BLOOD ISSUES

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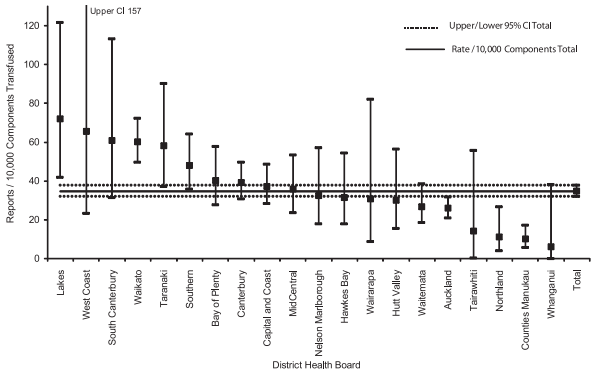
NZBS 6th Annual Haemovigilance Report 2010 – A Summary

The NZBS is responsible for all aspects of the transfusion process from the donor to the recipient; a vein to vein service. The Haemovigilance programme, managed by the NZBS, tracks untoward events anywhere along the transfusion chain in both donors and recipients.

The number of reports submitted to the Haemovigilance Office continues to increase, possibly reflecting an increased awareness by clinical staff of the importance of the programme. Internationally, Haemovigilance Programmes have contributed to the increasing safety of provision of blood to patients. For example in New Zealand, recent efforts by the Blood Service have been focused on Transfusion Related Acute Lung Injury (TRALI) risk reduction. A degree of success can be accredited to the introduction of male only sourced FFP but the three TRALI reports in 2010 involving red cell and platelet components demonstrates that further work is required with NZBS now actively working on methods to reduce the risk of TRALI associated with platelets.

The success of the Haemovigilance scheme in New Zealand relies heavily on the support of doctors, nurses and laboratory staff. NZBS is most appreciative of this. Figure 1 below shows the site of origin for the reports from 2010 and illustrates that some DHBs have higher reporting rates than others. Confidence intervals for several hospitals are below the overall mean which suggests a level of under-reporting. Future efforts will be directed at understanding why these differences exist.

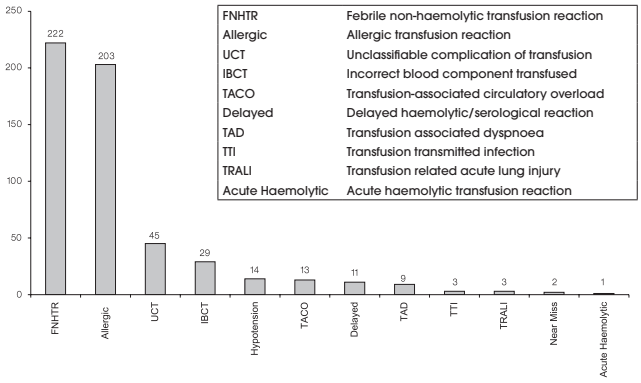
Figure 1: Haemovigilance Reports per 10,000 Components



Twelve adverse event categories are defined with a nationwide data collection form and follow up system. (Figure 2). During 2010 there were 635 reported events (a 14% increase from 2009) involving 566 patients. Eighty events were excluded as their causes were considered to relate to the patient's underlying condition rather than to the transfused component leaving a total of 555 evaluable events. Events are categorised according to severity using a scale from 1 to 4; Grade 1=minor, Grade 2=severe (patient required hospitalisation or extended hospitalisation), Grade 3=life threatening (patient required major intervention - ICU, intubation etc…), Grade 4=death.

The majority of adverse events in 2010 were Grade 1 (89%), most frequently Febrile Non-Haemolytic Transfusion Reaction (FNHTR) or Allergic events. Twelve percent were classified as Grade 2 or Grade 3 (71 events). There was one Grade 4 involving a possible TRALI episode which resulted in the death of the patient. This event was not reported to the NZBS until three months after it occurred and shortly before a coroner's inquest.

Figure 2: Reported Events by Category



Haemovigilance schemes provide an opportunity to examine the frequency and causes of adverse events and provide a barometer on the overall safety of blood transfusion. For example, a real concern for patients is the risk of acquiring viral infections from blood components. In 2009 and 2010 there were no reports of viral infections. There were however three reports of bacterial infections in 2010. One of these reports was a confirmed Yersinia enterocolitica infection in a 20 day old red cell unit. Culture results were positive in both the patient and unit.

During 2010 there were 13 reports classified as Transfusion Associated Circulatory Overload (TACO). This complication of transfusion is often not perceived by clinicians as a "transfusion reaction" and therefore not reported to blood banks. However this adverse event is surely not a planned outcome and should be reported to the Haemovigilance Office through the local hospital blood bank. One TACO event involved a child where the prescription for 2 units of red cells did not specify that the units should be paediatric units and the dose was not prescribed in mL/kg as is usual in paediatrics. The child's Hb increased from 66g/L to 197g/L. Figure 2 shows that the majority of reports are FNHTR with 98% of

these being classified as non-serious. These types of reactions are generally not harmful to the patient but are distressing to them. Research has shown that pre-storage leucodepletion has reduced the frequency of such reactions but their persistence despite universal pre-storage leucodepletion suggests that further investigation is warranted. On-going reporting of such reactions will assist the blood service to monitor the impact of any new initiatives in this area.

Haemovigilance reports show that blood transfusions are not a benign procedure and that clinical staff need to consider carefully the decision to transfuse and be aware of adverse reactions as well as reporting these to the local hospital blood bank. Reporting will assist in making safer products and a safer transfusion procedure.

References:

Source: NZ Blood National Haemovigilance Programme Annual Report 2010. www.nzblood.co.nz

Wrong Blood In Tube

Collection of a blood sample from the correct patient who is intended to receive a blood transfusion is the first step in the process of safe transfusion. Errors made in the collection of the pretransfusion sample are serious because they may set in motion the assignment of blood of the incorrect ABO group for the intended recipient, which if transfused, could lead to serious patient morbidity / mortality. The transfusion of ABO incompatible blood is associated with a haemolytic transfusion reaction; shock, renal failure, disseminated intravascular coagulation and the possibility of death.

"Wrong blood in tube" (WBIT) is where a correctly labelled request form and sample are received at a blood bank for pretransfusion testing and when the results of the ABO & RhD grouping are different to historical results of the patient. The sequence for WBIT events occurs when "patient X's" blood is collected in a specimen tube, labelled with identification information from "Patient Y". The specimen is tested in the laboratory and the results are reported on Patient Y but the blood in the tube is actually from Patient X. These WBIT events are an example of a serious "near miss" event which if not discovered could have led to the transfusion of an incorrect blood component. Adverse consequences are often prevented by stringent criteria for specimen acceptance and careful comparison of the current patient's results to historical results.

The bigger problem is when WBIT occurs in patients who are tested and transfused for the first time where there are no historical records to check the current results against.

The NZBS Blood Management System, Progesa, allows hospital blood banks in New Zealand to access historical pretransfusion testing results, irrespective of where the testing was carried out. This capability assists in the detection of WBIT events.

Within the six NZBS managed blood banks approximately 60% of the patients sample received for pretransfusion testing will have a historical ABO RhD grouping result. All WBIT incidents are reported and the frequency and rate per 10,000 pretransfusion samples received is monitored. WBIT incidences within non-NZBS blood banks are managed within each individual District Health Board (DHB) blood bank, according to local policy.

To study the overall frequency of WBIT events in New Zealand for 2009 and 2010, blood banks were invited to supply the number of WBIT events where the current sample received was identified as being WBIT. Information was received from 14 DHB managed blood banks and was also available from the six NZBS managed blood banks.

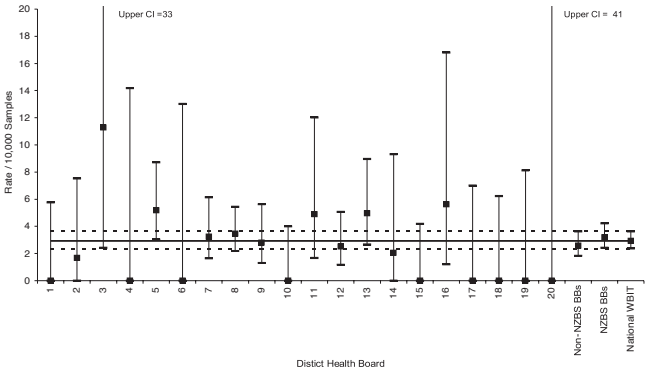
Because WBIT can only be detected by a discrepancy between the current sample result and that of a prior test, chance alone might produce a result in the correct ABO RhD groups (silent WBIT errors) even if the wrong patients group is taken, a correction factor (1.6) was applied in the study to determine the corrected WBIT events.

The table provides information on the incidence of WBIT for the NZBS blood banks, DHB blood banks and nationally for the period 2009 - 2010.

	Number WBIT	Sample with Historic Blood Group	Corrected WBIT Frequency	Rate / 10,000 Samples (95% CI)
DHB Blood Banks	21	129,984	1:3,869	2.6 (1.8 to 3.6)
NZBS Blood Banks	32	159,799	1:3,121	3.2 (2.4 to 4.2)
National	**53**	**289,783**	**1:3,417**	**2.9 (2.4 to 3.6)**

There is no significant difference (p>0.05) between the WBIT rate in the DHB blood banks and the six NZBS blood banks. The national frequency of WBIT for the time period analysed was 1 in 3,417 samples (range 1 in 886 to >1 in 11,601). The national rate for WBIT per 10,000 samples received is 2.9 (95% CI 2.4 to 3.6). International studies have reported a median rate of WBIT of 1 in 2,000 samples.

WBIT Rate/10,000 Samples with 95% Confidence Intervals



A total of 53 (85 when corrected for ABO/RhD silent errors) WBIT events were detected between 2009–2010, these events were only detected because a historical ABO & RhD blood group was available. Only approximately 60% of pretransfusion samples however have a historical group. It is possible that during the time period analysed there were a further 35 (56 when corrected for silent errors) WBIT events that were not detected as 40% of pretransfusion samples did not have a historical ABO RhD group that could be used for a comparison with the grouping result of the current pretransfusion sample received.

The results overall are consistent with international data. In recent years blood banks across New Zealand have moved to a consistent set of requirements around sample labelling and acceptance. This consistency brings a number of benefits particularly so when staff move between DHBs. Clearly a risk exists that a patient for whom there is no historic record in Progesa will receive a transfusion of the incorrect group because of an unidentified WBIT event. No such events have however been reported to the Haemovigilance Office in the last 5 years. Some DHBs are currently considering ways to further reduce risks in this area. This usually involves a requirement for a second sample to be tested before blood components are released for transfusion. Such approaches will potentially lead to an increase in the use of Group O red cells in emergency situations. This is not desirable. Ideally any change to current policies around pre-transfusion testing should be addressed nationally rather than different solutions being developed at different sites.

A Clinical Audit of RhD Immunoglobulin in New Zealand

RhD Immunoglobulin (Anti-D) is used to prevent Rh Haemolytic Disease of the Fetus and Newborn (HDFN), a severe and potentially fatal fetal complication of pregnancy caused by blood group incompatibilities between mother and fetus. Since the introduction of RhD Immunoglobulin, a fractionated plasma product, with the Rhesus Intervention Programme in New Zealand in 1968, there has been a significant reduction in the incidence and severity of HDFN. Despite this programme some women still become sensitised.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, (RANZCOG), Guidelines state that all RhD negative women who have not actively formed their own anti-D antibody should be offered RhD Immunoglobulin for the following indications:

First Trimester Indications
Dose: 250 IU

- Chorionic Villous Sampling
- Miscarriage
- Termination of pregnancy
- Ectopic pregnancy

Second and Third Trimester Indications
Dose: 600 or 625 IU

- Obstetric Haemorrhage
- Amniocentesis, Cordocentesis
- External cephalic version of a breech presentation
- Abdominal Trauma

Routine Antenatal Anti-D Prophylaxis (Australia only):
Dose: 600 or 625 IU

- All RhD negative women who have not actively formed their own anti-D antibody at approximately 28 weeks gestation and again at approximately 34 weeks gestation.

Post-natally, within 72 hours:

- All women who deliver an RhD positive baby should have quantification of feto-maternal haemorrhage to guide appropriate prophylaxis.

Aim:
The aim of the audit was to assess:

- the proportion of RhD negative mothers appropriately treated with RhD Immunoglobulin following birth and
- other indications for RhD Immunoglobulin by tracing RhD Immunoglobulin issues

Method:
A retrospective audit was undertaken by Transfusion Nurse Specialists at Auckland, Waikato, Mid-Central, Capital & Coast, Canterbury and Otago District Health Boards (DHBs) and by Clinical Nurse Specialists (Transfusion) at Counties-Manukau and Waitemata DHB's. Fifty births within Public Hospitals and Birthing Centres at each DHB where the mother was known to be RhD negative were assessed along with a further eighty issues of RhD Ig from blood banks or Donor centres at each DHB, ensuring these did not overlap with the previously assessed births. Data was obtained from NZBS, DHB and community laboratories, clinical notes and Lead Maternity Carers.

Results:

A total of 460 births from RhD negative mothers (22 September 2009–1 January 2009) and 630 RhD Immunoglobulin prescriptions (25 November 2008 – 18 June 2009) were audited.

In the first part of the audit, 96% of RhD negative women who gave birth to RhD positive babies received RhD Immunoglobulin and 98% of those received it within 72 hours of birth. Cord bloods, used to determine the blood group of the baby, were consistently sent for RhD testing, with overall 99% of cord bloods from RhD negative mothers tested.

RhD Immunoglobulin should not be given to women who have already developed an immune anti-D antibody. The last antibody screen prior to birth was positive in 6% of mothers. The majority of these were probable passive anti-D antibodies (i.e. secondary to recent RhD Immunoglobulin administration), but four mothers (1%) had an immune anti-D antibody. Nevertheless, one of these 4 women received RhD Immunoglobulin. Seven women (2%) had antibodies to blood groups other than D.

In the second part of the audit, the majority of requests were for births and third trimester obstetric indications. Although no formal Ministry of Health (MOH) policy exists for routine antenatal anti-D prophylaxis, 5% of requests were for this indication. Only 3 of the 46 requests (7%) relating to events occurring in the first trimester received the recommended 250IU dose of RhD Immunoglobulin. The remaining cases received 625IU. This is noteworthy in that first trimester indications are the only area where a smaller dose (250 IU) of RhD Immunoglobulin is routinely recommended.

In both parts of the audit it was noted that four of the eight DHBs seldom performed Kleihauer tests. The difference between the DHBs who did or did not perform Kleihauer tests (87% vs 2%) was highly statistically significant. This marked difference correlated with the absence of, or knowledge of, a policy on Kleihauer testing within the DHB.

Administration was documented in 99% of available records and consent in 93%.

The documentation of administration and consent for RhD Immunoglobulin could not be established in 6% of doses because the respective records either could not be found or were not provided by the LMC.

Conclusion:

Overall, this multi-centre audit on the use and prescribing of RhD Immunoglobulin has shown that midwifery and obstetric practitioners are generally compliant with RANZCOG and ANZSBT guidelines although there is room for improvement, particularly around post-partum provision of RhD Immunoglobulin, Kleihauer testing, first trimester dosing and documentation of RhD Immunoglobulin consent and administration.

Recommendations:

1. That clinical staff be reminded of the significance of post-exposure anti-D prophylaxis, both at birth and antenatally.
2. That communication between LMCs when handing over patients includes whether or not RhD Immunoglobulin administration has occurred.
3. That clinical staff need to be further educated on the availability and clinical indications for the 250IU RhD Immunoglobulin dose.
4. That clinical staff be reminded of the importance of maintaining true and accurate records of the prescribing, consenting and administration of RhD Immunoglobulin.
5. That the importance of testing for fetomaternal haemorrhage is reiterated, and that this is promulgated in DHB policies throughout New Zealand.
6. That laboratories anticipating a large increase in Kleihauer testing give consideration to technologies such as gel agglutination micro columns as a screening test.

Planned Introduction of a Subcutaneous Immunoglobulin Product (EVOGAM)

Currently patients who require regular immunoglobulin treatment normally receive this in hospital by intravenous infusion of Intragam P. This is effective but not always convenient for the patient. Over the last few years CSL Biotherapies has been progressing development of a new subcutaneous immunoglobulin product. This will be called EVOGAM. The product has recently been registered in Australia by the Therapeutic Goods Administration (TGA). Registration by Medsafe in New Zealand is expected during the next few months.

Intragam P is a 6% product (i.e. 6g per 100ml). EVOGAM will be provided as a 16% concentration. It will need to be infused using a pump and specific training will be needed for patients. EVOGAM will enable some patients to receive their immunoglobulin treatment at home. Early indications are that this will be a popular option for many patients. Additional information on the product will be provided as soon as Medsafe registration has been achieved.

eProgesa Project Update

The eProgesa project to upgrade NZBS's national Blood Management System is approaching completion with go-live planned for later this year.

Lead Users at each of the DHB's will be managing the training delivery and assisting at go-live and all Blood Bank staff will be trained to use the eProgesa application. The main difference between the two applications is the user interface which looks and feels different, but the opportunity to introduce new functionality in future projects is significantly increased.

The availability of information in Hospital results systems and the electronic transmission of test results and work lists from laboratory analysers will not be affected by this project, except during the go live weekend.

Communication and contingency plans for the go live weekend are currently being prepared with input from Blood Banks. The impact on NZBS's services during go live are expected to be minimal.

Any questions, concerns or feedback in relation to the project should be addressed to Allison Eldon (eProgesa Project – Change Manager) on (09) 523 2884 or email allison.eldon@nzblood.co.nz