



National
Haemovigilance
Office

Executive Summary of
Annual Report 2003



Haemovigilance has been defined as:

"A set of surveillance procedures, for 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"

Executive Summary of Annual Report 2003

The remit of the National Haemovigilance Office (NHO), is to receive, collate and follow up reports of adverse reactions/events relating to the transfusion of blood and blood components from hospitals, healthcare institutions and GP's. It is the professional responsibility of each healthcare worker to report such incidents. Feedback information is provided to those making the report as appropriate. This confidential and anonymised scheme is dedicated to the promotion of best transfusion practice at all stages in the transfusion chain from donor to

recipient. The reports are analysed and the findings are published in the form of the Annual Report which makes recommendations for future practice. The NHO recognises the efforts of the hospital based Transfusion Surveillance Officers (TSO's) and the contribution of the transfusion Medical Scientists and Consultant Haematologists without whom this programme would not be possible.

NHO-CONFIRMED REPORTS BY CATEGORY TABLE 1

Total Incidents	IBCT	A/A	TACO	DHTR	AHOSTR	PAD	TTI	TRALI
180	115	23	14	9	8	6	4	1
100%	64%	13 %	8%	5%	4%	3%	2%	1%

IBCT	Incorrect Blood Component / Product Transfused.
A/A	Severe Acute Anaphylactoid or Anaphylactic Reaction.
TACO	Transfusion Associated Circulatory Overload
DHTR	Delayed Haemolytic Transfusion Reaction
AHOSTR	Acute Haemolytic or Other Severe Transfusion Reaction.
PAD	Pre-deposit Autologous Donor Incident.
TTI	Suspected Transfusion Transmitted Infection.
TRALI	Transfusion Related Acute Lung Injury.

There were no reports received in the Transfusion-Associated Graft-versus-Host Disease (TAGvHD) or Post Transfusion Purpura (PTP) categories.

This executive summary outlines the predominant findings and recommendations from the 2003 NHO Annual Report. The detailed findings, recommendations, cases and references may be found in each relevant chapter throughout the report.

Denominator

The number of units issued in this period is given in Table 2. These figures do not account for units discarded in hospitals.

UNITS ISSUED BY IBTS 2003 TABLE 2

Component	Total Issues
Red Cells & Whole Blood	130,088
Platelets	16,521
Solvent Detergent Plasma	21,757
Fresh Frozen Plasma	414
Cryoprecipitate	908

Participation

100% (81) of hospitals participated in the scheme in 2003. 47 of those hospitals (58%) reported a transfusion reaction or event compared to 41 hospitals (49%) in 2002. This shows an increase in hospital reporting of 9%.

Incorrect Blood Component Transfused

Incorrect blood component transfused (IBCT) was the most common adverse reaction/event reported. There were 115 cases in this category. These incidents have been stratified by level of severity as follows:

- Level 1 - life threatening or potential for permanent injury, 62 cases (54%).
- Level 2 - very unlikely to cause permanent harm or have the potential for minimal or transient harm, 32 cases (28%).
- Level 3 - no realistic potential for harm, 21 cases (18%).

These 115 cases were further categorised into site of first error.

SITE OF FIRST ERROR TABLE 3

Site of first error	Cases
Hospital Transfusion Laboratory	38 (33%)
Prescription/Request	37 (32%)
Sampling	14 (12%)
Supply Centre	1 (1%)
Administration	10 (9%)
Site of Collection	10 (9%)
Initial Clerking	3 (2%)
Unclear	2 (2%)

IBCT Findings

Wrong Blood

- There were 13 level one incidents where the patient received wrong blood components.
- Twelve of the incidents originated in the laboratory.
- Five of these involved the transfusion of ABO incompatible red cells, all of which occurred on call. Four of these occurred when a medical scientist not normally working in blood transfusion provided cross call cover.
- Signs and symptoms of varying severity were displayed by the patients from mild fever, tachycardia, hypotension and temporary increase in bilirubin. There were no fatalities.
- In one case, the compatibility label was attached to an un-crossmatched but fortunately compatible unit of red cells.
- Three incidents involved transfusion of SD treated plasma all of which were ABO incompatible.
- Three incidents, two of which originated in the laboratory on call involved platelet transfusions where units that were assigned for certain patients were transfused to different patients. One incident occurred at administration when the units were remotely checked from the patient.

Failure to give Antigen Negative Blood

- There were seven cases reported where antigen negative blood should have been provided as the patient had current or previously detected antibodies.
- Communication failures between medical and laboratory staff and between transferring hospitals were evident in two cases.
- As with the ABO incompatible incidents, four cases occurred on call.
- Historical records were not accessed in three cases.
- There was failure within laboratory work-up procedures in three cases.

Transfusions Based on Incorrect or Absent Haematology Results

- This year, there were seven reported cases, six involving red cells and one involving plasma, where the transfusion was based on inaccurate or old haematology results.
- Of the six red cell transfusions, three were prescribed and administered based on old Hb results. Three cases involved prescriptions on incorrect Hb results.
- The unnecessary plasma transfusion was based on abnormal coagulation results due to heparin in the sample.

Unnecessary Components Transfused

- We received 11 reports of inappropriate/unnecessary transfusions due to erroneous prescriptions.
- Five of these incidents involved an inappropriate prescription of plasma for warfarin reversal in non-bleeding patients contrary to guidelines.
- Four cases involved red cells, two of which were for treatment of iron deficiency in young women.
- Two cases involved the transfusion of platelets.

Collection Storage or Improper Handling of Components

- There were 10 cases in total.
- Two cases demonstrate the dangerous practice of re-transfusing already pierced or 'spiked' units, which were stored in a satellite fridge for 15 and 24 hours respectively before transfusion.
- Three incidents concerned units of red cells, which had been left out of the fridge in excess of the recommended time and then returned to the fridge and later transfused.

Failure to supply Special Requirements in CMV negative and/or Irradiated Components

- There were 12 cases reported in this category, 11 of which are classified as level 2 incidents.
- Eight cases occurred due to prescription and/or request errors.
- In three cases errors in the hospital transfusion laboratory led to the issue of units which did not meet special requirements.

- In one case, CMV negative and irradiated platelets were requested from the supply centre. However, due to stock shortage, CMV safe leucodepleted platelets were issued but the irradiation request was overlooked
- In six cases the final bedside checking procedure should have alerted clinical staff to the lack of provision of special requirements and prevented the transfusion of these components.

Incorrect Details Recorded During Initial Admission

- There were five cases in this category.
- In one case a patient was hospitalised and treated using a different patient's record.

IBCT – Anti-D Immunoglobulin Incidents

- There were eleven incidents in total reported which involved Anti D. Six of the incidents involved the incorrect administration of Anti D, four involved a delay in the administration and there was one incident where Anti D was omitted.
- In the six cases involving incorrect administration, three arose from making incorrect assumptions rather than checking the patient records.
- In one of these cases Anti D was administered in error to a Rh positive mother. The cord blood result reported to the ward led to the assumption that the mothers group was Rh D negative.
- In one case Anti D was administered in error to the mother on receipt of a Kleihauer result. The infant was being nursed in another area and was in fact Rh D negative.
- In the third case, the mother had already been sensitised to Anti D.
- The four incidents involving a delay in the administration of anti D involved respectively, a patient nursed outside the speciality area, cord bloods not taken, incorrect cord blood result obtained and undocumented telephoned results from the laboratory to the ward.
- In one case, where Anti D was omitted, the Rh D negative stamp normally placed on the patients record was absent, the patient was discharged early and arrangements were not put in place to check cord results.

IBCT Recommendations

Clinical

- Best transfusion practice should be an integral part of induction training and education programmes for all staff involved in prescribing, ordering and administering transfusions. New staff or those returning to work following a long period of absence have particular training needs.
- Hospitals must have secure documented procedures in place and provide formal training for staff involved in blood sampling and transfusion.
- Electronic forms of patient and blood component/product identification are now available and are recommended as they provide the highest degree of security. Where these systems are not available, manual bedside identification procedures must be strictly adhered to.
- Positive patient identification at sampling is essential and must include a secure ID band at the time of pre-transfusion sampling and administration, which must contain three identifiers, full name, date of birth and a unique hospital number.
- In order to help reduce sampling errors, 24-hour/extended phlebotomy services are recommended.
- It is desirable where possible to transfuse only when adequate staff are on duty and to avoid routine transfusions at night.
- Protocols covering massive transfusions are required which include timeframes for the provision of crossmatched, group specific and un-crossmatched blood.
- There should be a designated person to check and record units during transfusion for massive haemorrhage to ensure traceability of all blood components and products.
- Alert stickers placed on the front of the medical record to inform clinical staff of special transfusion requirements is recommended. This is particularly important when patients are being transfused in clinical areas not normally transfusing haematology/oncology patients.

Laboratory Operations

- Hospital laboratories should have a standard operational procedure or policy for acceptance and or rejection of inadequately labelled samples. This policy should cover amendments, which are acceptable, and those which require a further sample to be taken.
- Transfusion cover on call has been identified in this report as presenting a particular problem. The five ABO incompatible red cell transfusions reported this year occurred during the on call period. Due to these difficulties, it is recommended that only emergency blood samples should be processed on-call.
- Adequate numbers of properly trained laboratory staff are needed to ensure the safety of transfusion.
- Medical scientists providing cross call cover from other disciplines should have the opportunity for rotation through the transfusion laboratory. Regular training to become familiar with current practice, and correct products for issue must also be provided.
- During emergencies, a system should be in place to allow for additional staff members to be called in if assistance is required.
- Previous transfusion records, manual or computer, should be available at all times and checked. Once a clinically significant red cell antibody has been detected in the past, the patient should always receive antigen negative blood, even though the antibody is no longer detectable, except in an emergency situation where antigen negative blood is not available.
- Records of patients transfused in another hospital should be confirmed with the original hospital, if possible.
- An uninterrupted working environment should be maintained during compatibility testing of units to avoid distraction and or transposition.
- A dedicated area should be available in the laboratory for labelling products and only units for one patient should be labelled up at any one time. Electronic systems for labelling and checking would enhance the security of the process.

- Computer systems should be designed with audible alarms/alerts to minimise opportunities to override screen warnings. An audit trail of any overrides should also be kept.

Improperly Stored or Handled Components

- Under no circumstances should any blood product or component that has been pierced or 'spiked' with an administration set or other device be stored with the intent of re-use.
- A patent IV canula should be confirmed prior to collection of the unit.
- Documentation containing three minimum identifiers must be brought to the fridge when collecting a unit of blood in order to verify patient identification.
- Inspection of the unit and documentation at the time of collection may identify abnormalities in either the unit or labelling.
- If there is a delay in transfusion it is necessary to return the unit to controlled storage within thirty minutes and inform the laboratory.
- Satellite fridges must be incorporated within the monitoring procedures of the hospital blood bank. Units unused within 24 - 48 hours should be collected and returned to the hospital blood bank.
- Hospitals, which accept blood-accompanying patients on transfer, need policies which outline acceptance criteria for such units.

Hospital Records

- A unique medical record number (MRN) must be available for all patients on a 24-hour basis.
- Previous admissions should be confirmed to ensure previous MRN number and records are retrieved.
- If the patient is admitted via the A&E Department and given an emergency number, it must be possible to merge this number at a later stage with the MRN.
- All healthcare professionals must be aware of the importance of correct patient identification and ensure that details accompanying patients requiring transfer to another facility for further treatment are correct.

Inappropriate/Unnecessary Transfusions

- All clinical staff involved in transfusion must be familiar with guidelines for administration of components which will help avoid unnecessary transfusions.
- SD plasma or FFP is only required for the reversal of over anticoagulation in the presence of major bleeding or emergency surgery
- Patients with iron deficiency respond quickly to specific therapy and rarely need transfusion.

Transfusions Based on Inaccurate/Absent Haematology Results

- The most recent Hb result must be confirmed prior to prescribing and administering a red cell transfusion. When transfusing more than one unit, regular monitoring of post transfusion Hb levels is strongly recommended, ideally on a unit-by-unit basis.
- Care is needed in laboratory identification of haematology samples.
- Where anomalous Hb results are found, a repeat Hb sample should be obtained before a decision to transfuse is made.

Improving Communication

- Where ever possible requests for components should be made in writing. Hospitals need to develop protocols for exceptions such as emergencies or remote geographical locations of laboratories.
- An electronic ordering system for blood should be developed similar to systems already available for blood test ordering.
- Systems and procedures are required to highlight special transfusion requirements particularly where care is shared between two centers.
- Phoned reports should be clearly entered on the patient's medical record and should include details of date, time and name of the person giving the result and a legible signature.
- Errors in communication can be minimised by using automated transfer of laboratory information to allow access to current records.

Anti-D Immunoglobulin

- There is a need to develop a co-ordinated system to ensure that decisions to issue and administer Anti-D are not made on assumptions but on the documented Rh group of the mother, her antibody status and the Rh group on the cord blood. The findings in this report illustrate the difficulties in ensuring this happens.
- While many hospitals issue Anti-D through the laboratory as they have access to both the mother and/or baby's group and antibody records and can issue the Anti-D labelled for the patient, the findings suggest a co-ordinated approach is necessary to ensure correct issue of product.
- Whether the hospital blood banks or the clinical areas take responsibility for prophylactic Anti-D administration, there is a need for education of all staff involved in prescription/administration of Anti-D prophylaxis.
- Hospitals should have a system in place to check the Rh D status of all deliveries in the previous 24 hours to ensure that cord bloods are taken from Rh D negative mothers at the time of delivery. If an omission does occur, a sample can then be taken from the baby for analysis.
- Both the prescriber and the person administering anti-D should always check the most recent report of the patient's Rh D and antibody screen and the Rh D status of the cord blood.
- Laboratory errors can occur during the night when laboratory scientists, not normally working in transfusion, are providing cross call cover. It may be prudent to process samples which lead to the issue of anti-D the following morning. However, this needs to be balanced against the fact that patients are now being discharged earlier following delivery so it is important that systems are in place to ensure that these patients are not missed.
- For successful immunoprophylaxis, anti-D should be given as soon as possible after the sensitising event, but always within 72 hours. However, if it is not given before 72 hours every effort should still be made to administer the anti-D because a dose given within 9-10 days may provide some protection.

Severe Acute Anaphylactoid or Anaphylactic Transfusion Reactions - Findings

- There were 23 AA cases. Thirteen out of 23 reports (57%) were associated with the transfusion of platelet concentrates. Seven of these (54%) were associated with pooled platelet concentrates and six involved apheresis platelets.
- Nine (39%) were associated with red cell transfusions.
- Only one reaction was associated with SD plasma.
- In three cases there was failure to administer pre-medication cover, which had been recommended as a result of previous repeated transfusion reactions. In all three reactions, receiving pre medication cover may have prevented or lessened the severity of the patient's symptoms.
- Nine of the 23 anaphylactoid/anaphylactic (A/A) cases (39%), involved children \leq 18yrs of age.
- In most cases, the reactions were not severe and responded quickly to treatment. In one case, however the patient required adrenaline to control the symptoms. None of the 23 patients required ITU admission as a result of their reaction.
- Eight patients (35%), seven of them children, were prescribed washed components for future transfusion.

Acute Haemolytic and Other Severe Acute Transfusion Reactions - Findings

- These reactions accounted for 4% of incidents reported (8 of 180). All eight cases involved the transfusion of red cells. The reactions occurred during transfusion and although in all cases the patients recovered within 24 hours, one case involved a day case patient who required hospitalisation overnight.
- In three cases, the patient had irregular red cell antibodies detected.
- Although all the reactions involved the development of a fever or rigors, in only five cases were both the patient and the unit cultured and bacterial contamination definitely excluded as the cause of the symptoms. In one case, the reaction on investigation was found to be due to infection in the patient's Hickman line.

- Six cases involved transfusions in patients with underlying malignancies. In some of these cases, where no other cause was discovered, the symptoms may have been due to the underlying disease rather than the transfusion.

A/A and AHOSTR Recommendations

- Protocols and training for the management of severe acute reactions should be in place in each hospital and all staff involved in transfusion should be familiar with their use.
- The importance of only prescribing transfusions that are necessary cannot be over emphasised. Inappropriate transfusions increase donor exposure unnecessarily and can put the patient at risk of a transfusion reaction.
- Where patients are transfused in day care settings, it is important that written post-transfusion information is given to the patient prior to discharge explaining whom to contact and symptoms to look for, in case of a reaction following discharge.
- Where patients are receiving shared care, systems must be in place so that all relevant details relating to transfusion such as history of reaction/allergy and/or pre-medication requirements can be communicated between centres effectively.
- Every patient should be carefully monitored during transfusion with special emphasis placed on the start of each new unit. Individual units should be commenced slowly, and the patient observed closely, for the first 15 minutes / 50 mls as severe reactions are most likely to occur within this time.
- Classical allergic or anaphylactoid reactions do not routinely require culture of the unit or pack. However where atypical symptoms such as fever are present or where skin manifestations are absent, it is important to culture the implicated unit/s and the patient to exclude underlying sepsis and/or bacterial infection in the unit and in the case of red cells exclude red cell incompatibility

Transfusion Associated Circulatory Overload - Findings

- TACO accounted for 14 (8%) of the incidents reported. Special care should be taken when transfusing patients with diminished cardiac, respiratory or renal function and also patients with significant chronic anaemia.
- 12 cases (86%) were associated with the transfusion of red cells.
- One case involved transfusion of eight units of SD plasma for warfarin reversal. Although the patient was very ill before the transfusion, it is likely that the transfusion contributed to mortality.
- The final case involved the transfusion of multiple blood components in the massive transfusion setting.
- 11 cases (79%) involved elderly patients, the majority of whom were extremely ill prior to transfusion and had multiple underlying conditions.
- In five cases the patients were in a positive fluid balance prior to transfusion.
- Seven of the 14 patients did not have an intake and output record.
- While six of the patients were already on diuretics, only one patient received extra cover prior to transfusion.

TACO Recommendations

- All patients receiving blood components should be assessed carefully. Particular attention should be paid to at risk patients, i.e. low weight, frail, elderly, infants and children, or patients with a history of cardiac, respiratory and renal insufficiency. In susceptible patients, transfusions should be administered slowly (1ml/kg of body weight/hour).
- An accurate intake and output record should be maintained.
- The risk of overloading the circulation can be minimised by administering a prophylactic diuretic in addition to maintenance diuretic therapy.
- Transfusion should be on a unit-by-unit basis, with a medical assessment of the patient prior to commencing transfusion and before administering any further component.

- It may be prudent to transfuse only one unit in a 24-hour period in high-risk patients. Some subjects take as long as 24 hours to readjust blood volume and the effects of the transfusion of large amounts of blood must always be carefully monitored, particularly in those patients whose venous pressure is already raised before transfusion has begun.

Delayed Haemolytic Transfusion - Findings

- This category accounted for 5% of incidents reported (9 of 180).
- The commonest antibodies, which were identified, were Rh, Duffy and Kidd.
- Three cases fell within the SHOT grade 1 category, four were grade 3 and two fell within the grade 4 category.
- There were no fatalities associated with the reactions.

DHTR Recommendations

- A careful transfusion history which includes transfusion and pregnancies and access to and checking of previous transfusion records is important.
- Use of three cell screening panels, sensitive antibody screening techniques and satisfactory participation in external quality assurance schemes such as NEQAS, should minimise failures to detect weak antibodies.
- As antibodies can develop rapidly, patients requiring repeated transfusions, depending on the interval between transfusions should have a fresh sample submitted within 24-72 hours of a transfusion.
- When investigating a DHTR a serum sample should be used for antibody detection as some antibodies, particularly weak complement binding antibodies not detectable in plasma specimens may be detected in serum samples.
- Where there are multiple antibodies, it may not always be possible to find fully compatible blood and that it may be necessary to issue least incompatible blood. In these cases specialist advice should be sought as inordinate delays in transfusion may be detrimental to the patient and outweigh the risks of transfusion.

Suspected Transfusion Transmitted Infection - Findings

- There were four cases of suspected TTI, two HBV, one HCV and one HIV. This category accounted for 2% of incidents reported (4 of 180). In the four cases, after extensive investigation, infection through transfusion has been excluded.

Transfusion Related Acute Lung Injury - Findings

- This category accounted for 1% (1 out of 180) incidents reported. Two reports were submitted and on analysis one fatal case was considered to be definitely attributed to TRALI. In the other case, the diagnosis of TRALI was considered extremely unlikely and this case was re-categorised as a TACO incident.
- The fatal case was associated with a platelet transfusion. The donor was found to have Class 1 HLA IgG antibodies and has been permanently deferred. It was not possible to perform HLA typing of the patient nor was cross-match carried out between the patient's cells and the donor's serum. However, based on the close temporal association of symptom onset with the transfusion, the clinical picture and the post-mortem features, it was felt that this fatality was very likely to be due to TRALI.

TRALI Recommendations


- It is important that hospital staff be made more aware of this complication which occurs within six hours of transfusion. This would also facilitate prompt investigation and case review.
- The IBTS has put in place measures to minimise the risk from TRALI including avoiding the use of plasma from female donors both for suspension of pooled platelets and as FFP. From early 2004 new and lapsed female apheresis donors with a history of pregnancy have been deferred from donating.
- SD Plasma which is the standard plasma product, has not to date, been implicated in TRALI.

Pre-Deposit Autologous Donation - Findings

- This category accounts for 3% of the total incidents reported (6 out of 180).
- Symptoms reported ranged from feeling sleepy, light headed, or nauseous, to actually fainting. The onset of symptoms also varied greatly from those occurring during the donation process to delayed symptoms up to over five hours after the donation.
- All of the donors were female.
- None of the incidents resulted in hospitalisation of the donor. All of the donors recovered but none went on to donate again.
- The blood collected was transfused in only two of the six cases.

PAD Recommendations

- Pre-deposit Autologous Donation clinics must have procedures to deal with donor reactions.
- Particular attention at pre-donation assessment should be paid to first time donors, as these are more likely to have reactions. Female donors of lower weight are at an increased risk of adverse reactions. Attention should also be paid to psychological factors such as fear of needles, which may predispose the donor to an adverse reaction.
- Patients in a PAD programme, particularly those patients who donate more than one unit, may be more likely to require transfusion intra- or post-operatively. This increased likelihood brings with it increased risks, as autologous transfusion holds the same risks as allogeneic transfusion in terms of errors at the time of administration.
- It is essential that up to date criteria be used for identifying procedures where blood is likely to be needed.



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