HAEMOVIGILANCE POLICY

REASON FOR ISSUE: Full re-write.

1. INTRODUCTION

NZBS has had an active Haemovigilance Programme in place since 2005.

The International Haemovigilance Network defines haemovigilance as:

> *A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended 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.*

Participation in the programme by hospitals is voluntary but actively promoted by NZBS.

The data gathered by the programme enables NZBS to:

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

2. SCOPE

The scope of the Haemovigilance Programme includes:

- Donor adverse events (DAE), resulting from the blood donation process.
- Adverse events in patients related to the transfusion of blood components or fractionated blood products.
- Errors and near misses that relate to specific patients.
- Lookback activities.

3. KEY RESPONSIBILITIES

- Transfusion Nurse Specialists (TNS): Provide haemovigilance education to hospital clinical staff.
- Transfusion Medicine Specialists (TMS): Encourage hospital clinical staff to raise haemovigilance reports when applicable. Raise haemovigilance awareness among peers.
- Clinical Surveillance Manager (CSM): Manage adverse event data and provide reports to Clinical Governance. Collate and edit the Haemovigilance Annual Report. Coordinate lookback activities.

4. 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.

- **Error**

  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. Includes, but is not limited to, avoidable transfusion, delayed transfusion, transfusion of incorrectly stored blood and under- or over-transfusion.

- **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.

- **Pharmacovigilance**

  That part of haemovigilance that relates to fractionated blood products.

5. DOCUMENTS

5.1 Related Documents

- 111F009 Form - Acute Transfusion Reaction (ATR) - Notification to Blood Bank
- 111F042 Transfusion-Related Adverse Event Notification to NZBS
- 111F003 Fractionated Blood Product - Adverse Event Notification
- 111M021 Reporting Haemovigilance Adverse Events in K2
- 111M003 Notification of Adverse Reactions and Adverse Events Associated with Fractionated Blood Products
- 111M018 Management of Pharmacovigilance Case Reports

6. DATA MANAGEMENT

- Nintex K2 browser-based process automation software is used for recording all events. Data is stored in a SQL database.
- Legacy DAE records (prior to 2022) are stored in:
  - National V:\AccessDatabases\Donor Incident Database\QualityData_2010.accdb
- Legacy haemovigilance and pharmacovigilance records (prior to 2023) are stored in:
  - HV case files - National V:\Clinical\Haemovigilance\Case files
  - HV data - National V:\Clinical\Haemovigilance\Haemovigilance Database Access 2003.accdb
  - FP case files - National V:\Clinical\Pharmacovigilance\1. Case files
  - FP data - National V:\Clinical\Pharmacovigilance\2. Database

7. REPORTING AND REVIEWING ADVERSE EVENTS

7.1 Donor adverse events

7.1.1 The process for reporting DAEs is described in:

- 107M005 Reporting of Adverse Events Related to Blood Donation

7.2 Blood components

7.2.1 The process for reporting adverse events associated with blood components is described in:

- 111M021 Reporting Haemovigilance Adverse Events in K2

7.3 Fractionated blood products

7.3.1 The process for reporting and management of adverse reactions relating to the infusion of fractionated products is detailed in:

- 111M003 Notification of Adverse Reactions and Adverse Events Associated with Fractionated Blood Products
- 111M018 Management of Pharmacovigilance Case Reports

7.4 Review of case reports

7.4.1 All DAEs are reviewed by a MO, TMS or Clinical Nurse Specialist Donor Health.

7.4.2 All haemovigilance and pharmacovigilance cases will be reviewed by the local team (TMS, TNS and Blood Bank). Once submitted all cases are reviewed by the CSM.

7.4.3 A Haemovigilance review team consisting of the CSM, three TMSs and a TNS meets weekly to review the more complex haemovigilance/pharmacovigilance cases and assign classifications.

8. CLINICAL GOVERNANCE REPORTING

A quarterly report summarising year-to-date haemovigilance activities is prepared for each Clinical Governance – Patient Services meeting.

9. HAEMOVIGILANCE ANNUAL REPORT

The Haemovigilance Annual Report is widely distributed to Blood Bank and Clinical teams across the country. It is collated and edited by the CSM and details data and information from the previous calendar year. The report contains information including but not limited to:

- Component and product usage
- Analysis of reported adverse reactions and events
- Bacterial monitoring of platelet concentrates
- Donor infectious disease testing and lookback
- Adverse events associated with blood donation
- Errors and near misses, including wrong blood in tube (WBIT).

10. INTERNATIONAL ORGANISATIONS

10.1 NZBS is a member of the International Haemovigilance Network (IHN) https://ihn-org.com/ . This organisation aims to standardise haemovigilance activities to support benchmarking of data.

10.2 NZBS utilises internationally agreed definitions developed by the International Society of Blood Transfusion (ISBT) when evaluating and classifying adverse events. https://www.isbtweb.org/isbt-working-parties/haemovigilance.html