. The transfusion was discontinued immediately, and following immediate review Dexamethasone was administered intravenously. IgA levels were normal. It was recommended that the patient receive antihistamine and steroid cover 1 hour prior to future transfusions and saline washed cellular components be used.

AA Case 15

This elderly patient was admitted for an elective procedure with coagulopathy secondary to liver cirrhosis. The patient had a previous uneventful transfusion history. 1½ hours into transfusion of the 3rd unit of FFP the patient became dyspnoeic and developed urticaria and hypertension. Following immediate review the patient was successfully treated with Piriton, Hydrocortisone and salbutamol nebuliser. IgA levels were normal and the patient recovered with no ill effects.

AA Case 16

This patient, with a malignant haematological disorder, required platelet transfusion for thrombocytopenia with active bleeding. Following 200 mls of pooled platelet concentrate symptoms of dyspnoea, anxiety, fever, hypertension and falling oxygen saturation developed. Transfusion was discontinued completely. Piriton and Hydrocortisone given intravenously, with nasal oxygen and paracetamol also given. Pack was not cultured. Patient was cultured with no growth. IgA levels not done. Patient recovered with no ill effects.

AA Case 19

This patient with malignant disease, required platelet transfusion for thrombocytopaemia post-chemotherapy. Following transfusion of approximately 140 mls of pooled platelet concentrate, symptoms of rash and hypotension developed. Patient also became verbally unresponsive for 40 seconds. Transfusion was discontinued completely. Hydrocortisone and Piriton were given intravenously. Patient and pack cultured – no growth. IgA levels were normal. Patient recovered with no ill effects.

AA Case 22

This patient required transfusion of 6 units of FFP prior to emergency surgery for repair of an abdominal aortic aneurysm with an associated coagulopathy. Previous transfusions had been administered uneventfully. Within 1 hour of completion of the transfusion, the patient developed dyspnoea, urticaria, shivering, bronchospasm, backpain and headache. Hydrocortisone and Piriton were administered intravenously with effect. This patient went

to theatre immediately following the reaction and suffered repeat bronchospasm there. IgA levels were not measured. After a period in ICU for an underlying condition, this patient recovered with no ill effects.

Acute Haemolytic and Other Severe Acute Transfusion Reaction

Definition: Acute Transfusion Reactions are defined as those occurring within twenty four hours of transfusion. The major concern in evaluating these reactions is to exclude bacterial contamination of the unit or haemolysis due to incompatible red cells¹¹.

For the purpose of this report Acute Haemolytic Transfusion Reactions occurring due to incorrect blood transfused are captured in the 'Incorrect Blood Component Transfused' chapter.

Anaphylaxis/Anaphylactoid transfusion reactions are also reported within a separate chapter.

This category accounted for 17% of incidents reported (i.e. 14 of 85).

In most cases the cause of these reactions was not fully clarified, but it is likely that immune reactions between the recipient and donor white cells and/or plasma proteins was responsible. Although all red cell and platelet concentrates are leucodepleted prestorage by the Irish Blood Transfusion Service (IBTS) since November 1999, the occurrence of the described reactions suggest that prestorage leucodepletion may reduce, but not abolish, severe non-haemolytic acute transfusion reactions.

FINDINGS AND RECOMMENDATIONS

- ◆ None of the cases reported showed evidence of haemolysis due to red cell incompatibility or evidence of bacterial contamination. The reactions described in this category are likely to represent cases of severe non haemolytic transfusion reactions.
- ◆ Symptoms of chest pain, back pain and in one case, pain along the vein into which the transfusion was being infused, often described in association with haemolysis, were found in four patients.
- ◆ In three cases, dyspnoea and fever were features, raising the possibility of Transfusion Related Acute Lung Injury (TRALI) as a diagnosis. TRALI also shares some of the features of febrile non-haemolytic transfusion reactions such as fever and dyspnoea, and can be difficult to distinguish. However, the fact that clinical symptoms resolved rapidly on Paracetamol therapy alone in two cases and the absence of X-ray changes - characteristic of TRALI - in the third, made diagnosis of TRALI unlikely. Other causes of respiratory distress and fever must be evaluated and donor and/or recipient serum investigated for the presence of Human Lymphocyte Antigen (HLA) or granulocyte-specific antibodies in order to outrule TRALI. These cases highlight the need to further investigate atypical transfusion reactions.
- ◆ In some cases clinical features can be related to the patient's underlying condition, making it difficult to determine the cause of symptoms and signs which may/or may not be transfusion related.
- ◆ It is of interest that two reactions occurred in association with antibodies, which are not considered to be of clinical significance – anti-Bg and anti-c detected by enzyme only.
 - ❖ A third occurred in a patient without detectable antibodies who developed anti-K some months later.

- ◆ One reaction occurred in a patient, in whom an indication for transfusion did not exist, The symptoms suffered during any transfusion reaction reinforce the need to treat appropriately and **only transfuse** where an alternative therapy does not exist.
- ◆ It is recommended that where a severe transfusion reaction occurs, the transfusion should be discontinued and not recommenced until a full documentation/serological investigation and medical review has been undertaken.
- ◆ In a number of cases, full serological/bacterial culture of patient and packs was not undertaken. It is particularly important to fully investigate severe acute symptoms occurring during the transfusion in an effort to identify the cause of the symptoms. A protocol for blood pack culture is available by writing to the Quality Assurance /Quality Control Department of the IBTS.

Table 6 Acute Haemolytic and other Severe Acute Transfusion Reactions (AHOSTR)

**Included as a full case report*

Case No	Component Transfused	Age/ Gender	Symptoms	Investigations	Treatment & Outcome	Volume Transfused
AHOSTR Case 1	Red Cell Concentrate (RCC)	58 years Female	Fever, chills, anxiety, dyspnoea, hypertension and chest pain.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack cultured-no growth.	Transfusion discontinued. No medication given. Patient recovered with no ill effects.	50 mls
AHOSTR Case 2*	RCC	45 years Male	Fever and dyspnoea.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack cultured-no growth.	Transfusion discontinued. Paracetamol given. Patient recovered with no ill effects.	100 mls
AHOSTR Case 3*	RCC	48years Male	Fever, chills, tachycardia, hypotension, nausea and vomiting.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Neither patient nor pack cultured.	Transfusion discontinued. Paracetamol given. Patient recovered with no ill effects.	100 mls.
AHOSTR Case 4	RCC	22 years Female	Fever, chills, nausea and headache.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack cultured-no growth.	Transfusion discontinued. Paracetamol and Stemetil given. Patient recovered with no ill effects.	50 mls.
AHOSTR Case 5	RCC	77 years Female	Fever, chills and restlessness.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack cultured-no growth.	Transfusion discontinued. Piriton and Nalaxone given intravenously (IV). Patient recovered with no ill effects.	250 mls.

Case No	Component Transfused	Age/ Gender	Symptoms	Investigations	Treatment & Outcome	Volume Transfused
AHOSTR Case 6	RCC	25 years Female	Fever and metallic taste.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack cultured- no growth.	Transfusion discontinued. Paracetamol given. Patient recovered with no ill effects.	100 mls.
AHOSTR Case 7	RCC	77 years Male	Fever and rigor.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Patient cultured- no growth. Pack not cultured.	Hydrocortisone and Piriton given IV and Paracetamol orally. Transfusion recommenced after 30 minutes and proceeded uneventfully.	1 complete unit.
AHOSTR Case 8*	RCC	27 years Male	Fever, rigor and backpain.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Both patient and pack cultured- no growth.	Hydrocortisone and Piriton given IV and Paracetamol orally. Transfusion recommenced after 30 minutes and proceeded uneventfully.	Not recorded.
AHOSTR Case 9*	RCC	69 years Female	Vomiting, rigor and dyspnoea.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Antibody screen negative pre-transfusion. Anti-c detected in enzyme only on pre and post transfusion samples following the event. IgA level normal. HLA antibody negative. Chest x-ray showed no new changes.	Required nasal oxygen 60%. Recovered with no ill effects within 24 hours.	50-90 mls.

Case No	Component Transfused	Age/ Gender	Symptoms	Investigations	Treatment & Outcome	Volume Transfused
AHOSTR Case 10*	RCC	81 years Male	Fever and chills.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Antibody screen negative post the event. Neither patient or pack cultured. Anti-Kell detected 4 months later when re-presented.	Transfusion discontinued. Paracetamol given orally. Recommenced transfusion but symptoms recurred and transfusion discontinued completely. Patient recovered with no ill effects.	Symptoms developed during 3rd unit.

Table 7 AHOSTR Cases

In the following cases it was difficult to confirm whether the transfusion was a causative factor in symptom development.

Case No	Component Transfused	Age/ Gender	Symptoms	Investigations	Treatment & Outcome	Volume Transfused
AHOSTR Case 11*	RCC	52 years Female	Restlessness, anxiety, gastrointestinal symptoms/cramps, flushed and lightheaded.	Repeat crossmatch 12 days later pre-operatively identified leucocyte antibodies anti-Bg. Documentation checks performed, serological checks not undertaken.	Transfusion discontinued completely. No medication given. Patient recovered with no ill effects.	30-50mls
AHOSTR Case 12*	Pooled Platelet Concentrate	75 years Male	Rigors, tachycardia and rising blood pressure.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack and patient cultured -no growth.	Transfusion discontinued completely. Hydrocortisone and Piriton given IV. Patient subsequently died from underlying illness.	Volume transfused not recorded.
AHOSTR Case 13*	RCC	78 years Male	Dyspnoea, fever, hypertension, tachycardia with irregular heart rate, chills and rigors.	ABO and Rhesus D incompatible transfusion outruled. Pack cultured – no growth.	Transfusion discontinued completely. No medication given. Patient already in Intensive Care Unit (ICU), subsequently died from underlying illness.	Two units plus 50mls of 3rd unit
AHOSTR Case 14*	RCC	23 years Male	Chills, backpain, restlessness, hypotension and pain at infusion site.	ABO and Rhesus D incompatible transfusion outruled. No evidence of haemolysis. Pack cultured – no growth. IgA level normal.	Transfusion discontinued completely. No medication given. Transferred to High Dependency Unit (HDU) for continuous monitoring. Recovered with no ill effects.	Three units discontinued, 4 units completed under continuous monitoring.

Nine cases of Acute Haemolytic or Other Severe Acute Transfusion Reaction displaying features of special interest are described in more detail.

AHOSTR Case 2

Following 100 mls of transfusion of RCC, the patient developed fever, dyspnoea and the transfusion was discontinued. The patient responded to Paracetamol and recovered with no ill effects. However, as the patient had asymptomatic iron deficiency anemia, this transfusion did not meet clinical criteria for transfusion.

AHOSTR Case 8

This patient required ongoing transfusion support for anemia secondary to a bone marrow failure syndrome. During the first unit of RCC, after approximately 2 hours, the patient developed fever, rigors and backpain. Following review the transfusion was discontinued temporarily. Piriton and Hydrocortisone were given intravenously, and Paracetamol orally. The patient recovered with no ill effects and the transfusion was recommenced and completed uneventfully. Subsequently, serological studies confirmed no incompatibility.

In the following four cases the patient either had antibodies which are not considered to be of clinical significance or developed clinically significant antibodies subsequent to the transfusion.

AHOSTR Case 3

This patient had a previous transfusion history and required a transfusion postoperatively. Following less than 100 mls of RCC symptoms of fever, chills, hypotension, tachycardia, nausea and vomiting developed. The transfusion was discontinued and Paracetamol given. The patient recovered with no ill effects. Anti-Bg antibodies were detected in this patient prior to transfusion. Anti-Bg antibodies which are directed against certain leucocyte antigens and expressed to a variable degree on red cells are considered not to be of clinical significance and are not routinely screened for in pre-transfusion testing although they may give rise to problems in identification in the cross-match. The reaction in this patient may have been associated with the presence of Bg antibodies or the patient may have developed additional HLA antibodies as a result of previous transfusions that may account for this reaction.

AHOSTR Case 9

This patient was being transfused with RCC for a haemoglobin of 7.8 g/dl following surgery. Following 50-90 mls of the transfusion, the patient developed dyspnoea, vomiting and rigors. The transfusion was discontinued and the patient required 60% oxygen for 24 hours. Pre-transfusion the antibody screen was negative and DAT positive. Retrospective testing of the pre-transfusion sample and a repeat post-transfusion sample showed anti-c by enzyme testing only. There were no new changes on chest x-ray. IgA levels were normal and HLA antibodies negative.

AHOSTR Case 10

This elderly patient, with a history of falls and angina exacerbated by anaemia was transfused. During the transfusion, the patient became pyrexial, the transfusion was discontinued and Paracetamol was given. When the temperature returned to the baseline, the transfusion was recommenced but the temperature increased again, and the transfusion was discontinued completely. Investigations post transfusion showed the antibody screen as negative. Four months later, the patient was regrouped and crossmatched and the antibody screen showed anti-Kell. On this admission the patient was transfused with Kell negative blood without symptoms.

AHOSTR Case 11

This patient required the discontinuation of a unit of RCC following the transfusion of 50mls., having received 2 units uneventfully. During the third unit symptoms of restlessness, gastrointestinal cramps and flushing with associated lightheadedness

developed. Symptoms resolved without medication. The reaction was not reported to the TSO and hence was not investigated. Twelve days later the patient was having a repeat crossmatch pre-operatively, at this time anti-Bg antibodies were identified. The reaction in this patient may have been associated with the presence of Bg antibodies or other HLA antibodies as a result of previous transfusions.

The following cases are more probably attributable to the patients' underlying medical condition, thus highlighting the difficulties in determining whether the symptoms were associated with the transfusion.

AHOSTR Case 12

A patient with a malignant haematological disorder required one unit of pooled platelets. Fifteen minutes after commencement, the patient developed rigors, tachycardia and hypertension. Following medical review the transfusion was discontinued. The pack cultured negative. The patient's medical condition deteriorated and he died from his underlying disease.

AHOSTR Case 13

A patient required 3 units of RCC for haemoglobin of 6.8 g/dl associated with haemorrhage. After 50 mls of the third unit, symptoms of dyspnoea, fever of 38°C, hypertension, chills, rigor, tachycardia and Premature Ventricular Contractions (PVC) developed. Transfusion was discontinued immediately and the patient was reviewed with no medication prescribed. ABO and Rhesus D incompatibility was ruled out and the unit cultured negative.

This patient had a similar episode the following night when no blood transfusion was being administered, both episodes occurring approximately 20 minutes following repositioning of patient. Subsequently the patient's blood cultures grew gram-positive organisms. It is likely that the reaction was not related to the blood transfusion but associated with sepsis and possibly with concomitant severe anxiety.

AHOSTR Case 14

This patient required a transfusion of RCC for anemia secondary to haemorrhage and developed chills, backpain, pain around intravenous site, fever and hypotension during the first unit. The patient was re-grouped and crossmatched and went on to react against a further 2 units which were abandoned. The patient was restless and monitored in HDU during transfusion and had episodes of extreme anxiety. Blood cultures were negative. On pre and post transfusion serology no antibodies were detected. IgA levels were normal. Following further review and specialist consultation an additional 4 units were administered without further adverse reactions.

TRANSFUSION ASSOCIATED CIRCULATORY OVERLOAD

Definition: Large volume/rapid transfusion of blood and blood components can lead to circulatory overload. This is particularly the case in the elderly, the very small or the patient with cardiac compromise in the non-bleeding situation, where rapid transfusion of blood or blood components can quickly lead to circulatory overload with congestive cardiac failure⁵.

This category accounted for 9.5% of incidents reported (i.e. 8 of 85)

FINDINGS AND RECOMMENDATIONS

- ◆ Reports received indicate that transfusion associated circulatory overload is associated with considerable morbidity. In one reported case with underlying cardiac disease, it may have contributed to mortality. In response to these reports, particularly associated with the administration of Fresh Frozen Plasma (FFP), the National Haemovigilance Office (NHO) issued an information leaflet on the use of FFP (see Appendix 1). This included:
 - ❖ Firm indications for the use of FFP
 - ❖ Suggested infusion times
 - ❖ Management of anticoagulation in the preoperative period
 - ❖ Conditional uses of FFP
- ◆ The risk of volume overload and ensuing respiratory distress is increased with the very small, elderly, cardiac or respiratory compromised patient.
- ◆ Careful attention should be paid to the patient's fluid balance prior to transfusion of any blood component. In those patients considered to be at greater risk of developing circulatory overload, the transfusion should be administered slowly and the patient must be closely monitored for early signs and symptoms⁵. In addition, the use of diuretic therapy should be considered as a prophylactic measure in those patients considered to be at risk.

Table 8 Transfusion Associated Circulatory Overload (TACO)

* included as a full case history review

Case No	Age/Gender of Patient	Volume Transfused	Rate of Transfusion	Symptoms & Outcome	Pre-existing Problems
TACO Case 1	51 years Female	Pooled Platelet Concentrate 150mls. approximately	Over 30 minutes.	Worsening dyspnoea, tachycardia and falling pO ₂ . Responded to intravenous (IV) diuretics.	Respiratory dysfunction, oxygen saturation 85% pre transfusion.
TACO Case 2	72 years Male	4 units of Fresh Frozen Plasma (FFP)	Prescribed as 'Stat'. Rate of administration not documented.	Worsening dyspnoea, hypotension, substernal discomfort and falling pO ₂ . Full recovery following nasal oxygen and Angised.	Respiratory dysfunction. Cardiac failure on diuretic medication prior to transfusion.
TACO Case 3	18 years Female	3 units of Red Cell Concentrate (RCC)	Each unit administered over 3 hours.	Worsening dyspnoea, tachycardia and fever. Chest x-ray showed signs of fluid overload. Responded to IV diuretics and nasal oxygen	Underlying malignancy with lung metastases. Positive fluid balance prior to commencing transfusion.
TACO Case 4*	63 years Male	2 units of FFP	Over 30-40 minutes	Worsening dyspnoea, tachycardia, hypotension, falling pO ₂ and rising pCO ₂ developed during transfusion. Patient subsequently died from underlying disease, circulatory overload may have contributed to mortality.	Respiratory dysfunction. Cardiac failure on diuretic medication prior to transfusion.
TACO Case 5*	75 years Female	2 units of RCC	2 units administered over 5½ hours	Dyspnoea, hypertension and tachycardia developed during 2nd unit. Widespread crepitations on chest auscultation. Responded to IV diuretics, Betaloc and nasal oxygen.	Previous hospital admissions with myocardial infraction, mitral stenosis & cardiac failure. On diuretic medication prior to admission.

Case No	Age/Gender of Patient	Volume Transfused	Rate of Transfusion	Symptoms & Outcome	Pre-existing Problems
TACO Case 6*	59 years Male	2nd unit of FFP almost complete	Rate of transfusion not prescribed, 2 units administered over 1 hour.	Hypertension, dyspnoea, tachycardia, rigors, vomiting, and cold & sweaty. Falling pO ₂ and rising pCO ₂ , colour cyanosed. Pulmonary oedema and audible wheeze on auscultation with production of frothy sputum. Falling urinary output. Required Intensive Care Unit (ICU) admission and ventilation for 24 hours. Responded to IV diuretics, Hydrocortisone, Piriton, Aminophylline and Maxolon. nasal oxygen increased to 60%.	Post Coronary Artery By-pass Graft (CABG) with persistent Atrial Flutter. On oral anticoagulant, INR 10. For Cardioversion. On oral diuretics daily prior to admission.
TACO Case 7	74 years Male	1 unit of RCC	Over 4 hours	Dyspnoea and hypertension developed during 2nd unit. Responded to IV diuretics, sublingual Adalat and nasal oxygen.	No underlying respiratory or cardiac dysfunction.
TACO Case 8	30 years Female	7 units RCC, 1 dose of platelets, 4 units of FFP, 5L crystalloid and 2.9 L colloid	During massive bleeding episode	Tachycardia, falling oxygen saturation, pulmonary oedema and cardiomegaly on chest x-ray. Responded following treatment with intermittent positive pressure ventilation (IPPV), Frusemide IV and physiotherapy.	Haemorrhage. No pre-existing cardiac or respiratory dysfunction.

Three cases Of Transfusion Associated Circulatory Overload displaying points or features of special interest are described in more detail.

Case No. 4

A 63-year-old patient, with an INR of 8.8 and evidence of bruising due to over-anticoagulation, required a transfusion of FFP. The patient had underlying ischaemic heart disease, with left ventricular failure and chronic obstructive pulmonary disease. Four units of FFP were prescribed. The rate of administration was not prescribed. The first two units were transfused over 30-40 minutes and following completion of the second unit, the patient developed symptoms of dyspnoea, tachycardia, falling oxygen saturation and increasing pCO₂ levels. The transfusion was discontinued and the patient received intravenous Frusemide, Hydrocortisone and Piriton. This patient subsequently died as a result of underlying medical condition, however circulatory overload may have contributed to mortality.

Case No. 5

This 75-year-old patient with severe haematemesis was transfused with 2 units of RCC. There was an underlying history of myocardial infarction and mitral stenosis with left ventricular failure. This patient was on routine diuretic therapy at home, which was discontinued on admission due to hypovolaemia. The first unit was transfused uneventfully over 4 hours. During the second unit (1 ½ hours after commencement) symptoms of dyspnoea, hypertension, tachycardia and falling oxygen saturation developed. There were widespread crepitations on chest auscultation. The transfusion was discontinued and intravenous Frusemide and Cyclimorph and nasal oxygen were given with good response. The patient made a full recovery.

Case No. 6

A 59-year-old patient with atrial fibrillation/flutter following Coronary Artery Bypass Graft presented for cardioversion with an INR of 10 due to over-anticoagulation. The patient was on routine oral diuretic prior to transfusion. Three units of FFP were prescribed. The rate of administration was not prescribed but the first two units were administered over 1 hour. Patient observations were not recorded. Towards the end of the second unit the patient developed symptoms of hypertension, dyspnoea, tachycardia, rigors and vomiting. He became cold and sweaty, pO₂ fell and pCO₂ began to rise. He became cyanosed and there was a falling urinary output. A wheeze was audible on auscultation and frothy sputum was produced. A diagnosis of pulmonary oedema was made which responded to intravenous diuretics, Hydrocortisone, Piriton, Aminophylline and Maxolon. The patient was ventilated for 24 hours and recovered with no ill effects.

Suspected Transfusion Transmitted Infection

This category accounted for 8% of incidents reported (i.e. 7 of 85).

To date none of these incidents have been confirmed, see Table 8 for details.

The National Haemovigilance Office (NHO) collects reports of all transfusion-transmitted bacterial and parasitic infections, and suspected transfusion-transmitted viral infections. There were no incidents of bacterial or parasitic transfusion-transmitted infections reported during this reporting year.

The onset of symptoms related to a transfusion-transmitted viral infection may occur several weeks to years after the date of transfusion. Therefore, reports received within this category are not necessarily the result of components transfused during this reporting period. Infections presenting weeks, months or years after a transfusion are termed post-transfusion infections (PTI). These may indeed be due to the transfusion of an infected or contaminated unit, but equally, infection may have been acquired from another source. Investigation of markers of infection in an implicated donation, or in subsequent samples from the donors of implicated donations, can confirm transfusion as the probable cause of infection, or identify the need to investigate other possible sources¹². Such investigations may involve microbiological testing of many donors and may take several months to complete. A post transfusion infection is confirmed as transfusion-transmitted once investigations are complete and the following criteria are fulfilled:

- ◆ the recipient had evidence of infection following the transfusion, with no evidence of infection prior to the transfusion
and, either
- ◆ at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection
or
- ◆ at least one component received by the infected recipient was shown to have been contaminated with the same infectious agent¹².

Much concern has been voiced in recent years regarding the risk of transfusion-transmitted infection, and much quality assurance effort has been directed toward appropriate testing and handling of blood after collection¹³. 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 Human Immunodeficiency Virus (HIV) is less than 1 per 3.3 million components transfused and for Hepatitis B Virus (HBV) it is approximately 1 per 100,000 components transfused¹⁴.

Up to November 1999 the estimated risk for Hepatitis C (HCV) was less than 1 per 500,000 components transfused¹⁴, however, with the introduction of Nucleic Acid Amplification Testing for HCV since then, it is estimated that the risk of transfusion-transmitted HCV has been reduced to 1 per two million components transfused.

The risk of receiving an incorrect blood component is in fact greater than the risk of receiving a transfusion transmitted infection. Over the 4 year period since the United Kingdom Serious Hazards of Transfusion (SHOT) began reporting, confirmed reports of Transfusion Transmitted Infection accounted for 2.5% of incidents in comparison to the Incorrect Blood Component Transfused which accounted for almost 60%^{10,12,15 & 16}.

This report reflects similar findings in this country with a greater incidence of reported Incorrect Blood Component Transfused (37%) compared with reports of suspected Transfusion Transmitted Infection (8%).

A total of nine incidents were reported to the NHO during this reporting period, of which two did not progress as subsequent investigation showed no evidence of infection in the recipient. Of the remaining seven incidents, three were HCV, two were HBV and one was HIV. The remaining incident was a co-infection with HCV/HBV.

- ◆ In four of the seven cases, (two HCV, one HBV and one HIV) transfusion has been definitively excluded as the cause of the infection.
- ◆ In one case of Hepatitis B infection could not be definitively excluded as one donor could not be traced. However, there were other risk factors in the recipient.
- ◆ In the case of co-infection with both Hepatitis B and Hepatitis C, the patient, who has required multiple transfusions, had also received transfusions and initial hospital treatment outside this country. This is considered to be the likely source of the infection, but investigations into the Irish Blood Transfusion Service (IBTS) donors are on-going. To date the transfusions have been excluded as the source of Hepatitis C, further tests are awaited on donor blood to exclude HBV.
- ◆ In the remaining case, a case of Hepatitis C infection reported as relating to a transfusion in 1993, investigations are ongoing at time of reporting.

Table 9 Suspected Transfusion Transmitted Infection (TTI)

Case No.	Year of Transfusion	Adult or Child	Viral Marker	Number of donors	Outcome
TTI Case1	1999	Adult	HBV	3	Transfusion excluded as cause of infection.
TTI Case 2	1994	Adult	HCV	6	Transfusion excluded as cause of infection.
TTI Case 3	1993	Adult	HCV	2	Transfusion excluded as cause of infection. Recipient has other existing risk factors.
TTI Case 4	1992	Adult	HIV	11	Transfusion excluded as cause of infection.
TTI Case 5	1993	Adult	HBV	2	Unable to trace one donor. Recipient has other existing risk factors.
TTI Case 6	1998-1999	Child	HBV & HCV	108	Investigations ongoing. Previously treated outside this country with blood components/products.
TTI Case 7	1993	Adult	HCV	4	Three donors excluded. Investigations ongoing. One donor untraced to date

Delayed Haemolytic Transfusion Reaction

Definition: Delayed haemolytic transfusion reactions are defined, for the purpose of this report, as those occurring more than 24 hours following the transfusion of a blood component. A haemolytic transfusion reaction occurs when antigen-positive red blood cells are transfused to a patient who develops an alloantibody to that antigen. It results in the lysis or accelerated clearance of red blood cells due to immunologic incompatibility between the blood donor and the recipient¹⁷.

This category accounted for 2% of incidents reported (i.e. 2 of 85)

FINDINGS AND RECOMMENDATIONS

- ◆ The need to conserve supplies of Rhesus D negative blood for pre-menopausal females and difficulties with provision of adequate amounts of Rhesus D negative blood are likely to lead to an increase in the development of anti-D antibodies and the possibility of increased incidents of delayed haemolytic transfusion reactions in the future.
- ◆ Because of the need to conserve supplies of Rhesus D negative blood hospitals should have policies to cover switching patients from Rhesus D negative to Rhesus D positive blood when stocks are low or when massive bleeding is anticipated.
- ◆ Careful history taking in relation to transfusion and pregnancies by the requesting physician is important. However, up to 12% of patients do not realise that they have had a transfusion⁶, therefore access to and checking of previous transfusion records are essential.
- ◆ As antibodies can develop rapidly, patients being repeatedly transfused, depending on the interval between transfusions should have a fresh sample submitted within 24-72hrs of a planned transfusion in accordance with British Committee for Standards in Haematology (BCSH) Guidelines⁷.

Table 10 Delayed Haemolytic Transfusion Reactions (DHTR)

Case No.	Component	ABO & Rhesus Group of Patient	ABO & Rhesus group of component transfused	Age & Gender of patient	Clinical Setting	Pre-existing condition	Interval between transfusion & onset of symptoms	Signs/Symptoms and Treatment	Outcome
DHTR Case 1	6 units of Red Cell Concentrate (RCC)	Group A Rhesus D negative	Group A Rhesus D positive	71 years Female	Massive intraoperative haemorrhage	Underlying malignancy	6 days	Raised bilirubin and Lactate Dehydrogenase (LDH). Anti-C and anti-D detected. Positive Direct Antiglobulin Test (DAT).	Patient died - not related to transfusion.
DHTR Case 2	8 units of RCC	Group O Rhesus D negative	Group O Rhesus D positive	78 years Male	Haemorrhage leading to symptomatic anaemia	Bladder carcinoma Haematuria	24 days	Jaundice, raised bilirubin and LDH, haemoglobinuria, falling haemoglobin and evidence of deteriorating renal function. No evidence of Disseminated Intravascular Coagulation (DIC). Anti-C+D+E antibodies present.	Recovered with no ill effects. Total serum bilirubin elevated for less than one week.

The following are details of the Delayed Haemolytic Transfusion Reaction cases reported to the National Haemovigilance Office

DHTR Case 1

This elderly female patient with an underlying malignancy was Rhesus D negative with anti-C + D antibodies. She required an unexpected massive transfusion intraoperatively needing a total of 22 units of Rhesus D negative RCC. Further massive haemorrhage occurred, and following discussion with the Consultant Haematologist, as the antibodies were no longer detectable, it was decided to switch to Rhesus D positive blood to avoid further depleting the Rhesus D negative supply. The patient was then transfused with Rhesus D positive RCC as a life saving measure and bleeding subsequently was controlled. Six days later a rising bilirubin and raised LDH developed but there was no associated fall in haemoglobin or evidence of renal dysfunction. The patient subsequently died from her underlying condition.

DHTR Case 2

This elderly male Rhesus D negative patient had received 11 units of Rhesus D negative blood three months previously. On this occasion, the patient presented with haemorrhage and a haemoglobin of 5.1g/dl. requiring repeat transfusion. The pre-transfusion antibody screen was negative. To conserve Rhesus D negative blood, it was necessary to transfuse 8 units of Rhesus D positive RCC. Twenty-four days later the patient developed jaundice with a falling haemoglobin, rising bilirubin, rising LDH, haemoglobinuria and evidence of deteriorating renal function. There was no evidence of DIC. The DAT was positive and antibody screen at this time showed anti-C+D+E antibodies. The patient recovered with no ill effects and subsequently had an uneventful transfusion of Rhesus D negative blood.

Unusual Transfusion Reactions

Definition: These transfusion reactions include those that did not fit criteria for any other category, but which were serious and of significance to the Haemovigilance programme.

This category accounted for 1% of incidents reported, (i.e. 1 of 85).

The patient reported the unusual symptom of joint pain associated with a febrile transfusion reaction.

Unusual Case 1

This patient was transfusion dependent, and on this occasion the transfusion of two units of Red Cell Concentrate (RCC) was completed uneventfully in a day ward setting. Later that evening at home, the patient developed dyspnoea, fever and joint pain. The patient contacted the hospital and returned for review the following day. The pack had been discarded following the patient's discharge and was unavailable for laboratory investigations. The patient recovered with no ill effects.

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Information on the National Haemovigilance Office may be accessed through the Irish Blood Transfusion Service Web site @ www.ibts.ie

NATIONAL HAEMOVIGILANCE OFFICE (NHO)

National Blood Centre

James's Street

Dublin 8

Tel: (01) 432 2800

Fax: (01) 432 2930

Appendix 1

National Haemovigilance Office

As we have recently had some reports of serious adverse events associated with the transfusion of Fresh Frozen Plasma (FFP), here is some updated information for your notice board.

Points to note

- ◆ Risk of volume overload leading to respiratory distress with severe morbidity/mortality especially using rapid infusion rates with very small and/or elderly recipients
- ◆ Occasional severe Anaphylactoid reactions especially with rapid infusion rates.
- ◆ Dosage of FFP generally depends upon the clinical situation and underlying disorder but 12-15 mls/Kg is a generally accepted starting dose. It is important to monitor the response both clinically and with measurement of prothrombin time (PT), partial thromboplastin time (PTT) or specific factor assays.¹
- ◆ The recent British guidelines recommend infusion of a unit of plasma to an uncompromised adult over 30 minutes.²
- ◆ Coagulation factor replacement in the massively haemorrhaging patient may require faster infusion rates.
- ◆ In the elderly, the very small or the patient with cardiac compromise in the non-bleeding situation, transfusion rates for plasma should not exceed 2-4 mls/kg per hour.³
**If a slower transfusion rate is needed, the plasma can be thawed in divided doses as once thawed a unit of plasma should be transfused within 4 hours.*

TABLE 1 SUGGESTED TIMES FOR INFUSION IN THE NON-BLEEDING PATIENT:

Patient Weight	Units Required	Rate of Transfusion per hr	Duration of Transfusion	
			Min	Max
20 kg	1 unit	40 mls – 80 mls	2½ hrs	5 hrs*
30 kg	2 units	60 mls – 120 mls	3¼ hrs	6½ hrs*
40 kg	3 units	80 mls – 160 mls	3¼ hrs	7½ hrs*
50 kg	3 units	100mls – 200 mls	3hrs	6 hrs*
60 kg	4 units	120mls – 240 mls	3¼ hrs	6½ hrs*

Firm indications for giving FFP include⁴

- ◆ Replacement of clotting factors where there is evidence of critical deficiency and where there is no specific factor concentrate available.
- ◆ To correct depletion of coagulation factors in bleeding associated with thrombolytic treatment.
- ◆ For reversal of the effects of oral anticoagulation associated with serious bleeding if prothrombin complex and factor VII concentrates are not available.
- ◆ Used in Thrombotic Thrombocytopenic Purpura (TTP) as the treatment of choice in conjunction with plasma exchange.

Fresh Frozen Plasma is not routinely necessary in the management of over anticoagulation with Warfarin, but only in selected cases as set out in Table 2.

Table 2 Recommendations for management of bleeding and excessive anticoagulation⁵

3.0 < INR < 6.0 (target INR 2.5)	1. Reduce warfarin dose or stop
4.0 < INR < 6.0 (target INR 3.5)	2. Restart warfarin when INR < 5.0
6.0 < INR < 8.0, no bleeding or minor bleeding	1. Stop warfarin 2. Restart when INR < 5.0
INR > 8.0, no bleeding or minor bleeding	1. Stop warfarin 2. Restart warfarin when INR < 5.0 3. If other risk factors for bleeding, give 0.5-2.5 mg of vitamin K (oral)*
Major bleeding	1. Stop warfarin 2. Give prothrombin complex concentrate 50 units/kg or FFP 15 ml/kg 3. Give 5mg of vitamin K (oral or i.v)

*Age > 70, patients with previous history of bleeding, patients with epistaxis.

Managing Anticoagulation in the Perioperative Period

Elective surgery: Stop anticoagulant for three days prior to surgery

Emergency surgery: Where surgery cannot be postponed, reverse anticoagulant with low dose Vitamin K⁵ as above

Due to near-complete absorption, oral Vitamin K is as effective as intravenous, with the delay in action hardly influenced by the absorption time. However, only 0.5 mgs is required to reduce the INR from >5 to a target of 2.0-3.0⁵

Conditional Uses only indicated in the presence of bleeding & disturbed coagulation

- ◆ Massive transfusion
- ◆ Liver disease
- ◆ Cardiopulmonary bypass surgery
- ◆ Special Paediatric indications

Fresh Frozen Plasma should not be used for the treatment of hypovolaemia, nutritional support, immunodeficiency states, formulaic replacement in association with red cell transfusion or for plasma exchange treatments apart from the exchanges for Thrombotic Thrombocytopenic Purpura.

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- 4 Contreras, M.Ed., *ABC of Transfusion*, 3rd edition, BMJ Books 1998.
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<p>These are guidelines only and must never replace clinical assessment for each patient. Consult a senior member of your hospital medical staff if you have any queries.</p>

Appendix 2

National Haemovigilance Office (NHO)

located at
The National Blood Centre,
James's Street
Dublin 8
Tel: 01 432 2854

"NIL TO REPORT" FORM

This card is for cases seen during the period 1 January to 31 December 2000

If you have seen no adverse events, please tick "Nothing to Report"

If you have reported cases to the NHO in the stated period please tick "Incident(s) already reported"

*NB Cards must be returned to NHO by **Tuesday 20th March 2001** for inclusion in this year's report.*

Nothing to report

Incident(s) already reported to NHO

Please complete:

Number of units transfused during 2000

Red cells _____

Platelets _____

Plasma _____

Whole blood for Neonatal use _____

Paedipack for Neonatal Use _____

Cryoprecipitate _____

Autologous blood _____

A receipt as proof of your participation in the NHO scheme, will be forwarded on completion and return of this form. Complete anonymity will be observed.

Please sign below dotted line, this section will be removed by NHO on receipt of form

.....

Signed: _____

Hospital: _____