HAEMOVIGILANCE POLICY

REASON FOR ISSUE: New document describing Haemovigilance System

1. INTRODUCTION

NZBS has adopted the Council of Europe definition that states that haemovigilance is:

> "… The organised surveillance procedures related to serious or unexpected events or reactions in donors or recipients and the epidemiological follow up of donors…"

The data gathered from the voluntary reports to the programme enables NZBS to:

- provide the clinical community with a reliable source of information about untoward effects of transfusion
- recommend corrective measures for preventing the recurrence of particular events or dysfunction in the transfusion process
- warn hospitals and blood services about adverse events that could involve more individuals than a single recipient e.g. transmission of infectious diseases, problems with blood bags, solutions or blood processing etc.

It covers all activities of the blood chain from donor to recipient, i.e., "vein-to-vein". This encompasses untoward events in the whole transfusion chain from the collection of blood and its components from blood donors to the follow-up of recipients.

2. SCOPE

Clinicians in New Zealand are requested to notify all adverse reactions or events arising from, or in association with the use of blood components/products prepared by NZBS.

- Reportable Events / Reactions
- Adverse reactions to transfused blood components/products
- Events involving incorrect blood component transfused (IBCT)
- Near misses
- Adverse events occurring at any point from collection through to transfusion relating to a reagent, item of equipment or breach in policy, e.g., anticoagulant effect, collection bag defect, co-administration of inappropriate IV fluid.

3. PRIVACY

Haemovigilance has been declared a protected quality assurance activity under Section 54 of the Health Practitioners Competency Assurance Act 2003 as notified by the Health Practitioners Notice 2006, published in the New Zealand Gazette on 6 April 2006. The effect of this declaration is that subject to certain circumstances:

- Any information that becomes known solely as the result of Haemovigilance is confidential; and
- Any documents brought into existence solely for the purposes of Haemovigilance are confidential; and
- The persons who engage in Haemovigilance in good faith are immune from civil liability

The data is entered into a secure database; clinician and patient names are not included. The paper records are destroyed on publication of the annual report and the unique patient identifier is then deleted from the database.

4. KEY RESPONSIBILITIES

- Hospital clinical staff reporting adverse reaction or event.
- Transfusion Safety Officer, in most cases Blood Bank Charge Scientists and Transfusion Nurse Specialists. Assist with the completion of form and send completed to the National Haemovigilance Office.
- NZBS Transfusion Medicine Specialists. Review haemovigilance forms and provide advice on management of adverse reactions when contacted.
- NZBS National Haemovigilance Group. Document adverse events and reactions, review reports and prepare annual report. The National Haemovigilance Group comprises a number of Transfusion Medicine Specialists and a Scientist.

5. DEFINITIONS

- **Adverse Event**

  An undesirable and unintended occurrence before, during or after transfusion of a blood component/product, which may be related to the administration of the component/product. It may be the result of an error or an incident and it may, or may not, result in a reaction in the recipient.

- **Adverse Reaction**

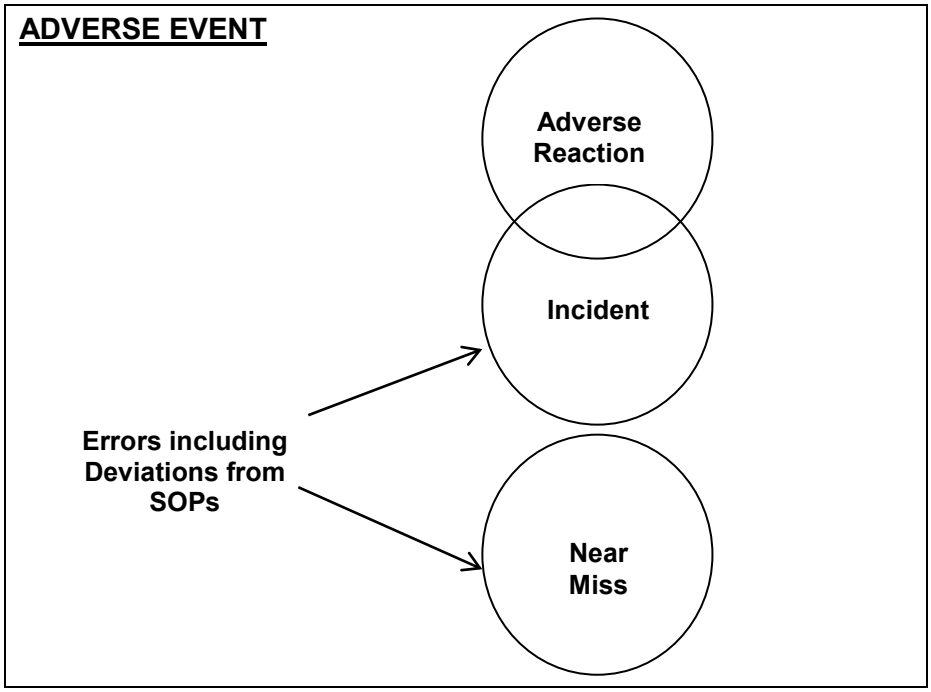
  An undesirable response or effect in a patient temporally associated with the administration of a blood component/product. It may, but need not, be the result of an incident.

- **Incident**

  A case where a patient is transfused with a blood component/product which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that may have lead to mistransfusion/s. It may or may not lead to an adverse reaction.

- **Near Miss**

  An error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to mistransfusion or to a reaction in a recipient.



6. DOCUMENTS

6.1 Required Documents

- 111F009 Transfusion-Related Adverse Reaction Notification Form
- 111F042 Transfusion-Related Adverse Event Notification Form
- 111F003 Notification of Suspected Adverse Reaction to Fractionated Blood Product
- Electronic folders and files (restricted access)
  - National V:\Clinical\Haemovigilance
  - Microsoft Access™ Database

7. PROCEDURE FOR REPORTING ADVERSE REACTIONS TO BLOOD COMPONENTS

7.1 Event Notification to Local Blood Bank

- The clinical notification form, Notification and Investigation of Adverse Transfusion Reaction (111F009) is provided in pads of 10 forms for use in hospital wards and other clinical area where transfusion of blood components may occur.

- Form 111F009 is used to notify the blood bank staff or the Transfusion Nurse Specialist or Transfusion Medicine Specialist of an adverse event or reaction to blood components.
- Data is transcribed from the form 111F009 onto the Transfusion Related Adverse Event Notification Form (111F042) and any further data (e.g., imputability, severity score) required to complete the form is obtained from the clinical staff concerned. The details may be obtained by requesting the clinical staff to complete form 111F042, or verbally requesting the necessary additional information.
- A NZBS Transfusion Medicine Specialist must be notified of all severe (Grade 2-4) reactions.

7.2 Local Blood Bank Action

- The completed form, 111F042, is forwarded to the National Haemovigilance Office by either mail, fax or as an email attachment together with any relevant clinical or laboratory documentation.

7.3 National Haemovigilance Office

- Receipt of the report is acknowledged and the date received and acknowledged is recorded.
- A hard copy of electronic notification forms received are printed.
- The forms are reviewed by the Transfusion Medicine Specialist at the location of the National Haemovigilance Office on receipt and where required, additional information is requested.
- The information is entered into the Access™ Database and the next sequential haemovigilance number recorded on the notification form and all associated information.
- The paper records are filed by sequential number in a file.
- The National Haemovigilance Group meets at regular intervals to review all haemovigilance reports. The review process includes:
  - Classification of the adverse event/reaction
  - Assigning imputability and severity scores
  - Make requests for additional information

8. PROCEDURE FOR REPORTING ADVERSE REACTIONS TO FRACTIONATED PRODUCTS

Reporting of adverse reactions relating to the transfusion of fractionated products, detailed in the section of the NZBS Clinical Compendium entitled Clinical Policies and Procedures - Managing Notification of Adverse Reactions to Fractionated Blood Components (111M003), is performed using the form - Notification of Suspected Adverse Reaction to a Fractionated Blood Product (111F003).

9. ANNUAL HAEMOVIGILANCE REPORTS

The Annual Haemovigilance Report published each year details data and information from the previous calendar year. The report contains information including but not limited to:

- Component usage
- Analysis of reported adverse reactions and events
- Adverse events associated with the transfusion of fractionated products
- Bacterial monitoring of platelet concentrates
- Donor infectious disease testing
- Adverse events associated with blood donation
- NZBD Blood Bank request form and sample labelling errors

10. CLINICAL ADVISORY GROUP (CAG) REPORTS

A report on haemovigilance activities is prepared for each scheduled CAG Meeting.

11. INTERNATIONAL HAEMOVIGILANCE NETWORK (IHN)

NZBS is an active member of the IHN. This organisation aims to standardise haemovigilance activities to support benchmarking of data. NZBS utilises internationally agreed definitions1 when evaluating and classifying adverse events.

New Zealand's annual haemovigilance data is entered into the IHN database International Surveillance of Transfusion-Associated Reactions and Events database (ISTARE). The database records haemovigilance data using common definitions. This allows international comparisons, information sharing and benchmarking.

ISTARE aims to capture all adverse reactions and incidents (events) in recipients of blood components that can certainly, probably or possibly be imputed to blood transfusion. It also records adverse events in blood donors.

12. REFERENCES

1. Proposed Standard Definitions for Surveillance of Non Infectious Adverse Transfusion Reactions. International Society of Blood Transfusion Working Party on Haemovigilance www.isbtweb.org/working-parties/haemovigilance/definitions