Blood Protocol – Fractionated Products

Contents

Purpose

To ensure the blood product is safe to transfuse

To ensure that the right patient receives the right blood product at the right time at the right rate and the right prescribed dose

To monitor the patient closely to detect a potential adverse reaction

Definition

Fractionated blood products are blood plasma derivatives (partially purified therapeutic preparation of human plasma proteins).

Scope

Registered Nurses, IV Endorsed Enrolled Nurses, Nurse Practitioners

Registered Midwives, Lead Maternity Carers,

Medical Officers

Anaesthetic Technicians

Students of Nursing and Midwifery in an observation role only.

Supporting Material

2408295	Blood Protocol – Pre-Transfusion
2408294	Blood Protocol – Adverse Transfusion Reaction
2405524	Hand Hygiene Policy
2407578	Infection Prevention and Control
2403034	Peripheral Intravenous Therapy
2401678	Roles and Responsibilities Policy
2401682	Student Nurse-Midwife Roles and Responsibilities Policy
2403338	QMR022B Blood and Blood Product Transfusion Sheet ("QMR form")
2402957	Checklist – Caring for patients who decline blood products
NZBS 111F075	Approval for Immunoglobulin Intragam®P, Privigen®(IVIg) and Evogam®(SCIg)
NZBS 111i004	Leaflet - Anti-D immunoglobulin
NZBS 111i010	Leaflet - Immunoglobulin Products - IntragamP®, Privigen®, Evogam®
NZBS 111i012	Leaflet - Albumex®4 and Albumex®20
NZBS 111i014	Leaflet - Blood Coagulation Factor Concentrates
NZBS 111i305	Leaflet - Normal Immunoglobulin, Hepatitis B immunoglobulin, Tetanus Immunoglobulin, Zoster Immunoglobulin

These pamphlets are available from the Transfusion Nurse Specialist (81620) or Blood Bank (80310)

Safety Notice

ALL staff have permission to call **STOP** during the infusion process or at any stage where there are any concerns about patient safety.

Immunoglobulin (Ig) Approval

Approval will be sought by Blood Bank staff on receipt of a QMR022b requesting any of the blood products listed below.

- Rhophylac (RhD immunoglobulin (IV))
- Zoster immunoglobulin-VF
- Rabies immunoglobulin
- Hepatitis B immunoglobulin 400iu (s29 medicine)
- Thrombotrol®-VF (except cardiac theatres)
- Coagulation factors
    - Riastap (s29 medicine)
    - Prothrombinex®VF (>50iu/kg in acute bleeding)

Praxabind & Novoseven can be approved by either an NZBS Medical Officer or CDHB Haematologist

Contact the Infusion Registrar (027 232 6556) for any clinical/technical advice or Infusion Nurse Specialist (81620; 021 577 532) for administrative advice.

IV Immunoglobulin (IVIg)

Intravenous immunoglobulin (IVIg) is an expensive medication with increasing demand.

There are two intravenous normal immunoglobulin (IgG antibodies) products available in New Zealand. They are not interchangeable. These products are indicated for replacement immunoglobulin therapy and immunomodulatory therapy.

Approval to treat is required before prescribing. If urgent, please contact the Transfusion Registrar (027 2326556) or Blood Bank (80310) after hours.

Doses are rounded up or down to the closest bottle size by the approver.

Intravenous Immunoglobulin (IVIg) Approval Process	
Immunoglobulin Online Approval **(IgO)**	A Registrar or Consultant must apply for access to IVIg (short or long term use) via the New Zealand Blood Service (NZBS) Immunoglobulin Approval portal known as IgO: https://igo.nzblood.co.nz/account/login If you are not an approved requester in IgO submit your details via the *Clinical Registration* tab. Only approved clinicians can submit an IVIg request. Many senior clinicians across Transalpine Haematology, Immunology, Paediatrics, ICU, Neurology and Dermatology have been pre-registered. The specific IVIg product preparation is determined by NZBS – do not prescribe

	until you receive confirmation of what product (ie. Intragam®P or Privigen®), dose and duration has been approved On-going review of IVIg therapy occurs at least once every twelve months within the IgO portal.
IVIg criteria for use	NZBS and CDHB have adopted the National Blood Authority (NBA) *Criteria for Clinical use of Immunoglobulin* to guide clinical decisions to ensure optimal dose, frequency and reviews occur (including IgO levels, if needed). Locate at https://www.criteria.blood.gov.au
Information	Further advice can be obtained via • Blood Bank who will navigate you to the clinical team for information and support • CDHB Intranet - https://prism.cdhb.health.nz/Pages/default/Resources.aspx • NZBS/CDHB Blood Resource Folder https://www.clinicaldata.nzblood.co.nz/resourcefolder/ivig.php?dhbid=2 • Medsafe: https://www.medsafe.govt.nz/profs/Datasheet/i/IntragamPinj.pdf https://www.medsafe.govt.nz/profs/Datasheet/p/privigeninj.pdf

If approval is not given, either the Transfusion Registrar or Transfusion Medicine Specialist will contact the requester to discuss. Only approved IVIg products can be issued by Blood Bank.

Intravenous Immunoglobulin Administration

1. Check the patient weight (kg) is documented. Induction and maintenance treatment doses are calculated on patient weight.
2. Send a pre-Transfusion testing (PTT) blood sample to Blood Bank if there is no confirmed ABO history in Health Connect South
3. Provide written information (NZBS leaflet) to support informed consent https://www.nzblood.co.nz/assets/Transfusion-Medicine/PDFs/111i010.pdf
4. Consent must be obtained by the Prescriber
5. Prescribe on the National Medication Chart ensuring –
   - **the right product** is prescribed. Intragam®P or Privigen® are not interchangeable and have different rates of administration.
   - **the right dose is stated in grams and volume in mLs**
6. Requests for Blood Bank issue requires clear identification of **which IVIg product** is required, **in grams,** on the QMR022b form

Considerations

Administration (particularly doses more than 0.4g/kg) should be commenced as early as practicable to avoid the risks associated with overnight administration. Commencing late in the day should be avoided unless the need is urgent (eg. Kawasaki Disease, Guillain-Barre Syndrome (GBS), Idiopathic Thrombocytopenia Purpura (ITP)).

Blood products cannot be infused with any other medications or fluids in the same administration line (exception is Normal Saline), however concurrent medications or infusions via other lumens in patients with central venous access is permissible as rapid dilution occurs once in the bloodstream.

There is no need to slow an infusion down if changing between bottles of different batch numbers.

Hydration: Ensure your patient is adequately hydrated as patients with pre-existing renal impairment, diabetes mellitus, volume depletion, sepsis, paraproteinaemia, or those taking concomitant nephrotoxic drugs or who are more than 65 years old are at risk of acute renal failure. Renal function should be monitored in these patients.

In patients at risk for **acute renal failure**, thromboembolic adverse reactions, IVIg products should be administered at the slowest rate of infusion as per prescription to avoid reactions.

IVIg contains no preservatives to prevent bacterial growth so each bottle should be infused within 4 hours of spiking.

Slower infusion rates will diminish rate related symptoms such as headache, shivering, tachycardia and BP alterations.

Patients with Group A red cells should be monitored for haemolysis (see manufacturer's instructions) as Intragam®P and Privigen® contain anti-A and anti-B antibodies.

Passive Transfer of Antibodies and Interference with Serological Testing: After injection of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.

Glucometers: Intragam®P contains maltose. If blood sugar levels are required, check if your glucometer is sensitive to maltose as sensitivity may lead to false elevated blood sugar level measurements.

Rate of Administration

Intragam®P (6g/100mL)

Adult rate:

- start infusion slowly (1mL/min) for first 15 minutes increasing gradually to a maximum of 3-4mL per minute over further 15 minutes.

Paediatric rate:

- start at 1mL/kg/hr (or 0.5mL/kg/hr for first infusion) for the first 15min, then
- double every 15 minutes up to a maximum rate of 5mL/kg/hour.
- See also the Starship Hospital Clinical Guidelines - https://www.starship.org.nz/guidelines

Privigen® (10g/100mL)

Privigen is used for short term treatment or patients intolerant of Intragam®P. The first infusion should be administered at an initial rate of 0.3 mL/kg/hour.

- If the infusion is well tolerated, the rate can be doubled at 30 min intervals to a maximum rate of 2.4mL/kg/hour, at the discretion of the healthcare professional and as tolerated by the patient.
- For subsequent infusions a similar step-wise approach can be used, as tolerated. i.e. commence at 0.3mL/kg/hour, increasing the rate every 30 minutes, as above.
- For PID and CIDP, the maximum infusion rate is 4.8 mL/kg/hour, but only from the fourth infusion onwards.
- For all other conditions, the maximum infusion rate is 2.4 mL/kg/hour.

Rhophylac RhD immunoglobulin (1500iu – 300mcg)

Supplied in NZ for **intravenou**s anti-D administration for large fetomaternal bleeds or for the patient with haemorrhagic disorders eg. chronic ITP.

- Supplied as single use pre=-filled 2mL glass syringe with twist off closure system designed to connect directly to most needle free intravenous devices via a Luer-Lok™. IV systems with connectors containing an internal spike, or positive displacement valves are not compatible.
- Recommended rate is 2mL (1500iu) per 15-60 seconds.
- If multiple vials are required administer each vial every 60 seconds
- Rhophylac does not have full NZ registration so consultation with an NZBS Transfusion Medicine Specialist is required prior to product release to a patient.
- Patients receiving large doses of RhD immunoglobulin must be monitored due to risk of haemolytic reaction.
- Recommended dose administration rate is 3000iu every eight hours.

Pre-Infusion Checks for IV Immunoglobulin

All pre-infusion checks are to be performed at the patient's side

Two authorised IV certified personnel are required for all blood infusion procedures.

Double independent checking requires two independent checks performed at the patient's side prior to commencing any infusion. This is to ensure the right patient receives the right infusion at the right place and right time. Health professionals performing a double independent check are referred to as the "first checker" and "second checker".

- The **"second checker"** completes the administration checks FIRST identifying any problems and correcting them. The "**first checker**" does the final check immediately prior to commencing infusion.
- IV endorsed Enrolled Nurses are only able to perform the second checker role.
- Students are only able to observe infusion practice or participate as a "third checker".

In non-emergency situations one independent checker should be the Health Professional caring for the patient – an IV certified RN or RM, Anaesthetic Technician or Medical Officer. This person is recognised as the **"first checker"** and has overall responsibility for the blood product infusion.

Once the second checker has completed the blood administration checks, the **"first checker"**

- repeats the same bedside checks and determines that it is safe to proceed with the infusion
- commences the infusion
- **remains with the patient for the first fifteen minutes** to detect early signs of a reaction
- **completes the first set of observations**, and
- Reassesses the patient before leaving the patient bedside.

Remaining observations and patient monitoring may be delegated to another health professional after the first fifteen minutes of patient monitoring and recorded observations.

Do not spike any Product until you have completed the bedside checks.

Patient Identification

Complete the independent checks **immediately prior to commencing infusion**.

Ask the patient to state their full name and date of birth. Use open questions to avoid yes/no type answers.

In community settings the patient must have photo ID as proof of identification.

In the hospital inpatient setting, check that you have the correct patient and that a wristband is being worn. **No Wristband = No Infusion.** Confirm the patient's identity against their wristband details (details must be clearly readable) including family and given names in full, NHI number, and date of birth.

Ensure the patient wristband details or photo ID match the patient identifiers on the -

- Completed consent form (signed and dated by the patient/identified welfare guardian or identified NOK). Take note of any expiry date on the consent form.
- Prescription on the National Medication Chart
- Record of Infusion sheet (QMR022b)
- Blood product swing label

Prescription – check for

- the right blood product to be infused
- Calculate the starting rate.

Blood product

- Check the batch number(s) match those documented on the QMR form. Multiple bottles of the same batch may be pooled together.
- Check the expiry date(s)
- Check each bottle for sediment, turbidity or discolouration. Return to Blood Bank if any concerns.

All documentation must match exactly.

Any discrepancies noted during the administration checking process must be reported to Blood Bank immediately before proceeding with the infusion. Blood Bank will advise on what action to take.

Procedure

Adhere to infection control principles

Explain the procedure to the patient

Allow product(s) to reach room temperature, away from direct sunlight or any heat source.

Use a vented infusion set or a standard infusion set with a venting spike. A filter is not needed.

Electronic infusion pumps are recommended

Infuse once the bottles have reached room temperature.

Prime the giving set with the blood product

Document the time each bottle is spiked on the QMR form as a reference to ensure that each bottle will finish within **four hours**.

To finish each bottle in 4 hours or less

- children under 15 kg should only receive the 5g bottle size.
- children weighing 15-30 kg should only receive 5g or 10g bottle sizes.
- children and adults weighing 30kg or more can receive 5g, 10g or 20g bottle sizes.

An infusion begins when the first drop of donor blood reaches the patient bloodstream

Advise the patient on signs and symptoms of an infusion reaction. Most reactions are mild however it is important to recognise reactions early and seek medical advice.

Ensure the call bell is within easy reach of a patient, that they are easily visible and can get attention quickly should signs and symptoms of an infusion reaction develop.

Observations

Immunoglobulin products should be given with caution to patients with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.

Document a baseline TPR & BP **up to one hour prior** to commencing infusion. A full set of inpatient observations is required to inform NZEWS and the EWS action plan.

Outpatient settings must document temperature, respiration rate, heart rate and BP

Observe the patient closely for the first fifteen minutes of the infusion

- Continuous cardiorespiratory monitoring for babies under 12 months of age
- Observations must be recorded
    - Every 15 minutes for the first hour
    - Twice in the next hour, then
    - Hourly for the remaining duration
    - Final set at conclusion of infusion
    - more frequently if the patient's condition gives cause for concern

Recipients should remain under observation for 20 minutes following administration in case they experience an immediate adverse event requiring treatment.

Privigen administration and monitoring should also include urine output and serum creatinine

Prolonged administration >6hrs using large doses may result in thrombophlebitis at the infusion site.

Post Infusion

For patients who are naïve to human Ig, switched from other Ig, or who have had a long interval since previous Ig infusion, monitor for 1-hour post infusion.

- Monitor patients for 20 minutes for each subsequent infusion

Intramuscular Immunoglobulin

Must not be administered IV given the potential for severe adverse reactions.

Avoid in patients with a low platelet count. Subcutaneous product may be an alternative option.

Immunoglobulin products are contraindicated in individuals who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection.

Should be given slowly by deep intramuscular injection using an appropriately sized needed and care should be taken to draw back on the plunger of the syringe before injection to be certain that the needle is not in a blood vessel.

A dose of more than 5mLs should be administered in divided doses at different IM sites. Consider alternative product such as IV administration when large doses of immunoglobulin are required

RhD Immunoglobulin -VF *(Anti-D)*
See RANSCOG guidelines for RAADP and Sensitising Events

- 250iu for first-trimester indications
- 625iu post-partum or following an antenatal sensitising event after 12 weeks gestation, or following termination after 12 weeks
- 625iu for bleeds less than 6mL foetal red cells (positive Kleihauer test)
- Consult a Transfusion Medicine Specialist
- For fetomaternal bleeds greater than 6mL or for other indications
- For other exposures to RhD positive red cells (e.g. platelet infusions or bone/tissue implantation)
- If Anti-D is given for large fetomaternal bleeds, febrile reactions due to haemolysis of the RhD positive cells are common. Consider pre-medicating with paracetamol and ensure the patient is well hydrated.
- Routine antenatal anti-D prophylaxis (RAADP) is recommended by RANZCOG for RhD negative women. 625 IU RhD Immunoglobulin is administered at 28 & 34 weeks gestation.

Other intramuscular (hyperimmune) blood products

Normal Immunoglobulin-VF - is the only non-specific IM blood product usually used for hepatitis A and measles prophylaxis; occasionally used as a replacement immunoglobulin for hypogammaglobulinaemia.

Zoster Immunoglobulin-VF

Hepatitis B Immunoglobulin-VF

HyperHEP™ (neonatal Hepatitis Ig)

Tetanus Immunoglobulin-VF

Berirab®P (rabies; s.29)

Human Coagulation Factors

Biostate® *(factor VIII + von Willebrand's)*

FEIBA NF® *(factor VIII inhibitor)*

RiaSTAP® *(Fibrinogen; s.23)*

Fibrogammin® *(factor XIII; s.29)*

Prothrombinex®VF *(factors II, IX, X)*

Allow the vials to reach room temperature (between 20°C and 30°C) before reconstituting.

Infuse promptly. Do not refrigerate Prothrombinex®VF once it has been reconstituted.

IV infusion should be completed within 3 hours of reconstituting bottle.

Multiple vials of the same product may be pooled together. Draw up into a syringe and administer via a syringe pump or by IV bolus.

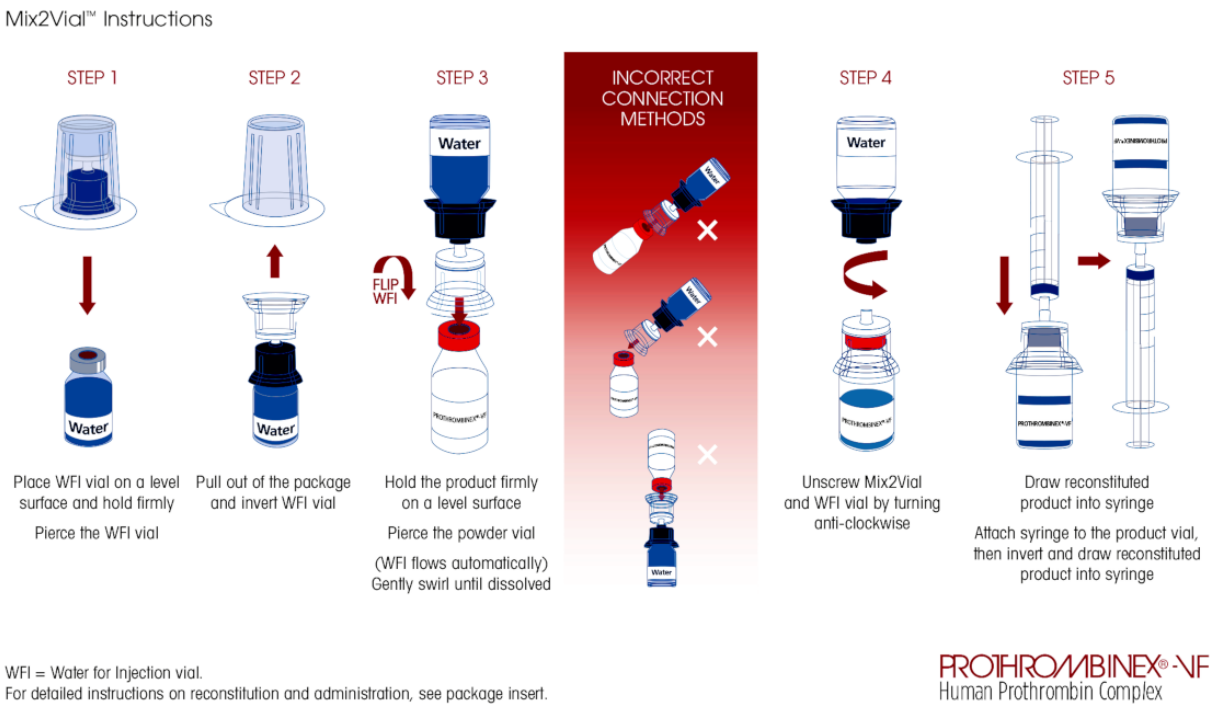
Rate: Infusion or slow IV push at 3 mL/min (180mL/hour) or 7 minutes a vial.

Note! Administering Prothrombinex®VF to patients who are not warfarinised substantially increases the risk of thromboembolism

Mix to Vial Transfer System

The sterile Mix2Vial® Needleless Reconstitution System enables simple, fast, vial-to-vial transfer and mixing between two vials for the reconstitution of Prothrombinex®VF.

If the vacuum in the vial is lost during reconstitution with the Mix2Vial® device, the transfer with the transfer set will not work. Keep the bottles sitting on a flat surface to maintain the vacuum.



Immunoglobulin - Subcutaneous

Subcutaneous immunoglobulin products should not be infused intravenously because of the potential for severe adverse reactions including shock.

Evogam®
Hizentra®

Other Blood Products supplied by NZ Blood Service

Albumex (*Albumin)*

- Hypokalaemia, thrombocytopenia and prolonged prothrombin times may be worsened with Albumex infusions.
- **Monitor rate-volume closely** to assess for signs of volume overload. Ensure blood pressure is monitored regularly during administration. Myocardial function should also be monitored e.g. central venous pressure, arterial pressure and pulse rate.
- For volume expansion/resuscitation, *Albumex® 4* (4%) may be administered as a rapid infusion to restore perfusion / blood pressure.
- *Albumex® 20* (20%) is hyperoncotic; it increases volume by four times by drawing fluid from the extravascular spaces into the vascular system.

Thrombotrol®VF (Antithrombin III)

Berinert®P (C1 esterase inhibitor; s.29)

Recombinant Clotting Factors

Pharmaceutically manufactured clotting factors that are not derived from blood donations.

They are often confused with blood-donation-derived clotting factors and because some Blood Banks hold these on behalf of their hospitals.

Blood Bank holds a supply of rFVIIa (NovoSeven) for emergencies only. All other recombinant clotting factors are kept in Pharmacy.

Factor VIIa: NovosevenRT must be approved by ICU consultant, Anaesthetist, Haematologist or TMS.

Factor VIII: Advate, Adynovate, KogenateFS, Refacto, Xyntha

Factor IX: Alprolix, BeneFIX, RIXUBIS

Safe Infusion Practice

Contact the Transfusion Nurse Specialist (81620) or Blood Bank (80310) if any concerns

QMR forms

Original QMR022b forms should be sent to Blood Bank. This is to avoid duplication of records.

If a request for issue is scanned to Blood Bank, the issued blood product will be returned to the requesting area with the scanned form. The scanned form then supersedes the original form. Any infusion documentation including administration checks or signatures MUST NOT be transcribed onto the original form.

Documentation

A complete **Record of Transfusion** includes -

- Completed Consent and Prescription including sample signatures / MCNZ registration number
- Completed QMR form with signatures confirming independent bedside checks were performed prior to administration
- Record start and finish times on the QMR form.
- Swing label(s) +/- batch stickers adhered to QMR form
- Clinical Progress note including
    - Indication for infusion
    - signs or symptoms outside normal limits that occurred, and any corrective or clinical actions taken
    - Reference to any Adverse Transfusion Reaction (ATR) - Notification to Blood Bank form (NZBS111F009) if indicated

Controlled Storage of Blood Products

If there is a delay in infusing blood products, return them to Blood Bank immediately or store at 2-8°C in an NZBS approved blood refrigerator. Refer to local policy.

Do not refrigerate after the bottles have reached room temperature.

During storage protect the bottles from light.

Freeze-dried preparations must be infused immediately after reconstitution. Do not re-refrigerate.

Products not containing an antimicrobial preservative must be transfused within 3-4 hours of breaking the product seal.

Lamson Tube

The Lamson system is NOT to be used to transport blood products. Blood Products need to be collected from Blood Bank or transported by Orderlies to prevent breakage of the glass bottles and minimise frothing of the plasma protein during transit. Frothing denatures the proteins.

ABO Compatibility

ABO compatibility does not normally need to be considered. Residual anti-A and anti-B in the final product are usually at clinically insignificant levels. However, in some situations such as high doses Intragam®P are being given to non-group O patients, these patients should be monitored for signs of intravascular haemolysis.

Medications and Vaccines

Do not add any medications to any fractionated blood products. Check manufacturer's instructions on the datasheet.

Passively acquired antibody can interfere with the response to live, attenuated virus vaccine therefore, administration of such vaccines eg. Measles and Varicella should be deferred for at least 3 months after passive immunisations with immunoglobulin preparations.

If immunoglobulin is administered within two weeks of vaccination with a live attenuated virus vaccine, the efficacy of the vaccine may be compromised. Consideration should be given to re-vaccination approximately three months after the immunoglobulin was given.

Datasheets – Manufacturer's Instructions

Specific information about the administration of each product is given in the product information sheet, which come packaged with each unit. Current versions of the data sheets can be accessed through the Clinical Information section of the NZBS website (*www.nzblood.co.nz*) or Medsafe website (*www.medsafe.govt.nz*).

Adverse Infusion Reactions

Blood Product reactions tend to be related to the infusion rate (i.e. faster rate = more severe reaction) and are most likely to occur during the first hour of the infusion.

Document any signs or symptoms outside normal limits that occurred and corrective or clinical actions taken.

Contact Blood Bank (80310) or Infusion Nurse Specialist (81620) for a Fractionated Blood Product Adverse Event Notification Form (NZBS 111F003)

Policy Measurement

CDHB transfusion guidelines are compliant with both the Australia and NZ Society of Blood Transfusion (ANZSBT) and New Zealand Blood Service (NZBS) recommendations.

NZBS DHB Clinical Oversight Programme (Audit) audits for documented evidence that:

- Blood components/products have been administered by a nurse or clinician with the appropriate training and certification to do so.
- Prescriptions are present, accurate and correctly completed
- Informed consent has been provided
- Adequate Record of Transfusion is retained in patient clinical notes for traceability that a blood product was used in the clinical setting. This includes the presence of the issued swing label, documented start and finish times and double independent check signatures evidencing patient ID and product checks have been completed prior to use.
- Policies and procedures related to valid informed consent, prescribing, transfusion administration support safe transfusion practice

References

ANZSBT. (2019). Guidelines for the Administration of Blood Products

NZBS 111G122 Transfusion Medicine Handbook

NZ Blood Service Resource folder

RANSCOG Guidelines. (2019).