

# CLINICAL BUSINESS RULE COVER SHEET



Health  
South Eastern Sydney  
Local Health District

## Prince of Wales Hospital and Community Health Services The Royal Hospital for Women

<b>NAME OF DOCUMENT</b>	<b>Blood Component Management and Administration</b>
<b>TYPE OF DOCUMENT</b>	<b>Clinical Business Rule</b>
<b>DOCUMENT NUMBER</b>	<b>POWH CLIN018</b>
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<b>EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR</b>	<b>Director of Nursing and Clinical Services Director of Clinical Services (Medicine)</b>
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<b>KEY TERMS</b>	<b>Blood transfusion, blood storage, blood administration, blood transportation</b>
<b>SUMMARY</b>	<b>This document outlines the requirements for prescribing, transporting, administration, monitoring, documentation and management and reporting of adverse events for blood and blood components within the Prince of Wales Hospital and Community Health Services.</b>

**COMPLIANCE WITH THIS DOCUMENT IS MANDATORY**

Feedback about this document can be sent to [SESLHD-POWHPolicy@health.nsw.gov.au](mailto:SESLHD-POWHPolicy@health.nsw.gov.au)

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### Blood Component Management and Administration

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#### 1. PURPOSE & SCOPE

This document outlines the requirements for prescribing, transporting, administration, monitoring, documentation and also management and reporting of adverse events for blood and blood components within the Prince of Wales Hospital and Community Health Services.

Patients may be admitted to the Hospital in the Home (HITH) service for the transfusion of red cells in a residential care facility. A direct referral from a General Practitioner or Prince of Wales Hospital (POWH) MO to the PACS MO is required to initiate this service<sup>58</sup>.

Blood component therapy encompasses:

- Red Cell Concentrates
- Platelets
- Fresh Frozen Plasma, Cryoprecipitate and Cryo-depleted Plasma
- 4% Albumin and 20% Concentrated Albumin
- Intravenous Immunoglobulins
- Clotting Factor replacement products

#### 2. RESPONSIBILITIES

Medical Officers  
Registered Nurses  
Enrolled Nurses  
Porters  
Patient Services Assistants  
Phlebotomists

#### 2. DEFINITIONS

##### Definition of NHMRC grades of recommendations

Grade of Recommendation	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

**ARCBS:** Australian Red Cross Blood Service

**Baseline observations** – Vital signs taken within 30 minutes prior to planned procedure / transfusion.

**Cross-match** – blood products are issued to the named patient

**Fresh products**

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- Red cell concentrates
- Platelets- these are usually administered as one pool of four units of platelets or one apheresis unit. Pooled platelets are collected from multiple donations. Apheresis platelets are collected from one donor but are equivalent to 1 pool of random donor platelets.
- Fresh Frozen Plasma (FFP) – usual dose administered 30mL/kg (or 2 or 4 units)
- Apheresis Cryoprecipitate – usually administered as a dose of 3 units (or 6 units of whole blood derived cryoprecipitate)

**Group & Hold** – the blood sample is grouped and screened for antibodies

**NH&MRC:** National Health and Medical Research Council

**Ordering** - mechanism by which Blood Bank are instructed to prepare and issue the component for transfusion

**PCA:** Patient Controlled Analgesia

**Prescription** - legal instruction to administer the blood product or blood component

**Transfusion therapy** – the administration of blood products and blood components

#### 4. COMPETENCY/ASSESSMENT

##### Medical Officers, Registered Nurses and Enrolled Nurses

Clinical Transfusion Practice on [BloodSafe e-Learning](#) via HETI Online <sup>1</sup> – every 5 years <sup>2</sup>

Blood & Blood Product Administration Competency Assessment ([Appendix 2](#)) – every 2 years

##### Enrolled Nurses

Can monitor patients receiving transfusions under the supervision of the Registered Nurse <sup>3</sup>.

Enrolled Nurses without notation (*i.e. holds Board approved qualifications in administration of medicines including administration of intravenous medications*) can also check blood products for administration with a Registered Nurse <sup>3</sup>. Enrolled nurses cannot administer blood products <sup>4</sup>  
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##### Blood Bank Staff

Clinical Transfusion Practice on [BloodSafe e-Learning](#) via HETI Online <sup>1</sup> – every 5 years <sup>2</sup>

##### Porters/Patient Services Assistants

Attend face to face training OR

Transporting Blood on [BloodSafe e-Learning](#) via HETI Online <sup>1</sup> – every 5 years <sup>2</sup>

##### Phlebotomists

Collecting Blood Specimens on [BloodSafe e-Learning](#) via HETI Online <sup>1</sup> – every 5 years <sup>2</sup>

#### 5. CLINICAL BUSINESS RULE

Blood and blood component therapy should only be given when the benefit to the patient outweighs the risk – where there is evidence of little or no benefit, blood and blood component therapy should not be considered a default treatment option.

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The risk of transfusion is often considered to be limited to viral transmission however, it has been shown that other hazards such as clerical errors in bedside patient identification, bacterial contamination of fresh products and transfusion associated lung injury cause greater morbidity and mortality, and should be taken into consideration when the transfusion decision is made.

Documented informed consent is mandatory and must be carried out by the prescribing Medical Officer (MO).

Overnight/out-of-hours transfusion should be avoided unless clinically indicated. Always check urgency with the Medical Officer and if there is doubt do not delay the transfusion<sup>5,6</sup>

#### 5.1 INDICATIONS FOR USE

Product	Indications for Use <sup>7</sup>
<b>Red Cell Concentrates</b>	<p>To increase oxygen-carrying capacity in anaemic patients with clinical symptoms and abnormal lab results. Indications based on Haemoglobin (Hb)</p> <p>&lt;70g/L      Low Hb may be acceptable in some situations</p> <p>70-100g/L    Surgery with major blood loss and signs and symptoms of impaired O<sub>2</sub> transport</p> <p>&gt;80g/L      Chronic transfusion regimen with signs and symptoms</p> <p>                  Bone Marrow Suppression / Failure</p> <p>&gt;100g/L     Specific indications only</p>
<b>Platelets</b>	<p>To control/prevent bleeding associated with deficiencies in platelet number or function.</p> <p><u>Used for prophylaxis when platelet count:</u></p> <ul style="list-style-type: none"> <li>• &lt; 10 x 10<sup>9</sup>/L      Bone Marrow Suppression / Failure</li> <li>• 10 - 20 x 10<sup>9</sup>/L    Bone marrow failure with risk factors (i.e. Sepsis, history / poor haemostasis control)</li> <li>• &gt; 50 x 10<sup>9</sup>/L      Surgery / invasive procedure</li> <li>• 50 – 100 x 10<sup>9</sup>/L    High risk surgery / procedure (i.e. neurosurgery)</li> <li>• Platelet function disorder (There is no reliable indicator in this situation)</li> </ul> <p><u>Used as therapy when platelet count:</u></p> <ul style="list-style-type: none"> <li>• &lt; 20 x 10<sup>9</sup>/L    Minor Bleeding</li> <li>• &lt; 50 x 10<sup>9</sup>/L    Massive haemorrhage</li> <li>• Refer to <a href="#">Clinical Business Rule: Critical Bleeding Protocol</a></li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>➤ Above indices are a guide only and each patient's clinical condition must be assessed</li> <li>➤ Platelets are not considered appropriate in patients with immune mediated platelet destruction such as Thrombocytopenia Purpura (TTP) in the absence of haemorrhage</li> </ul>

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Product	Indications for Use <sup>7</sup>
<p><b>Fresh Frozen Plasma (FFP)</b></p> <p>Please contact Haematologist on call to discuss FFP requests</p>	<p><b>FFP is NOT indicated for:</b></p> <ul style="list-style-type: none"> <li>• Management of coagulopathy without bleeding</li> <li>• Infusion prior to minor invasive procedures</li> <li>• Correction of coagulopathy of liver disease in non-bleeding patients</li> <li>• Reversal of anticoagulation (heparin and oral anticoagulants)</li> <li>• Haemophilia A and B or diagnosis of rare factor protein deficiencies (Factor II, V, XI, XIII – Cryoprecipitate is preferred)</li> </ul> <p><b>FFP is indicated for:</b></p> <ul style="list-style-type: none"> <li>• Single factor deficiencies (where specific concentrates are unavailable)</li> <li>• Bleeding with abnormal coagulation parameters: Acute Disseminated Intravascular Coagulopathy (DIC), Thrombocytopenic Purpura (TTP), Heparin induced Thrombocytopenia (HIT)</li> <li>• Multiple factor deficiency, coagulopathy (coagulopathy studies &gt;1.5 of normal) and bleeding</li> <li>• Major invasive procedures: organ, endoscopic or transbronchial biopsy If INR ≥ 2.0 contact Haematologist for advice</li> <li>• Neurological procedures: neuraxial anaesthesia and lumbar puncture to achieve INR &lt; 1.5</li> <li>• <a href="#">Refer to Clinical Business Rule: Critical Bleeding Protocol</a></li> <li>• Specific indications during Therapeutic Plasma Exchange such as TTP</li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>➤ 3 Factor Prothrombinex and Vitamin K are the preferred reversal methods for reversal of warfarin related coagulopathy and bleeding (Refer to Clinical Business Rule: <a href="#">Warfarin- Guidelines for prescribing, administration, monitoring and dosage adjustment</a>)</li> <li>➤ Patients weight must be known as dose is 12 – 15 ml/kg Each FFP unit contains approximately 250ml</li> </ul>
<p><b>Cryoprecipitate</b></p>	<p>To control bleeding associated with fibrinogen deficiency to maintain fibrinogen &gt; 1.0g/L during:</p> <ul style="list-style-type: none"> <li>• Acute DIC</li> <li>• Isolated Fibrinogen Deficiency associated with bleeding or prior to invasive procedure</li> </ul> <p><a href="#">Refer to Clinical Business Rule: Critical Bleeding Protocol</a></p>

**N.B.** The NH&MRC guidelines have been superseded and prescription and appropriateness should now be guided by the [National Blood Authority- Patient Blood Management Guidelines for up to date information](#)

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#### 5.2 CONSENT <sup>1, 8, 9</sup>

A medical officer must obtain informed written consent from the patient before prescribing any blood and blood component as per [NSW Health Policy Directive PD2005 406](#).

#### Consent Criteria:

- Consent is documented on the standard SESLHD consent to medical treatment form or the SESLHD Blood and Blood Products Administration Form.
- Informed consent should contain a clear explanation of the potential risks and benefits of blood component therapy (including signs and symptoms related to adverse reactions) and alternative therapies, particular to the patient being treated including the right to refuse transfusion.
- Patient information leaflets should be provided and are available in a number of languages from the Clinical Excellence Commission: [Blood transfusion: Answers to some common questions for you and your family](#).
- A separate consent is required for each admission or every 12 months for patients with chronic illness requiring frequent blood/blood component transfusions providing the patient condition and requirements are stable.
- Informed consent must be updated **within** these time frames if:
  - The patient's condition changes
  - Alternative treatments are proposed
  - New risk factors of the treatment are identified
- An interpreter must be used wherever possible for patients of culturally and linguistically diverse communities, see POWH Business Rule [When and How to use Interpreters](#) and hearing impaired patients (Auslan Interpreter). In such cases, the interpreter must also sign the consent <sup>10</sup>.
- In the event of trauma or emergency where the patient or next of kin is unable to consent prior to administration, consent should be obtained as soon as practical after the event.

**Table 1: Risks of Transfusion-transmitted Infection Calculated on Blood Service Data <sup>11</sup>**

Agent and testing standard	Window period	Estimate of residual risk 'per unit' (a)
HIV (antibody + NAT)	5.9 days	Less than 1 in 1 million(1)
HCV (antibody + NAT)	2.6 days	Less than 1 in 1 million(1)
HBV (HBsAg + NAT)	15.1 days	Less than 1 in 1 million(1, 4)
HTLV 1 & 2 (antibody)	51 days	Less than 1 in 1 million(1)
vCJD [No testing]		Possible, not yet reported in Australia
Malaria (antibody)	7–14 days	Less than 1 in 1 million(2)

Notes: vCJD=variant Creutzfeldt-Jakob Disease; (a) The risk estimates for HIV, HCV, HBV are based on Blood Service data from 1 January 2013 to 31 December 2014. HBV risk based on blood service data from the January 2014 to the 16 April 2015. No HTLV incident donors recorded for the period 1 January 2013 to 31 December 2014.

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#### 5.3 REFUSAL TO CONSENT

An individual may refuse the use of blood or blood components as part of their treatment. This may be due to religious reasons (as for Jehovah's Witnesses) or for other personal reasons. In these situations alternative therapies may be necessary to treat or prevent anaemia and ensure adequate tissue oxygenation. The Health Care Record should contain clear documentation that the patient is aware that the planned procedure/treatment may entail a higher risk in the event of further complications. A clinical haematology review is recommended<sup>6</sup>.

Refusal of blood products must be documented in the patient's Health Care record. Clear documentation is necessary of the blood products the patient refuses consent to and acceptable alternatives for administration<sup>5, 6</sup>.

Refer to the following list if you suspect a patient may refuse transfusion:

- Surgical Team to notify Blood Bank (ext 29145) of all Jehovah's Witnesses patients. Blood Bank staff will enter the date and the member of staff who notified them and that the patient is Jehovah's Witnesses in the comments section in Patient Product Inquiry within eMR—specific detail of what the patient will and will not accept will not be documented in this section
- A Haematology AT referral and consult is recommended for all Jehovah's Witnesses patients who require surgery. Acceptable therapies will be discussed and documented in the clinical notes and will ensure Blood Bank have been notified. The surgical team will also need to discuss with the patient procedures they will or will not accept e.g. cell salvage
- Identify whether the patient has an Advanced Care Directive related to declining blood products, if so photocopy and put in the patient's health care record
- [Table 2](#) refers to blood and blood components that a Jehovah's Witness may or may not receive. The on-call haematologist will be able to help with further patient information and should be contacted via switch in cases of an emergency
- If the patient is unconscious or for other reasons is unable to make a decision for themselves and you have reason to suspect he/she may refuse blood or blood components for any reason, then the normal procedure for obtaining consent for a medical procedure through the guardianship board should be followed
- Contact details for Hospital Liaison Committee for Jehovah's Witnesses
  - 10 Eastbourne Avenue, Clovelly, NSW 2031
  - Tel: 02 9665 9918 or 0407 434 181
  - Email: [clovelly10@yahoo.com.au](mailto:clovelly10@yahoo.com.au)

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**Table 2: Treatment that may or may not be received by Jehovah's Witnesses** <sup>12, 13, 14, 15</sup>

Will receive non-blood volume expanders such as Haemacell, Saline, Ringer's Lactate	
May choose to receive as a matter of conscience	Will not receive
Albumin Cryoprecipitate Recombinant clotting Factor replacement products e.g. Factor VIII, Factor IX and rFVIIa Colony Stimulating Factors e.g. G-CSF & Erythropoietin Immunoglobulins Interferon Thrombin	Red Blood Cells Whole Blood Plasma  Platelets White Blood Cells Autologous collection and storage for later use
The following Surgical Techniques may be allowable – on condition that there is a continuous extra-corporeal circuit (blood must be kept in a constant link in the patient's circulatory system): haemodilution, cardiopulmonary bypass, intra/post-operative blood salvage & reinfusion, renal dialysis & apheresis.	

### 5.4 PRESCRIBING & ORDERING

The appropriateness of transfusion should be considered prior to ordering and prescribing blood products. Section 5.1 [Indications for Use](#) provides a guide to appropriateness of transfusion for fresh products. Haemodynamically stable patients falling outside the guidelines should not be transfused unless there are clear clinical indicators. Discussion with a Haematology Registrar or Consultant may assist this decision.

The indication for transfusion or other blood management strategies chosen must be documented in the patient's Health Care Record <sup>5, 6</sup>.

The following lists the minimum criteria for each <sup>6</sup>

#### Prescription must:

- Be documented legibly on the SESLHD Blood and Blood Products Administration Form, alternatively prescription on the Intravenous Adult Fluid Order is permitted.
- Contain patient identification details including family name, first name and date of birth or medical record number (MRN)
- Specify the blood component and volume to be delivered
- State date, time and rate at which the transfusion should take place
- State special requirements e.g. CMV negative, irradiated.

#### Ordering blood or blood components requires:

- Completion of a Blood Transfusion Request Form or eMR Form, including:
  - Patient identification details
  - Clinical notes
  - Pre-transfusion history
  - Blood products required



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- Transfusion checklist (including reason for transfusion)
- Requesting practitioner details
- Urgency of the transfusion
- Date and time the transfusion will take place
- Incomplete forms cannot be processed by Blood Bank, and will delay provision of blood to patients

**Note:** The person collecting the blood sample for cross match completes declaration and signature. See procedure for [Blood Sampling for Cross Match](#).

#### 5.4.1 Cross Matching

Blood sampling for group and hold or cross-match may be performed by a MO, RN, a Technical Assistant assessed as competent in venepuncture or a RN assessed as competent in blood sampling from a central venous access device or arterial line Refer to POWH Clinical Business Rules for [Venepuncture](#) and [Central Venous Access Devices](#).

A group and hold should be collected when it is anticipated that a blood component may be required for a patient. A cross match will be performed on request when it is known that blood components are definitely required.

Blood Bank MUST be informed as soon as possible if cross-matched products are not required.

The Maximum Surgical Blood Order Schedule (MS BOS) is a guide for pre- transfusion cross-matching in stable patients undergoing scheduled surgery. The MS BOS is shown in [Appendix 1](#).

#### Specimen Validity

##### **3 days**<sup>6, 16</sup>

- Patients with a history of transfusion within the last 3 months
- Patients who have been pregnant within the last 3 months
- Patients where transfusion history is not documented on the requested form

##### **7 days**<sup>6, 16</sup>

- Infants up to 4 months of age
- All other specimens

**eMR Warning: All samples in the patient's flow sheet on eMR are designated "current", whether or not they are valid for cross -match. Check Patient Product Inquiry screen through eMR for details on validity of crossmatch - if you are uncertain of the sample validity please contact Blood Bank extension 29145**

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#### 5.4.2 Cross Match Collection

Blood bank has a 'Zero Tolerance Policy' <sup>16</sup>

Samples will not be processed and re-collection will be required where there is a discrepancy between the form and the sample tube or Step 5 is not completed by the collector:

1. Perform pre-procedural requirements as per [Clinical Procedure Safety](#) Clinical Business Rule
2. Check patient identification with cross match form including family name, first name and Date of birth or MRN
3. Ensure the MO has completed all required sections of the cross- match form
4. Collect specimen in an EDTA (pink top) tube via
  - Venepuncture as per [Clinical Business Rule Venepuncture](#)
  - Central venous access device specimen collection as per [Clinical Business Rule Central Venous Access Devices](#)
  - Arterial line as per local unit policy
5. Specimen tubes **MUST BE hand written, DO NOT USE A PATIENT LABEL**  
Include patient's name, date of birth and MRN (when available)  
Date and time of collection and sign the tube.  
Ensure the information is identical to that on the request form.  
The collector must complete and sign the verification section on the request form.
6. Send sample and request to Blood Bank in a biological hazard bag.

#### 5.5 COLLECTION AND STORAGE OF BLOOD COMPONENTS

##### 5.5.1 Collection of Blood Products <sup>5, 6</sup>

1. Ensure the patient is ready to receive the transfusion
2. The patient has a signed consent form & prescription for the blood product
3. The patient has patent intravenous access
4. Check the blood component is ready  
(either via Patient Product Inquiry or phoning Blood Bank if not on eMR)
5. Complete an 'Authority to Issue Blood Products Form' (pink form), ensuring special requirements section for products is completed (i.e. Irradiated, CMV negative etc.).  
This form is completed by the MO or RN responsible for administering the blood product.
6. Blood products are collected from Clinical Specimen Reception  
(Level 4 Campus Centre) and may be collected by a PSA, Porter, EN, RN or MO

##### 5.5.2 Pneumatic Air Tube System

The pneumatic air tube system should not be used for obtaining or returning blood and blood components.

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### 5.5.3 Storage Requirements <sup>1,5,16</sup>

Blood Component	Storage Requirements	Guidelines if Transfusion Delayed
<b>Red Cell Concentrates</b> Only 1 unit may be collected at one time unless dedicated blood fridge is available or Massive Transfusion Protocol (MTP) is initiated	2 – 6 °C  In a designated blood fridge	Maximum time outside of storage requirements prior to commencing transfusion is 30 minutes.  Red cells must be infused within 4 hours of leaving controlled storage  If delay is anticipated immediately return to Blood Bank or designated blood fridge within 30 minutes.
<b>Platelets</b>	On a platelet rocker  <b>Do Not Refrigerate</b>	Platelets will start to clump as soon as they are removed from the rocker.  Commence infusion immediately, or return to blood bank for appropriate storage.
<b>Fresh Plasma Products (thawed)</b>  <b>Plasma Derivatives</b>	Once thawed infuse immediately  or  Store in Blood Bank fridge for up to 24 hours.	<b>FFP</b> and cryo-depleted plasma may be used up to 24 hours after being thawed depending on the indication for use.  If delay is anticipated return to Blood Bank ASAP  <b>Cryoprecipitate</b> must be used within 6 hours of thawing. Keep at room temperature. <b>Do not refrigerate.</b>
<b>Rh D Immunoglobulin</b>	Store in Blood Bank fridge	Maximum time outside of storage requirements prior to administration is 30 minutes.  If delay is anticipated immediately return to Blood Bank within 30 minutes.

Refer to Royal Hospital for Women: Rh D Immunoglobulin in Obstetrics Local Operating Procedure [http://www.seslhd.health.nsw.gov.au/rhw/Manuals/documents/Antenatal\\_Pregnancy%20Care/rhdob.pdf](http://www.seslhd.health.nsw.gov.au/rhw/Manuals/documents/Antenatal_Pregnancy%20Care/rhdob.pdf)

Fractionated Products	Storage Requirements	Guidelines if Transfusion Delayed
<b>Albumin 4%</b>	Below 25°C	Albumin must be infused within 4 hours of leaving controlled storage <sup>5</sup>  If delay is anticipated immediately return to Blood Bank
<b>Albumin 20%</b>	Albumex 20% 100 ml must be stored below 25°C Albumex 20% 10 ml must be stored at 2-8°C	
<b>Clotting factors</b>	2– 8°C in the Randwick Blood Bank Fridge	

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### 5.5.4 Designated Blood Fridges

- Refrigeration of blood and blood components must be in a designated blood fridge that complies with AS3864. Refer to Clinical Business Rule : [Blood in Satellite Blood Fridges: Correct Storage and Daily Checks](#)
- Designated blood fridges are available in:
  - Blood Bank
  - Haematology Oncology Day Care
  - Operating Theatres
  - Cardiothoracic Theatres

### 5.6 COMPATIBILITY

- Red cell ABO compatibility is outlined in Table 3
- Platelets will be ABO matched when possible however ABO incompatible units may be used at the discretion of the medical team depending on the patients' condition and indication for use.
- In regards to plasma products, when the ABO blood group is not available then AB FFP will be issued until the patient's blood group can be determined. If there is no group AB FFP then group A FFP may be used.

**Table 3: Red Cell Compatibility** <sup>17</sup>

Please note these guidelines refer to red blood cells and NOT plasma products

Donor→	O	A	B	AB
Recipient ↓				
O	✓			
A	✓	✓		
B	✓		✓	
AB	✓	✓	✓	✓

#### 5.6.1 Antibodies and Rhesus System <sup>17</sup>

- **Rhesus antigens are expressed on the surface of red cells. If a person is Rhesus positive (Rh +ve) they express the antigen and if they are Rhesus negative (Rh -ve) they do not.**
- If a patient is Rh +ve they may receive Rh -ve red cell concentrates, however: a Rh -ve male may receive Rh +ve red cell concentrates in an emergency. If this occurs it is essential that the patient and their consultant are informed and followed up by a Haematologist. A Rh -ve female of reproductive age should not receive Rh +ve red cell concentrates.
- The development of antibodies in blood may occur following transfusion or pregnancy. Most of these should be detected by subsequent antibody screens. The presence of significant antibodies in a recipient's blood may result in a delay in obtaining appropriate blood for transfusion.

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### 5.7 ADMINISTRATION <sup>5, 6, 18</sup>

The table displays infusion rates in stable, non-bleeding adult patients.

	Red Cell Concentrates	Platelets	Fresh Frozen Plasma (FFP) & Cryoprecipitate	4% Normal Serum Albumin Concentrated (Conc) Albumin 20%
<b>IV Lines</b>	New dedicated IV line Red Cells may follow platelets through the same line	New dedicated IV line Unless MTP Platelets should never follow Red Cells as debris in filter may trap platelets <sup>5, 6</sup>	New dedicated IV line	New dedicated IV line
<b>Frequency of IV line change</b>	Changed on completion or every 12 hours if continuing to transfuse <sup>5, 6</sup>	Changed on completion	Changed on completion or every 12 hours if continuing to transfuse <sup>5, 6</sup>	Changed on completion or every 12 hours if continuing to transfuse <sup>5, 6</sup>
<b>Filters</b>	170 – 200 micron filter to remove clots & clumps of debris	170 – 200 micron filter to remove clots & clumps of debris	170 – 200 micron filter to remove clots & clumps of debris	170 – 200 micron filter to remove clots & clumps of debris
<b>Infusion rates</b>	<b>Routine:</b> 1-3 hrs/bag  For patients at risk of circulatory overload transfuse more slowly with frequent monitoring, the use of diuretics should be considered  <b>Emergency:</b> As per MO- use blood pump set for rapid infusion preferably via <a href="#">blood warmer</a>	Start slowly & increase rate so that each pack is completed within 15-30mins	<b>FFP:</b> Start transfusion slowly then increase the rate so that the pack is transfused within 30 mins  <b>Cryoprecipitate:</b> Start transfusion slowly, then increase the rate so that the standard adult dose is given over 30-60minutes (i.e. rate of 10-20mL/kg/hr)	<b>4% Albumin</b> as ordered depending on clinical condition  <b>20% Albumin</b> usually 2-4hours.

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	Red Cell Concentrates	Platelets	Fresh Frozen Plasma (FFP) & Cryoprecipitate	4% Normal Serum Albumin Concentrated (Conc) Albumin 20%
<p><b>Vital Signs</b> If the patient is not in an open area that allows continuous visual observation consideration should be given to attending the patient for the first 30 mins of transfusion <sup>6</sup></p> <p>Increased monitoring and vigilance for signs of transfusion reaction is required in unconscious or anaesthetised patients <sup>6</sup></p>	<p>TPR + BP + Resps + Oxygen Saturation</p> <ul style="list-style-type: none"> <li>Baseline pre commencement (&lt;30 mins before commencement)</li> <li>15 min post commencement then hourly</li> <li>On completion of transfusion</li> </ul>	<p>TPR + BP + Resps + Oxygen Saturation</p> <ul style="list-style-type: none"> <li>Baseline pre commencement (&lt;30 mins before commencement)</li> <li>15mins post commencement or half way through transfusion, whichever is sooner</li> <li>On completion of pack</li> </ul>	<p>TPR + BP + Resps + Oxygen Saturation</p> <ul style="list-style-type: none"> <li>Baseline pre commencement (&lt;30 mins before commencement)</li> <li>15 minutes after commencement</li> <li>On completion of each pack</li> </ul>	<p>TPR + BP + Resps + Oxygen Saturation</p> <ul style="list-style-type: none"> <li>Baseline pre commencement (&lt;30 mins before commencement)</li> <li>Hourly and on completion</li> </ul>
<p><b>Co Administration</b> Administering two different types of blood components concurrently via separate IV access is not recommended in the event of an adverse reaction it is difficult to ascertain which component is responsible. Unless MTP activated <sup>6</sup></p>	<p>Morphine &amp; Ketamine diluted in normal saline <a href="#">PCA Administration</a> <sup>6</sup></p> <p>In emergency bolus medications can be administered via the same line. Stop transfusion, clamp IV line, flush the line with normal saline to clear blood from the line &amp; administer the medication, flush the line with normal saline, unclamp &amp; restart transfusion <sup>6</sup></p>	<p>Not applicable</p>	<p>Not applicable</p>	<p>Not applicable</p>

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	Red Cell Concentrates	Platelets	Fresh Frozen Plasma (FFP) & Cryoprecipitate	4% Normal Serum Albumin Concentrated (Conc) Albumin 20%
<b>Comments</b>	<p>Can be safely administered using the Volumat AGILIA Pump from Fresenius Kabi</p> <p>Within 30 mins of leaving blood fridge red cells must commence or return to designated blood fridge.</p> <p>Maximum infusion rate: 5mL/kg/hr.</p> <p>All transfusions must be completed within 4 hours of leaving designated blood fridge or the remainder discarded.</p> <p><b>Compatible IV solutions:</b> 0.9% Sodium Chloride solution (Normal Saline) albumin 4% or ABO compatible plasma and the current formulation of Gelofusine® (available in Australia) as stated in the Product Information <sup>6</sup></p>	<p>Can be safely administered using the Volumat AGILIA Pump from Fresenius Kabi</p> <p>Stored on horizontal rocker to prevent clumping – commence immediately or contact Blood Bank for advice on required storage conditions</p> <p><b>Compatible IV solutions:</b> 0.9% Sodium Chloride solution (Normal Saline) <sup>6</sup></p>	<p>Can be safely administered via a pump <sup>5</sup></p> <p>Advise Blood Bank to thaw 20 mins prior to administration</p> <p>Commence immediately or contact Blood Bank for advice on required storage conditions</p> <p>Each pack of FFP or cryoprecipitate should be completed within 4 hours of removal from Blood Bank</p> <p><b>Compatible IV solutions:</b> 0.9% Sodium Chloride solution (Normal Saline) <sup>6</sup></p>	<p>Can be safely administered via a pump <sup>6</sup></p> <p>Store protected from light</p> <p>Administration from glass bottles requires a vented system</p> <p>The product has a peel off label with a batch number to attach to the SEALS Blood Issue Report</p> <p>Used bottles must be discarded in medical waste and are not suitable for recycling <sup>6</sup></p> <p><b>Compatible IV solutions:</b> 0.9% Sodium Chloride solution (Normal Saline) <sup>6</sup></p>

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#### 5.7.1 Administration of Fresh Products<sup>5,6</sup>

Overnight/Out of hours transfusion should be avoided unless clinically indicated. Always check urgency with the Medical officer and if there is doubt do not delay the transfusion<sup>5,6</sup>

**DO NOT** connect/spike the blood product until you have carried out the compatibility check

Standard precautions should be used when administering/disposing of blood products (gloves and eye protection)<sup>5</sup>

1. **Check availability of product** using Patient Product Inquiry (eMR)
2. **Prepare patient** – ID band securely attached to patient, dedicated patent venous access, patient education, signed consent, prescription for transfusion, check and record baseline observations
3. **Request Product** – complete Authority to Issue Blood Products Form (pink form)
4. **Carry out compatibility check AT PATIENT'S SIDE** with another RN or MO using blood product (pack and label), SEALS Blood Bank Issue Report, and prescription immediately prior to administration.
  - Name (if patient is able ask them their full name and date of birth)
  - Date of birth
  - Medical record number
  - Blood group (including Rhesus status and any antibodies)
  - Donation number
  - Correct blood component
  - Special requirements i.e. CMV negative, irradiated etc
  - Expiry date
  - Integrity of pack – discoloration, clots or leaks
  - Crossmatch expiry (if the compatibility label attached to the red cell bag and the SEALS Issue Report differ, ensure the transfusion commences prior to the Issue Report date and time. The SEALS Issue Report will always override the crossmatch expiry label)

If a discrepancy is found during the bedside check, the blood component shall not be transfused until the discrepancy is resolved. Any discrepancies must be reported to Blood Bank immediately and if necessary, discussed with the on call Haematologist.

5. One of the two people involved in the checking process must spike and hang the blood product immediately after checking – if there is a delay then the checking process must be repeated. Administration sets can be primed with 0.9% Normal Saline solution or the blood



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product once it has been checked as detailed above – Refer to [Section 5.7](#) for information on administration sets and filters <sup>6</sup>.

#### 6. Documentation of procedure in patients notes

- a. Monitor and record vital signs as per [5.7 Administration](#)

#### **If reaction occurs STOP INFUSION IMMEDIATELY**

Refer to [5.7.8 Transfusion Reactions and Adverse Events](#) for further management.

- b. Record strict fluid balance on Daily Fluid Balance chart, especially for patients with cardiac and renal complications, at risk of fluid overload and who may require diuretic therapy.
- c. Record time each product was completed

#### 7. On completion flush the line with 50mL of 0.9% normal saline solution to clear line ensuring patient receives the entire product.

Adverse events may occur after completion of the transfusion <sup>6</sup>. Staff should be aware of any change in the patient's clinical condition that may be indicative of a post transfusion reaction and report this to the MO. Staff should also advise the patient to report any significant health changes as this may also indicate early signs of post transfusion reaction.

#### 5.7.2 Leucocyte depletion <sup>5, 6</sup>

All red cells and platelets issued by ARCBS are leucocyte depleted.  
Therefore additional bedside leucocyte filters are not required.

#### 5.7.3 Irradiation <sup>19</sup>

Irradiation of red cells is performed on at risk patients to prevent Transfusion Associated Graft versus Host Disease Refer to [5.7.8 Transfusion Reactions Types](#). Irradiation inactivates T-lymphocytes present in blood while preserving the function of other cells. Irradiated red cells are indicated in adult patients:

- Undergoing or planned bone marrow or stem cell transplantation (within the next 6 months, and at least 3 months post)
- All cases of Non-Hodgkin's lymphoma, including B- and T-cell NHL
- All cases of acute leukaemia
- With Hodgkin's disease
- Receiving purine analogues such as Fludarabine (consider for all cases of chronic lymphocytic leukaemia )
- Receiving Alemtuzumab for malignant and non-malignant disorders and transplantation
- With aplastic anaemia receiving immunosuppressive therapy
- With congenital cellular immunodeficiency

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- Directed donations (from blood relatives)
- Granulocyte transfusions

Separate indications exist in the paediatric setting

Stem cells are **NEVER** irradiated

Blood bank must be notified in writing or via eMR of patients requiring irradiated blood products. Please be aware that it takes 5 minutes to irradiate 1 unit of red cells and Blood Bank recommend contacting them (ext 29145) before sending the Authority to Issue Blood Products form (pink form) to save waiting.

The expiry date of red cells is altered once irradiated to:

- 14 days or
- 24 hours if the patient is at risk of hyperkalaemia

Since November 2010 all platelets supplied by NSW ARCBS have been irradiated at the ARCBS and are labelled as irradiated. The shelf life of platelets remains at 5 days.

#### 5.7.4 Cytomegalovirus (CMV) negative products

All red cell and platelet components are leucodepleted, and these are considered CMV-safe<sup>16</sup>

**Leucodepleted** products are safe for use in haemopoietic stem cell transplant recipients, haematology and oncology patients, solid organ transplants, immunodeficient patients including those with HIV

The administration of CMV negative products to CMV negative recipients is indicated in the following patients<sup>16</sup>:

- Pregnancy
- Intra-uterine transfusion
- Neonates up to 28 days
- Granulocyte recipients who are CMV-negative

CMV-negative paediatric allogeneic bone marrow transplant recipients may receive CMV-negative products in accordance with SCH local guidelines

#### 5.7.5 Blood Warming<sup>5, 6</sup>

Blood warming is required for patients with cold agglutinins or during large volume and rapid blood replacement. It may also be used when transfusion is required in a severely hypothermic patient or during the use of extracorporeal circuits and exchange procedures such as Red Cell Exchanges, Therapeutic Plasma Exchange or intra-operative blood salvage techniques.

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Blood and blood products **MUST NOT** be warmed using water or any method other than thermostatic alarmed coil warmers. It is recommended they undergo at least a 12 monthly maintenance and validation program.

Blood warmers must be used in accordance with manufacturer's guidelines and will be set to normal body temperature of 37°C or slightly less. Red cells should not be warmed above 41°C. Administration sets used with the warmer must be primed as for other blood administration sets prior to use.

Standard precautions should be used when administering/disposing of blood products (this includes gloves and eye protection) <sup>5</sup>

#### 5.7.6 Community Setting- Administration <sup>6</sup>

- The residential care facility Director of Nursing must approve the administration of red cells for each patient.
- The PACS MO must assess the patient for suitability of transfusion in a residential care facility.
- The residential care facility RN must be able to correctly identify the patient.
  - A POWH identification band, or label with patients full name and either date of birth or POWH MRN, will be placed on the patient for the duration of the transfusion.
- Once identification is verified, the compatibility check is performed with the PACS RN, and either a RN from the residential care facility or a MO.
- Commence red cells at a rate suitable for the patient, as prescribed by the MO, ensuring that completion will be within 4 hours from collection from Blood Bank.
- The PACS RN must record baseline observations and remain with the patient until the second set of observations is recorded at 15 minutes. If these are satisfactory the PACS RN may leave the patient in the care of the RN from the residential care facility.
- Observations will be documented and administration will continue as per hospital policy outlined in [5.7 Administration](#).
- Instructions for the management of adverse events and PACS contact numbers must be left with the residential care facility. In the event of an adverse event, the patient must have a medical review and assessment with a view to admission to POWH if required
- The PACS RN will return to the residential care facility prior to the end of the transfusion for completion, will disconnect IV lines, and remove the cannula if it is no longer required.
- A final set of observations and patient assessment should be performed at this time to ensure no adverse events have occurred.
- The patient will be reviewed the following day by PACS RN and/or Registrar to ensure post transfusion complications have not developed.

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- Refer to POWH Clinical Business Rule [Post Acute Care Services \(PACS\) Provision of Care- Hospital in the Home and Rehabilitation](#)

#### 5.7.7 Community Setting- Transporting Red Cells for Transfusion in the <sup>6</sup>

1. Notify Blood Bank that the transfusion is for a HITH patient when cross match is requested.
2. When completing the “Authority to Issue Blood Products Form”, document that an esky is required.
3. Red cells for transport to the community will be packed by Blood Bank in a cooler box/esky suitable for transport.
4. Once red cells are packed and collected from storage in Blood Bank, they must be used for the patient they have been issued to and must be transfused within 4 hours from the time of collection.

#### 5.7.8 Transfusion Reactions and Adverse Events <sup>6, 21</sup>

Side effects of blood transfusion vary from mild to severe and life threatening. Early detection and prompt intervention is required to successfully manage severe reactions.

Reactions can occur at any time during or following a transfusion.

Acute transfusion reactions occur within minutes up to 4 – 6 hours from commencement, with the most severe occurring within the first 15 minutes.

Delayed transfusion reactions may occur within days to months following the transfusion and may also be severe and life threatening.

If any of the above complications develop, immediately activate a PACE Tier 1 or Code Blue call (level dependent on severity of patient status) via 777 and notify the treating physician.

Any suspicion of a transfusion reaction, inform Blood Bank (ext 29145)

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### 5.7.9 Reaction Management <sup>16, 20, 21</sup>

If the patient exhibits any of these signs or symptoms during or within 4 hours of a transfusion:

- **Rise in temp** > 1°C above baseline
- **Hypotension** diastolic BP drop of > 10% of baseline
- **Respiratory difficulty** shortness of breath, wheeze
- **Sudden onset of pain** flank, back or chest pain
- **Urticaria (hives) or Pruritis**
- **Dark Urine**
- **Bleeding, oozing (DIC)**

**Stop transfusion immediately**

Maintain IV access with 0.9% Sodium Chloride

- Record patient vital signs incl. BP, Pulse, Temp & Respirations
- **Re-check Identification of patient and unit of blood**
- Contact MO to review the patient
- Inform Blood Bank - Ext 29145

**Following Medical Review**

**Rise in Temperature  $\geq 1.5^\circ\text{C}$**

**Rise in Temperature  $> 1^\circ\text{C}$  but  $< 1.5^\circ\text{C}$   
without any signs of a serious reaction**

**Suspected Haemolytic Transfusion Reaction**

**Stop transfusion** and report to Blood Bank

**Do not recommence Transfusion**

Continue to monitor vital signs and administer supportive treatment until stable.

**Investigations**

- Return unit of blood to Blood Bank with blood culture request form
- Patient blood cultures
- Re-cross match patient
- Haemoglobin and Direct Antiglobulin Test
- Urinalysis – haemoglobinuria, protein
- Monitor urine output & fluid balance
- Haptoglobins – after 12 hours

**Send to blood bank**

3 EDTA + 1 Clotted tube, first void urine and all blood units – Transfused or not  
Blood Bank will complete Reaction Investigation

**Non Haemolytic Transfusion Reaction  
Slow or stop Transfusion**

**Recommended Management**

- Circulatory Overload – treat as heart failure.
- Allergic reaction – antihistamine, as for anaphylaxis
- Febrile reaction – antipyretics, antihistamine, bacterial examination (Blood unit and patient)
- Endotoxaemia – as for septic shock

Transfusion may be recommenced at a slower rate depending on the severity of symptoms, at the discretion of the Medical Officer following review and management of symptoms.

Unit must be completed or discarded within the time frame specified in Table 5

**Report all transfusion reactions or adverse events through IIMS**

**Document in patient's medical records**

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### 5.7.10 Transfusion Reaction Types <sup>21</sup>

Reaction Type	Signs and Symptoms
Mild allergic	Localised urticaria/rash, pruritis
Severe allergic	Hypotension, tachycardia, flushing, wheezing, anaphylaxis
Febrile	Unexpected fever >38C
Acute haemolytic	Rigors, fever, flank pain, pain along IV line, tachycardia, dyspnoea, hypotension, dark urine, uncontrolled bleeding
Bacterial contamination and septic shock	Very high fever, rigors, profound hypotension, nausea and/or diarrhoea
Transfusion Associated Circulatory Overload (TACO)	Respiratory distress, tachycardia, increased blood pressure, large positive fluid balance or compromised cardiac status
Transfusion Related Lung Injury (TRALI)	Acute respiratory distress, bilaterally symmetrical pulmonary oedema, hypoxaemia, chills, fever, bilateral lung infiltrates on chest x-ray, absence of other risk factors for acute lung injury (i.e. pneumonia, multiple trauma, aspiration). TRALI develops within 6 hours of transfusion.
Delayed haemolysis	Fever, jaundice, lower than expected haemoglobin following transfusion
Transfusion associated graft versus host disease (TA-GvHD)	Fever followed by skin rash, pancytopenia, abnormal liver function and diarrhoea. In adults the usual onset is 8-10 days post transfusion

Allergic, febrile and haemolytic reactions as well as TACO and TRALI are all acute transfusion reactions requiring immediate action. Initial symptoms for varying types of acute transfusion reactions are similar and may not allow immediate identification of the type of reaction.

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#### 5.7.11 Haemolytic Transfusion Reactions <sup>21</sup>

Haemolytic transfusion reactions occur due to the administration of an incompatible unit, most commonly ABO incompatibility. Correct compatibility checking procedures and antibody screening of the unit for transfusion is essential for prevention of this often fatal complication. The seriousness of sequelae following transfusion is directly proportional to the amount of incompatible blood transfused.

Non-fatal haemolytic transfusion reactions and delayed haemolytic transfusion reactions may occur following alloimmunisation creating the presence of minor erythrocyte antigens in the recipient that is not detected during routine antibody screening.

**Management:** Immediate cessation of the transfusion and investigation as outlined above. Supportive measures for the patient should include: maintenance of circulation/perfusion of organs and correction of bleeding abnormalities.

#### 5.7.12 Transfusion Related Acute Lung Injury (TRALI) <sup>21</sup>

TRALI is an acute respiratory distress syndrome occurring up to 6 hours post transfusion. Plasma products are most frequently implicated and carry the highest associated mortality with a frequency of approximately 1 in every 10,000 transfusions, however a non-immune mediated TRALI may also occur following the transfusion of stored platelets and red cells.

**Management** of TRALI requires respiratory support as dictated by the clinical presentation. All patients require oxygen support potentially including mechanical ventilation. TRALI is thought to be the most common cause of transfusion associated fatalities. All suspected TRALI should be notified to the haematologist or registrar on-call, and early ICU review obtained. The haematologist will notify ARCBS.

#### 5.7.13 TA-GVHD (Transfusion Associated Graft Versus Host Disease) <sup>19</sup>

Transfusion associated graft versus host disease is due to immunomodulation in the recipient. Patients at risk include those who are severely immunocompromised, and recipients of blood donated by family members. Immunomodulation of the recipient is related to transfused leucocytes present in transfused red cells and platelets. Symptoms are frequently non-specific with onset of symptoms around 10 days, but up to several weeks following the transfusion. Outcomes are generally poor with a high mortality rate.

**Management:** Difficult and often unsuccessful using immunosuppression with corticosteroids and other immunosuppressive agents such as cyclosporine.

**Prevention:** Gamma irradiation of red cells and platelets transfused to at risk patients

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#### 5.7.14 Transmission of Infection <sup>11</sup>

Transmission of viruses remains a risk with the transfusion of blood products. The incidence and risk of viral transmission has decreased significantly with improvement in screening techniques although may still occur. Residual risk is outlined in [Table 1: Risks of Transfusion-transmitted Infection Calculated on Blood Service Data.](#)

Australia has one of the safest blood supplies in the world in terms of viral safety. We publish estimates of the residual risks of transfusion-transmitted infection as a guide for clinicians in transfusion decision-making and informed consent processes.

#### 5.8 INTRAVENOUS IMMUNOGLOBULIN (IVIg)

IVIg is produced by the fractionation of pooled plasma to produce IgG concentrates. Criteria for use are set by the National Blood Authority and the product can only be ordered from Red Cross if these criteria are met. The appropriate forms must be downloaded from the NBA website and faxed to Red Cross on 02 9234 2050. For after hours and urgent enquiries call 1300 478 348

- Refer to <http://www.blood.gov.au/ivig-criteria> for the Criteria for the Clinical Use of IVIg in Australia
- Refer to <http://www.blood.gov.au/Ig-governance> for Ig product authorisation and management
- Please refer to the full Product Information for each product (note consumer information is also available)
  - [Intragam®10 – CSL Behring Australia](#)
  - [Privigen® – CSL Behring Australia](#)
  - [Flebogamma® DIF - Grifols](#)
  - [Octagam® - Octapharma](#)
  - [Kiovig® - Baxter Australia](#)
- Refer to the [National Blood Authority Australia Website](#) for Patient Information: Immunoglobulin Treatment



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Table 4: Description of Available IVIg <sup>22, 23, 24, 25, 26</sup>

Description	Intragam ®10	Flebogamma 5%	Flebogamma10%	Privigen 10%	Octagam 5%	Octagam 10%	Kiovig 10%
<b>Additives</b>	Glycine	Sorbitol	Sorbitol	L-proline	Maltose	Maltose	Glycine
<b>Need for reconstitution</b>	No	No	No	No	No	No	No
<b>Cautions</b>	<ul style="list-style-type: none"> <li>Different IVIg products have different infusion rates and some adverse reactions may be infusion rate dependent</li> <li>Infusion rates for the elderly, patients with renal or cardiac disease, acutely ill or febrile should be raised cautiously and will frequently not reach the maximum rate</li> <li>Maltose present in Octagam may cause falsely elevated glucose reading on blood and urine strips. Check product information for the test strips in use to ensure they are appropriate for use with maltose containing parenteral products</li> </ul>						
<b>Other considerations</b>	<ul style="list-style-type: none"> <li>First dose, changed product or dose after extended period of time (&gt; 8 weeks since previous dose)</li> <li>IgA deficiency</li> <li>&gt; 65 years of age</li> <li>Volume depletion</li> </ul>			<ul style="list-style-type: none"> <li>Elevated paraprotein levels</li> <li>Pregnancy/lactation</li> <li>Conditions with increased thrombotic risk</li> <li>Obesity</li> </ul>			
<b>Drug interactions</b>	<p>IVIg preparations should not be administered within 2 weeks of vaccinations, they may infer passive immunity for up to 3 months or impair the efficacy of live-attenuated vaccines for up to 1 year, seek MO advice</p>						

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#### 5.8.1 Guidelines for Administration of IVIg

1. IVIg must be ordered by a MO
2. Patient must have a signed written [consent](#) for blood product administration
3. Equipment for resuscitation must be readily available for use during the infusion
4. Prepare patient – ID bracelet or label, dedicated patent venous access, patient education, signed consent, prescription for transfusion, check and record baseline observations
5. Patient information available at the [National Blood Authority Australia](#) Website
6. Request product – complete Authority to Issue Form and send to Blood Bank
7. Prior to administration – wash hands and don non-sterile gloves, prime a new administration set with 0.9% Normal Saline and connect to patient
8. IVIg must be administered separately from other IV fluids or medications, administer via a dedicated line or lumen
9. Allow product to reach room temperature prior to administration
10. Carry out compatibility check - at patient's bedside by two RNs or MOs using IVIg product, SEALS Blood Bank Issue Report, prescription and consent. Check:
  - Name (if patient is able ask them their full name and date of birth)
  - Date of birth
  - Medical record number
  - Correct IVIg product
  - Dosage
  - Product/batch number
  - Expiry date
  - Integrity of product (**DO NOT USE** solutions that have deposits or are cloudy)
  - Consent validity
  - If a discrepancy is found during the bedside verification check, the blood component shall not be transfused until the discrepancy is resolved
11. Do not shake bottle as this can destroy IgG molecules in the protein rich formula
12. Remove plastic cap from bottle and wipe the exposed part of the rubber stopper with an alcohol wipe and allow to dry. Insert the spike of the giving set
13. Commence infusion as per [Table 5: IVIg Administration Rates and Observations for Adults](#) via an infusion pump
14. IVIg needs to be administered immediately after opening as IVIg does not contain anti-microbial agents
15. Doses are usually rounded off to the nearest bottle size; however any unused portion should be discarded
16. Monitor and record vital signs as per [Table 5: IVIg Administration Rates and Observations for Adults](#)
17. On completion flush the line with 50mL of 0.9% Normal Saline and then discard
18. Document procedure in patient's Health Care Record
19. If reaction occurs STOP INFUSION IMMEDIATELY. Refer to [Table 6: Adverse Reactions to IVIg and Clinical Management](#) and complete IIMS
20. Any sealed bottles of IVIg not administered return to Blood Bank as soon as possible

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Table 5: IVIg Administration Rates and Observations for Adults <sup>23,24,25,26,27</sup>

<b>1<sup>st</sup> infusion or &gt; 8 weeks since previous infusion</b> <b>(Patients switching from one IVIg brand to another should be treated as if it was an initial infusion)</b>		
<b>Flebogamma® DIF 5% (50g/L)</b> <b>Octagam® 5% (50g/L)</b>	<b>Intragam® 10% (100g/L)<sup>27</sup></b>	<b>Octagam® 10% (100g/L)</b> <b>Kiovig® 10% (100g/L)</b> <b>Privigen® 10% (100g/L)</b> <b>Flebogamma® 10% DIF (100g/L)</b>
<u>Commence at:</u> <ul style="list-style-type: none"> <li>1 mL/kg/hr for 30 minutes</li> </ul> <u>If tolerated increase rate:</u> <ul style="list-style-type: none"> <li>1 mL/kg every 15 minutes</li> </ul> <b>Maximum rate 5mL/kg/hr</b>	<u>Commence at:</u> <ul style="list-style-type: none"> <li>60mL/hr for 15 minutes</li> </ul> <u>If tolerated increase rate:</u> <ul style="list-style-type: none"> <li>60 mL/hr over 15 minutes</li> </ul> <b>Maximum rate 180mL/hr</b>	<u>Commence at:</u> <ul style="list-style-type: none"> <li>0.6mL/kg/hr for 30 minutes</li> </ul> <u>If tolerated increase rate:</u> <ul style="list-style-type: none"> <li>0.6mL/kg/hr every 30 minutes</li> </ul> <b>Maximum rates:</b> <b>Octagam® = 7mL/kg/hr</b> <b>Kiovig® = 6 mL/kg/hr (some patients may only reach 4mL/kg/hr)</b> <b>Flebogamma® DIF = 4.8mL/kg/hr</b> <b>Privigen® maximum rate 2.4 mL/kg/hr (1st 3 infusions)</b>

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Subsequent infusions (within 8 weeks of last infusion)		
<b>Flebogamma® DIF 5%(50g/L)</b> <b>Octagam® 5% (50g/L)</b>	<b>Intragam® 10% (100g/L)</b>	<b>Octagam® 10% (100g/L)</b> <b>Kiovig® 10% (100g/L)</b> <b>Privigen® 10% (100g/L)</b> <b>Flebogamma® 10% DIF (100g/L)</b>
<u>Commence at:</u> <ul style="list-style-type: none"> <li>1 mL/kg/hr for 30 mins</li> </ul> <u>If tolerated increase rate:</u> <ul style="list-style-type: none"> <li>To previously tolerated maximum rate</li> </ul> <p style="text-align: center;"><b>Maximum rate 5mL/kg/hr</b></p>	<u>Commence at:</u> <ul style="list-style-type: none"> <li>60mL/hr for 15 minutes</li> </ul> <u>If tolerated increase rate:</u> <ul style="list-style-type: none"> <li>180-240 mL/hr over 15 minutes</li> </ul> <p><b>Maximum rate 240mL/hr</b>  <b>Maximum rate 180mL/hr if has renal impairment or &gt;65 years</b></p>	<u>Commence at:</u> <ul style="list-style-type: none"> <li>0.6mL/kg/hr for 30 minutes</li> </ul> <u>If tolerated increase rate:</u> <ul style="list-style-type: none"> <li>To previously tolerated maximum rate</li> </ul> <p><b>Maximum rates:</b>  <b>Octagam® = 7mL/kg/hr</b>  <b>Kiovig® = 6 mL/kg/hr (some patients may only reach 4mL/kg/hr)</b>  <b>Flebogamma® DIF = 4.8mL/kg/hr</b>  <b>Privigen® = 4.8mL/kg/hr (2.4 for ITP)</b></p>
<b>Observations</b>  Blood pressure Pulse Temperature Respirations	<ul style="list-style-type: none"> <li>Baseline</li> <li>Prior to each rate increase or at least 15 minutes for 1st hour</li> <li>15 minutes post increase to maximum rate</li> <li>If patient stable and tolerating infusion, observations are to be performed hourly for the remainder of the infusion</li> <li>Patients should be observed 1 hour post initial infusion</li> <li>Subsequent infusions, patients are to be observed for minimum 20 minutes post completion of IVIg administration</li> <li><b>Do not increase rate if observations are outside normal limits or if patient displays any adverse symptoms</b></li> </ul>	

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### 5.8.2 Side Effects of Intravenous Immunoglobulin <sup>22, 23, 24, 25, 26</sup>

Reactions and adverse events to IVIg will more likely occur on first infusions or infusions after a long break, than on repeat infusions. Symptoms are diverse and will range from mild to severe. [Table 6: Adverse Reactions to IVIg and Clinical Management](#) indicates symptoms, potential causes and management strategies.

**Table 6: Adverse Reactions to IVIg and Clinical Management**

Severity	Symptoms	Causes	Action/Comments
<b>Mild</b>	<ul style="list-style-type: none"> <li>• Headache</li> <li>• Facial flushing / pallor</li> <li>• Non-urticarial skin rash</li> <li>• Itching</li> <li>• Nausea and vomiting</li> <li>• Slight fall in BP (&lt; 10-15mmHg, no SOB)</li> <li>• Abdominal pain</li> <li>• Pain at injection site</li> <li>• Chills</li> </ul>	<p>Usually infusion rate too high</p> <p>(symptoms resolve within 5–10 mins of stopping infusion)</p>	<ul style="list-style-type: none"> <li>• Stop the infusion</li> <li>• Notify a MO to review patient</li> <li>• Antihistamine may be required</li> <li>• If symptoms resolve recommened &amp; continue the infusion at a lower rate for the remainder of the infusion.</li> </ul>
<b>Moderate</b>	<ul style="list-style-type: none"> <li>• Mild – moderate elevation of serum transaminases</li> <li>• Transient impairment of renal function</li> </ul>	Immune response	<ul style="list-style-type: none"> <li>• Caution should be used in patients with a pre-existing renal impairment</li> </ul>
<b>Severe</b>	<ul style="list-style-type: none"> <li>• Precipitous fall in BP (&gt; 10-15mm/Hg with associated symptoms)</li> <li>• Dyspnoea</li> <li>• Chest tightness</li> <li>• Anaphylaxis</li> </ul>	Immune response	<ul style="list-style-type: none"> <li>• Stop infusion and call 777</li> <li>• Treat with oxygen and drugs (adrenaline, promethazine, corticosteroids) as ordered.</li> </ul> <p><b>NOTE</b></p> <ul style="list-style-type: none"> <li>• If anaphylactic reaction Occurs do not recommence infusion. Further treatment with IVIg is contraindicated.</li> </ul>
<b>Delayed Onset</b>	<ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Chest pain</li> <li>• Rigors</li> <li>• Aching legs</li> <li>• Flu like symptoms</li> </ul>	Complement release by macrophages as part of inflammatory response, in the presence of infection	<ul style="list-style-type: none"> <li>• Symptoms usually occur within 24 hrs.</li> <li>• Management of symptoms as ordered following medical review.</li> </ul>
	<ul style="list-style-type: none"> <li>• Thrombophlebitis</li> </ul>		<ul style="list-style-type: none"> <li>• Stop infusion</li> <li>• MO to review patient</li> </ul>
	<ul style="list-style-type: none"> <li>• Haemolytic anaemia</li> </ul>	Immune response causing red cell haemolysis	<ul style="list-style-type: none"> <li>• Usually transient</li> <li>• Can cause red cell sensitisation and difficulty in cross matching.</li> </ul>

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#### 5.9 CLOTTING FACTORS

Clotting factor concentrates are specific factors required to produce a clot. Replacement maybe required as prophylaxis prior to surgery in a patient with a known factor deficiency, such as Factor VIII for patients with haemophilia, or used during major haemorrhage following trauma or surgery. A haematologist should be consulted when the use of specific factor concentrates is indicated.

##### 5.9.1 Prothrombinex-VF<sup>28</sup>

Prothrombinex-VF<sup>TM</sup> is a plasma derived prothrombin complex concentrate that contains factors II, IX and X and small amounts of VII. Indications for use are during the emergency reversal of anticoagulation therapy (Warfarin reversal) and for the prevention and treatment of bleeding in patients with low levels of Factor II or Factor X. The use of Prothrombinex must be authorised by a haematologist unless part of a ROTEM protocol. Refer to [Clinical Business Rule Warfarin- Guidelines for prescribing, administration, monitoring and dosage adjustment](#) for reversal guidelines.

#### Availability

Request Product from Blood Bank

– complete Authority to Issue Blood Products Form (pink form)

500unit vials with 20mL water for injection and transfer filter set, refer to [product information](#) *Note:* Occasionally there are slightly more or less units in the vial, e.g. a 500unit vial may have 513 units or 489 units. Treat the vial as 500 units and give the total content. Do Not Discard any product.

#### Reconstitution<sup>28</sup>

Reconstitution should be performed immediately before administration and should not be stored for later use.

The transfer filter set ([Mix2Vial<sup>TM</sup>](#)) provided with the product must be used according to guidelines as set out in [product information](#).

#### Administration

Administer as a bolus intravenous injection over 5 minutes (approx. 3mL/min).

Dose: For warfarin reversal: 25-50 IU/kg<sup>30</sup>, commonly 30 IU/kg as a single dose.

The product has a peel off label with a batch number to attach to the SEALS Blood Issue Report

#### Adverse Events

Mild to moderate reactions include:

Nausea and vomiting

Fever

Rash / urticaria

Flare reaction at injection site

Shortness of breath

#### Severe reactions are rare, but include:

Allergic reaction, thromboembolic events (Pulmonary embolus, DVT and DIC)

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### 5.9.2 Praxbind (Idarucizumab) <sup>36</sup>

Praxbind is a monoclonal antibody for reversing the effects of Dabigatran (Pradaxa) in life-threatening bleeding. Currently Special Access Scheme (SAS) category A. Refer to [product information](#) and [Antithrombotic Management](#) intranet page. Praxbind is kept in Randwick Blood Bank and use must be authorised by a Haematologist.

### 5.9.3 Factor VIIa (NovoSevenRT®)

Refer to: [Clinical Business Rule: Recombinant Factor VIIa for Life Threatening Bleeding for administration guidelines](#) relating to Factor VIIa.

NovoSeven is kept in Randwick Blood Bank and use must be authorised by a Haematologist. Recombinant Products are manufactured in laboratories. They do not come from blood. They are made with recombinant DNA technology. These product are supplied by Blood Bank, however aren't theoretically a blood product therefore consent for blood & blood product administration is not required.

### 5.9.4 Factor VIII Concentrates <sup>30</sup>

Factor VIII is used for the prevention and control of bleeding in patients with Haemophilia A. The dose required depends on the patient's severity of haemophilia, weight and the Factor VIII levels required. The FVIII level desired varies with differing clinical situations. Administration should always be individualised to the patients needs as determined by the patient's Haematologist.

Refer [to Table 7: Availability Factor VIII Concentrates](#)

### Table 7: Availability Factor VIII Concentrates

Request Product from Blood Bank complete Authority to Issue Blood Products Form (pink form)

<b>Biostat</b> <sup>31</sup> Contains Von Willebrand Factor	250 IU	Supplied with a transfer filter kit ( <a href="#">Mix2Vial™</a> ) and vial containing sterile water for injection (5mL for 250IU and 10mL for 500IU) <a href="#">Refer to product information</a>
	500 IU	
<b>Thrombotrol VF</b> <sup>37</sup>	1000 IU	Supplied with a transfer filter kit ( <a href="#">Mix2Vial™</a> ) and vial containing sterile water for injection. Indications for use are complex and must be discussed with a Haematologist. Refer to <a href="#">Product Information</a> .
<b>Advate</b> <sup>32</sup>	250 IU	Supplied with a BAXJECT II transfer device (BAXJECT II is for single use only) and vial containing sterile water for injection (5mL), Refer to the <a href="#">product information</a> . Recombinant Products are manufactured in laboratories. They do not come from blood. They are made with recombinant DNA technology. These products are supplied by Blood Bank, however aren't theoretically a blood product therefore consent for blood & blood product administration is not required.
	500 IU	
	1000 IU	
	1500 IU	
	2000 IU	
	3000 IU	

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<b>Xyntha</b> <sup>33</sup>	250 IU	Supplied with plastic vial adaptor and pre-filled diluent syringe containing 0.9% sodium chloride solution (4mL) <a href="#">Refer to product information</a> . Recombinant Products are manufactured in laboratories. They do not come from blood. They are made with recombinant DNA technology. These product are supplied by Blood Bank, however aren't theoretically a blood product therefore consent for blood & blood product administration is not required.
	500 IU	
	1000 IU	
	2000 IU	

**Note:** Occasionally there are slightly more or less units in the vial, e.g. A 500 unit vial may have 513 units or 489 units. Treat the vial as 500 units and give the total content.  
**Do Not Discard any product.**

**Reconstitution** <sup>31 -33</sup> - Refer to [product information](#)

Multiple vials are often required. In this situation, reconstituted solution from multiple vials may be drawn up into a single syringe, however a separate transfer filter kit, or transfer needle and filter needle must be used for each product. They are for single use only.

### Administration

Administration will be ordered either as a bolus intravenous injection, loading dose, followed by a continuous infusion, or as intermittent bolus injections BD or TDS depending on the reason for administration and patient requirements.

Slow intravenous bolus injections are administered over 3-5 minutes (approx. 3mL/min). Intravenous infusions are titrated at a rate depending on the dose required.

The product has a peel off label with a batch number to attach to the SEALS Blood Issue Report

### To prepare Factor VIII for an intravenous infusion via a syringe driver:

1. Load the prescribed factor VIII (units and volume) into a 60mL syringe
2. Ensure that a separate filter needle is used to draw up each vial
3. Connect minimum volume extension tubing to the syringe and prime tubing
4. Attach an additive label to the syringe
5. Load the syringe into a syringe driver and set the rate as prescribed by the medical officer

### To prepare Factor VIII for an intravenous infusion added to an infusion bag:

1. Obtain 0.9% Sodium Chloride bag of the specified fluid volume (either 100mL, or 250mL)
2. Withdraw the equivalent volume of saline from the bag, which will need to be added E.g. If the volume to be added is 8,000 unit of factor VIII, and 1000U unit



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vials are supplied, the volume to be added will be 80mL. Therefore remove 80mL saline from the bag before adding the Factor VIII.

If the same dose is ordered and 500 unit vials are supplied, the volume to be added is 160mL. Therefore remove 160mL of saline before adding the Factor VIII.

3. Draw up the prescribed Factor VIII and load into the saline bag
4. Complete and attach an additive label to the fluid bag
5. Prime a standard IV administration set, if required
6. Commence infusion at the rate prescribed by the medical officer

#### Laboratory Monitoring

All patients' receiving Factor VIII require monitoring for bleeding and laboratory assays (APTT and FVIII levels). Blood for monitoring is generally collected in the morning and should be collected before administration of bolus doses. For patients with a continuous infusion ensure the blood is collected from the opposite arm to the infusion.

#### Adverse Events

Mild to moderate reactions include:

Headache	Skeletal pain	Anxiety	Flushing
Back pain	Dizziness	Chest pain	Fever
Arthralgia			

#### 5.9.5 Factor IX Concentrates <sup>30</sup>

Factor IX is used for the prevention and treatment of bleeding associated with Haemophilia B, also known as Christmas disease. Patients with Haemophilia B have a Factor IX deficiency. In NSW there is one plasma derived FIX concentrate (MonoFIX-VF, CSL) and 2 recombinant FIX preparations (Benefix, Wyeth and Rixubis, Baxalta)

The dose of Factor IX is calculated using a similar method to that of Factor VIII and is determined by the patients' medical condition and baseline Factor IX levels by the patients' Haematologist. The use of a particular FIX product will be determined by the patient's Haematologist.

#### Table: 8 Availability of Factor IX Concentrates

Request Product from Blood Bank complete Authority to Issue Blood Products Form (pink form)

<b>MonoFIX-VF</b> <sup>35</sup>	500 IU vial (50 IU factor IX per mL) 10mL vial of water for injection	Supplied with <a href="#">Mix2Vial™</a> and vial containing sterile water for injection, refer to <a href="#">product information</a>
	500 IU vial (100 IU factor IX per mL) 5mL vial of water for injection	

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	1000 IU vial (100 IU factor IX per mL) 10mL vial of water for injection	
<b>BeneFIX</b> <sup>34</sup>	250 IU	Supplied with vial adapter and pre-filled diluent syringe containing 0.234% sodium chloride solution, refer to <a href="#">product information</a> . Recombinant Products are manufactured in laboratories. They do not come from blood. They are made with recombinant DNA technology. These product are supplied by Blood Bank, however aren't theoretically a blood product therefore consent for blood & blood product administration is not required.
<b>Rixubis</b> <sup>38</sup>	250 IU 500 IU 1000 IU 2000 IU 3000 IU	Supplied with BAXJECT II vial adapter and vial containing sterile water for injection. Refer to <a href="#">Product Information</a> . Recombinant Products are manufactured in laboratories. They do not come from blood. They are made with recombinant DNA technology. These product are supplied by Blood Bank, however aren't theoretically a blood product therefore consent for blood & blood product administration is not required.

**Reconstitution** <sup>34, 35</sup> - Please refer to product information

Multiple vials are often required. In this situation, reconstituted solution from multiple vials may be drawn up into a single syringe, however a separate transfer filter kit, or transfer needle and filter needle must be used for each product. They are for single use only.

### Administration

Administration is given undiluted as a slow intravenous bolus injection over 3-5 minutes. The product has a peel off label with a batch number to attach to the SEALS Blood Issue Report

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#### Adverse events

Mild to moderate reactions include:

Headache

Nausea

Chills

Flushing

Fever

Vomiting

Lethargy

#### 5.9.6 Factor XI Concentrate

Plasma derived FXI is a freeze dried preparation of Human Factor XI is used for the prevention and treatment of bleeding associated with Haemophilia C. Patients with Haemophilia C have a Factor XI deficiency.

Indications and dosage require consultation with a Haematologist experienced in treating bleeding disorders.

#### Availability

Request Product from Blood Bank

– complete Authority to Issue Blood Products Form (pink form)

1000 IU vials

#### Reconstitution and Administration

Refer to product information supplied with FXI from Blood Bank

### 6. DOCUMENTATION

Consent Form

Adult Fluid Order Form

Daily Fluid Balance Form

Blood and Blood Products Administration and Consent Form

Authority to Issue Blood Products Form (Pink Form)

SEALS Blood Bank Issue Report

Between the Flags Observation form in eMR

MOSAIQ

Health Care Record

### 7. COMPLIANCE EVALUATION

Twice yearly Standard 7 auditing in clinical areas as per audit schedule

Reporting of mandatory training requirements in Bloodsafe eLearning and face to face module.

Review of IIMS by CNC Transfusion Medicine and Thalassaemia

Transfusion Committee review of IIMS relating to Blood and Blood Products at regular meetings.

Annual Red Cell audit coordinated by CNC.

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### 8. RELATED POLICIES/PROCEDURES/GUIDELINES/BUSINESS RULES

Number	Policy/Procedure/Guideline/Business Rule
1	NSW Health: PD2012_016 <a href="#">Guideline for the Management of Fresh Blood Components</a>
3	POW Nurse Educators. Consensus agreement. August 2015.
4	SESLHD (SESLHDPD/160). 2017 <a href="#">Medication: Administration by Enrolled Nurses.</a>
8	<a href="#">NSW Health: PD2005_406 Consent to Medical Treatment – Patient Information</a>
9	POWH/SSEH CORP002 Business Rule <a href="#">When and How to Use Interpreters</a>
10	<a href="#">NSW Health: PD2017_044 Interpreters - Standard Procedures for Working with Health Care Interpreters</a>
	<a href="#">NSW Health PD2017_032 Clinical Procedure Safety</a>
29	POWH CLIN061 2017 <a href="#">Warfarin- Guidelines for prescribing, administration, monitoring and dosage adjustment</a>
p. 3	POWH Clinical Business Rule 2015 <a href="#">Massive Transfusion Protocol</a>
p. 4	POWH Post Acute Care Services (PACS) Provision of Care- <a href="#">Hospital in the Home and Rehabilitation</a>
p. 8	POWH Clinical Business Rule 2015 <a href="#">Venepuncture</a>
p. 8	POWH Clinical Business Rule 2015 <a href="#">Central Venous Access Devices</a>
p. 9	POWH CLIN014 Clinical Business Rule 2016 <a href="#">Clinical Procedure Safety</a>
p. 16	POWH Clinical Business Rule 2012 <a href="#">Recombinant Factor VIIa for Life Threatening Bleeding</a>
	Australian Commission on Safety and Quality in Health Care, Standard 7: <a href="#">Blood and Blood products</a> , last updated 15/03/2012.

### 8. EXTERNAL REFERENCES

No	Reference
2	Health Education and Training Institute (HETI) <a href="#">NSW Mandatory Training Matrix</a> . Accessed 24/07/2017.
5	Australian Red Cross Blood Service. <a href="#">Flippin' Blood, Second Edition</a> . June 2012
6	Australia and New Zealand Society of Blood Transfusion Inc Royal College of Nursing Australia (2018) <a href="#">Guidelines for the Administration of Blood Products 3<sup>rd</sup> Edition</a>
7	<a href="#">National Blood Authority Australia. Patient Blood Management Guidelines</a> . 2011.
11	Australian Red Cross Blood Service <a href="#">Transfusion Risks and Factors Contributing to Adverse Events</a> (2016) <accessed 24/07/2017>
12	Hospital Liaison Committee for Jehovah's Witnesses, Jehovah's Witnesses: Guidelines to their non-blood medical management. Hospital Information Services, Box 280, Ingelburn, NSW 1890

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14	Hivey, S., Pace, N., Garside, J. P. and Wolf, A.R. 2009 Religious practice, blood transfusion, and major medical procedures. Paediatric Anaesthesia. 19 (10): 934-946 October 2009
15	Gilcreast, D.M., Avella, P., Camarillo, E. & Mullane, G. (2001) Treating Severe Anaemia in a Trauma patient who is Jehovah's Witness. Critical Care Nurse 21 (2): 69-82, April 2001
16	Australia and New Zealand Society of Blood Transfusion Inc Royal College of Nursing Australia (2016) <a href="#">Guidelines for transfusion and Immunohaematology Laboratory Practice</a> 1 <sup>st</sup> Edition
17	<a href="#">Australian Red Cross Blood Service: Component Compatibility</a> (2016) <accessed 24/07/2017>
18	Australian Red Cross Blood Service: <a href="#">Preparing to administer a Blood Components including equipment</a> (2016) <accessed 24/07/2017>
19	<a href="#">Australian and New Zealand Society of Blood Transfusion Ltd (2011) Guidelines for Prevention of Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD). 1<sup>st</sup> Edn.</a>
20	Tinegate, H et al (2012) <a href="#">Guideline on the investigation and management of acute transfusion reactions</a> . BCSH Blood Transfusion Task Force, British Journal of Haematology volume 159, issue 2.
21	Australian Red Cross Blood Service: <a href="#">Transfusion Reaction Immediate Action</a> (2017) <accessed 24/07/2017>
22	Australian Red Cross Blood Service: Intravenous Immunoglobulin (IVIg) <a href="http://www.transfusion.com.au/blood_products/fractionated_plasma/IVIg">http://www.transfusion.com.au/blood_products/fractionated_plasma/IVIg</a> <Accessed 21/02/2017>
23	<a href="#">Product Information Kiovig 10% Human Normal Immunoglobulin Baxter. Approved 30 November 2011</a> <Accessed 24/07/2017>
24	<a href="#">Product Information Octagam 5% Human Normal Immunoglobulin Solution for Infusion Octapharma. Updated 2017</a> <Accessed 24/07/2017>
25	<a href="#">Product Information Flebogamma 5% DIF Grifols</a> . Updated 2012 <Accessed 24/07/2017>
26	<a href="http://www.privigen.com/">http://www.privigen.com/</a> <accessed 24/07/2017>
27	Blood Watch. Comparison of Intravenous immunoglobulin products available under the National Blood Supply arrangement, February 2017.
28	<a href="#">Product Information Prothrombinex-VF Injection. CSL Limited. Recent amendment December 2017</a> <accessed 24/7/2017
30	<a href="#">Australian Red Cross Blood Service: Factor Concentrates (2017)</a> <accessed 24/07/2017>
31	<a href="#">Product Information Biostate Injection (Factor VIII)</a> . CSL Limited. Last Updated February 2013 <accessed 24/07/2017>

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32	<a href="#">Product Information Advate</a> Last updated March 2016 <accessed 24/07/2017>
33	<a href="#">Product Information Xyntha Revised January 2014</a> <accessed 22/11/2017>
34	<a href="#">Product Information BeneFIX May 2011</a> <accessed 24/07/2017>
35	<a href="#">Product Information MonoFIX-VF Amended December 2010</a> <accessed 31/07/2017>
36	<a href="#">Product Information Praxbind 2017</a> , <accessed 22/08/2017>
37	<a href="#">Product Information Thrombotrol VF, September 2014</a> <accessed 22/08/2017>
38	<a href="#">Product Information Rixubis, August 2016</a> <accessed 22/08/2017>

### 10. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
March 1996	0	Unknown
February 2003	1	POWH Blood Transfusion Working Party-Administration of Blood and Blood Products
Aug 2007	2	Tracy Clarke CNC Haem/Onc, Dr Susan MacCallum – Haematologist
Oct 2010	3	Emily Allen CNC Transfusion/Thalassaemia, Dr Susan MacCallum – Haematologist
March 2011	4	Elizabeth Hayes A/CNC Transfusion Medicine, Dr Susan MacCallum - Haematologist, Dr Tim Brighton – Haematologist. Approved by Prince of Wales/Sydney-Sydney Eye Hospital Policy and Procedure Review Committee
March 2012	5	Updated in line to reflect additional imported IVIg products available under the National Blood Supply arrangements. See Section 5.10. Approved by Prince of Wales/Sydney-Sydney Eye Hospital Policy and Procedure Review Committee for distribution.
June 2012	6	Elizabeth McGill A/CNC Transfusion Medicine Updated in line to reflect additional imported IVIg products available under the National Blood Supply arrangements. See Section 5.10. Approved by POW/SSEH Policy and Procedure Review Committee for distribution.
August 2012	7	Updated to reflect training and assessment requirements for clinicians. See page 1. Competency Assessment attached as Appendix 2. Approved by POW/SSEH Policy and Procedure Review Committee for distribution.
June 2013	8	Updated by E. McGill, K. Brown and S. MacCallum. Summary of changes to practice below. Section 5.2- Refusal to Consent- additional requirements include the need for the Medical Officer to document reason for refusal, products refused and that patient understands risk of further complications. Section 5.3 -Prescribing and Ordering- The indication for transfusion or other blood management strategies chosen must be documented in the patient's Health Care Record.

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	<p>Section 5.4- All blood samples must be witnessed (patient, person responsible or staff member ). The witness must sign the collection form confirming the name of the person from whom the sample was collected, against the name written on the specimen tube, is identical. From February 1<sup>st</sup> 2013 blood samples will be rejected by SEALS Blood Bank if there is no witness signature on the collection form.</p> <p>All cross match samples are now valid for 7 days (previously 10 days) with the exception of:</p> <ul style="list-style-type: none"> <li>• Patients with a history of transfusion within the last 3 months</li> <li>• Patients who have been pregnant within the last 3 months</li> <li>• Patient where transfusion history is not documented on the transfusion form</li> </ul> <p>Section 5.4.4- Red cells must be infused within 4 hours of leaving controlled storage (and not within 4 hours of being hung).</p> <p>Section 5.7- Administration must be changed on completion of the transfusion or every 12 hours (previously 8 hours) if continuing to transfuse, whichever comes first.</p> <p>There is no longer a limit on the number of units that can be transfused through a blood administration set as long as flow is maintained. Previously, one administration could be used for transfusing 4 units (8-10 in an emergency) of red blood cells provided the flow rate remained adequate.</p> <p>Section 5.7.2- Irradiation- Blood bank must be notified if blood product requires irradiation.</p> <p>Section 5.7.5- PCA Administration- The only diluents permitted with Co-administration of morphine, pethidine and/or ketamine diluted in Normal Saline solution (0.9% Sodium Chloride).</p> <p>Section 5.8- Requirements for concurrent administration of two different types of blood components to be minimised where possible (except where there is critical bleeding/massive transfusion). Time out is no longer required as the compatibility checking process at the patient bedside is sufficient.</p> <p>Added- Adverse events may occur after completion of the transfusion. Staff should be aware of any change in the patient's clinical condition that may be indicative of a post transfusion reaction and report this to the MO. Staff should also advise the patient to report any significant health changes as this may also indicate early signs of post transfusion reaction.</p> <p>Table 5 specifies infusion rates for non-bleeding adult patients. For patients at risk of circulatory overload it is usually necessary to transfuse more slowly with frequent monitoring and the use of concomitant diuretics should be considered.</p> <p>Table 5- Significant changes including: *Compatible intravenous solutions.</p>
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		<p>*All products can be safely administered via Volumat AGILIA Pump.</p> <p>*Red Cells now infused over 1-3 hours (previously 3-4 hours) and must be infused within 4 hours of leaving controlled storage (and not within 4 hours of being hung).</p> <p>*Vital Signs must be taken on completion of each Platelet pack.</p> <p>*FFP transfusion must be completed within 30 minutes (previously 20 minutes).</p> <p>*Cryoprecipitate rates have changed- refer to table 5.</p> <p>*Normal Serum Albumin bottles to be discarded via medical waste (not suitable for recycling). Observations hourly AND on completion.</p> <p>* Each pack of FFP or cryoprecipitate should be completed within 4 hours of removal from Blood Bank.</p>
July 2013	8	Interim approval by P. Bolton (Director of Clinical Services- Medical) and H. Walker (Director of Nursing and Clinical Services)
September 2013	8	Approved by POW/SSEH Policy and Procedure Review Committee for distribution.
June 2014	9	Updated. Table 5 (Section 5.8) updated to include requirement for monitoring oxygen saturations throughout administration of blood and blood products. Approved by POW/SSEH Policy and Procedure Review Committee.
November 2015	10	<p>Updated.</p> <p>Changes include:</p> <ul style="list-style-type: none"> <li>- Clinical Transfusion Practice course available on <a href="#">BloodSafe e-Learning</a> is required to be completed by Medical Officers, Registered Nurses and Enrolled Nurses every 5 years (previously every 2 years).</li> <li>- All staff who <b>check and/or</b> administer blood and blood products must be competency assessed at least every 2 years</li> <li>-Enrolled Nurses without notation can check and monitor patients receiving transfusions under the responsibility of the Registered Nurse, after completion of the Clinical Transfusion Practice course and competency but are unable to administer.</li> <li>-Blood Bank Staff are required to complete the Clinical Transfusion Practice course available on <a href="#">BloodSafe e-Learning</a> which can be accessed on HETI online every 5 years.</li> <li>-Porters/Patient Services Assistants must either attend face to face training or complete the Transporting Blood course available on <a href="#">BloodSafe e-Learning</a> which can be accessed on HETI online at least every 5 years.-Competency assessment updated.</li> </ul> <p>Approved by POW/SSEH Policy and Procedure Review Committee.</p>
January 2016	11	<p>Updated by E. McGill. Changes reflect the new imported IVIg products (Privigen 10% and Flebogamma 5% and 10% DIF) available under the National Blood Supply arrangements. See Section 5.10</p> <p>Approved by POW Drug and Therapeutics Committee (December 2015.)</p>
February 2016	12	<p>Updated by CNC Transfusion (Elizabeth McGill)</p> <ul style="list-style-type: none"> <li>• From February 1st 2016 Randwick Campus Blood Bank will stock apheresis cryoprecipitate and will eventually replace whole blood (WB) derived cryoprecipitate – 1 unit apheresis cryoprecipitate = 2 units WB derived</li> </ul>



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		<p>cryoprecipitate</p> <p>Section 4 updated to include this information</p> <ul style="list-style-type: none"> <li>Competency code for Enrolled Nurses – CSK 132973 – Appendix 2 updated</li> </ul>
March 2016	12	<p>Approved by POW/SSEH Policy and Procedure Committee for distribution.</p> <p>RHW logo added with approval from RHW Quality Manager.</p>
August 2016	13	<p>Section 5.2 updated by CNC Transfusion (Elizabeth McGill), after detailed incident review and confirmation of recommendations by Randwick Transfusion Committee.</p> <p>Approved by POW/SSEH Policy and Procedure Committee for distribution.</p>
June-September 2017	14	<p>Reviewed &amp; Updated by:</p> <p>Dr Susan MacCallum Haematology Senior Staff Specialist Leanne Crnek CNC Transfusion Medicine &amp; Thalassaemia</p> <p>5.1 Indications for Use – addition of specific guidelines for the use of FFP including treatment dose – addition of MTP&amp; ROTEM algorithm links</p> <p>5.4.2 Cross Match Collection - Witness to sign crossmatch collection form no longer required</p> <p>5.5.3 Storage Requirements – Albumin to be infused within 4 hours - RhD Immunoglobulin added</p> <p>5.7.4 CMV Negative Products - indications for use changed</p> <p>Table 5: IVIg Administration Rates &amp; Observations in Adults – Intragam P 6% removed – no longer supplied</p> <p>5.9.2 Factor VIIa (NovoSevenRT) now supplied by Blood Bank</p> <p>Approved by POWH/SSEH Policy and Procedure Review Committee for distribution.</p>
November 2017 – January 2018	15	<p>Updated to include- expiry date on issue report to be checked in section 5.7.1. Information added to section 5.9.3 in regards to Recombinant Products.</p>
February 2018	15	<p>Approved by POW/SSEH Policy and Procedure Committee for distribution.</p>
March 2018	16	<p>Natalie Murphy A/NM Policy, procedures and safety Updated broken hyperlinks.</p>
August 2018	17	<p>Leanne Crnek CNC Transfusion Medicine &amp; Thalassaemia</p> <p>Updated References &amp; hyperlinks</p> <p>Included Clinical Business Rule: Critical Bleeding Protocol &amp; hyperlinks</p>

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### Appendix 1 Maximum Surgical Blood Order Schedule <sup>16</sup>

The Maximum Surgical Blood Order Schedule is a guide for the routine supply of blood for elective surgical procedures in stable patients. Where a patient is unstable or identified as high risk for bleeding complications additional blood may be requested at the discretion of the surgeon. If a patient has clinically significant antibodies identified at least 2 units of antigen negative blood should be available during the operation regardless of the schedule recommendations.

Surgery	ORDER SCHEDULE (UNITS)	Surgery	ORDER SCHEDULE (UNITS)
<b>General Surgery</b>		<b>General Surgery (Cont.)</b>	
Abdomino-perineal resection	G&S	Splenectomy (massive)	2
Adrenalectomy	2	Sympathectomy	G & S
Appendectomy	Nil	Thyroidectomy	G & S
Bowel resection	G & S	Thymectomy	G&S
Cholecystectomy	G & S	Vasectomy	Nil
Colectomy (subtotal)	G & S	Whipples Procedure	G & S
Colostomy (Closure)	Nil		
Gastrectomy	2		
Gastric stapling	G & S	<b>Cardiothoracic/Vascular</b>	
Haemorrhoidectomy	Nil	AAA repair (elective)	2
Hartman's procedure	G & S	Angiogram	G & S
Hemicolectomy	G & S	Aorto-fem bypass graft	G&S
Hernia repair	Nil	Aorto-iliac bypass graft	G&S
Intra abdominal hernia	G & S	Aortic valve repair	2
Ileostomy	G & S	AV shunt	G & S
Laparoscopy	G & S	CABG	G & S
Laparotomy	G & S	Carotid endarterectomy	G & S
Liver biopsy	Nil	Embolectomy	G & S
Mastectomy	G & S	Empyema drainage	G & S
Mediastinoscopy	G & S	Fem-pop bypass	G & S
Melanoma (wide excision)	2	Femoral aneurysm	G&S
Nephrectomy	G&S	Iliac-fem bypass	G&S
Nephrolithotomy	G & S	Pneumonectomy	G&S
Orchidectomy	G & S	Pleurectomy	G & S
Pancreatectomy	G&S	Pulmonary lobectomy	G&S
Parathyroidectomy	G & S	Thoracotomy	2
Penile surgery	G & S	Varicose veins	Nil

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Surgery	ORDER SCHEDULE (UNITS)	Surgery	ORDER SCHEDULE (UNITS)
Proctocolectomy	2		
Renal Biopsy	G & S		
Renal Transplant	G&S		
Resection of liver	2		
Splenectomy	G & S		
<b>ENT / Head &amp; Neck</b>		<b>Neurological / Spinal</b>	
Craniofacial surgery	2	Craniotomy	2
Laryngectomy	G & S	Laminectomy	G & S
Maxillectomy	2	Scoliosis	4
Neck dissection	G & S	Spinal fusion	G & S
Oesophagectomy	2	Subarachnoid haemorrhage	G & S
Rhinoplasty	G & S		
Septoplasty	G & S	<b>Gynaecological</b>	
Tonsils and adenoids	nil	Caesarean (unless abn placentation)	G & S
		D&C	G & S
<b>Orthopaedic</b>		Ectopic (simple)	G & S
Amputation	G & S	Ectopic (ruptured)	2
Arthroscopy	Nil	Hysterectomy (Abdo / vaginal)	G & S
Fractured ankle	G & S	Laparoscopy	G & S
Fractured humerus	G & S	Myomectomy	G & S
Fractured NOF	G & S	Oophorectomy	G & S
Fractured shaft of femur	2	Ovarian Tumour	2
Fractured Tib/fib (open)	2	TOP	Nil
Fractured pelvis	2	Tubal Ligation	Nil
Nails / pins / plates long bones	G & S	Vaginal repair	nil
THR	G&S	Vulvectomy	G & S
THR revision	G&S		
TKR	G&S		
<b>Urological</b>			
Bladder neck incision / biopsy	G & S		
Cystectomy	G&S		
Cystoscopy + tumour resection	G&S		
Lithotripsy	Nil		
Prostatectomy (open)	G&S		
TURP	G & S		

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### Appendix 2 Competency Assessment

<b>Blood and Blood Product Administration Competency Assessment for: Registered Nurses, Enrolled Nurses and Medical Officers</b> This competency assessment is based on the POWH Clinical Business Rule Blood Component Management and Administration			
Element	Performance criteria	YES	NO
Eligibility verification	<ul style="list-style-type: none"> <li>Successfully completed BloodSafe: Clinical Transfusion Practice (available on HETI Online)</li> </ul>		
Pre-administration	<ul style="list-style-type: none"> <li>Can locate and understand the CBR: Blood Component Management and Administration</li> </ul>		
	<ul style="list-style-type: none"> <li>Verifies the prescription for the transfusion</li> </ul>		
	<ul style="list-style-type: none"> <li>Identifies the clinical indication for the transfusion</li> </ul>		
	<ul style="list-style-type: none"> <li>Checks that informed consent has been obtained and documented and performs/describes action required if consent is invalid or absent</li> </ul>		
	<ul style="list-style-type: none"> <li>Checks patient transfusion history for any previous transfusion reactions</li> </ul>		
	<ul style="list-style-type: none"> <li>Explains the procedure to the patient/carer including frequency of observations, potential signs and symptoms of a transfusion reaction and assesses their understanding of risks and benefits of blood/blood product transfusion (check patient has been offered and/or provided with written information)</li> </ul>		
	<ul style="list-style-type: none"> <li>Baseline observations are taken and documented within 30 minutes of commencement time of transfusion and understands the significance of this</li> </ul>		
	<ul style="list-style-type: none"> <li>Verifies patency of IV device and prepares required equipment (drip stand, pump, IV line) (EN without notation - PIVC only)</li> </ul>		
	<ul style="list-style-type: none"> <li>Checks Patient Product Inquiry on eMR to confirm product is ready to be collected from Blood Bank</li> </ul>		
	<ul style="list-style-type: none"> <li>Completes Authority to Issue Blood Products form</li> </ul>		
Storage and Transport	<ul style="list-style-type: none"> <li>Identifies documentation required for checking patient identity in the Blood Bank and describes/performs the process</li> </ul>		
	<ul style="list-style-type: none"> <li>States action required if blood/blood product cannot be administered or is not required</li> </ul>		
	<ul style="list-style-type: none"> <li>Identifies where blood products can be stored</li> </ul>		
Administration	<ul style="list-style-type: none"> <li>Correctly performs compatibility check at patient's bedside with an appropriate 2<sup>nd</sup> checker using: blood/blood product (pack and label), Blood Bank Issue Report, prescription, consent and patient ID band and checks:                             <ul style="list-style-type: none"> <li>Name (if patient is able ask them their full name and date of birth)</li> <li>Date of birth</li> <li>Medical record number</li> <li>Blood group (include Rhesus status and any antibodies)</li> <li>Donation number</li> <li>Correct blood component</li> <li>Special requirements i.e. CMV negative, irradiated etc.</li> <li>Expiry date</li> <li>Integrity of pack – discoloration, clots or leaks</li> </ul> </li> </ul>		
	<ul style="list-style-type: none"> <li>After completing the transfusion administration checklist describe actions taken if the details did not match identically</li> </ul>		

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	<ul style="list-style-type: none"> <li>Connect blood product to IV giving set (containing 170-200 micron filter) and commences transfusion as per MO order and CBR (RN &amp; MO only)</li> </ul>		
	<ul style="list-style-type: none"> <li>Reminds patient/carer to notify nursing staff if feeling unwell or displays any signs of a transfusion reaction</li> </ul>		
	<ul style="list-style-type: none"> <li>Ensures product is given over the appropriate time frame and observations are carried out in accordance with the CBR and aware of the importance of visual observation</li> </ul>		
	<ul style="list-style-type: none"> <li>Correctly displays/ describes disposal of all equipment on completion of transfusion</li> </ul>		
Management of Transfusion Reactions	<ul style="list-style-type: none"> <li>Describes common signs of a transfusion reaction</li> </ul>		
	<ul style="list-style-type: none"> <li>Describes the actions to be taken in the event of a transfusion reaction</li> </ul>		
Documentation	<ul style="list-style-type: none"> <li>Documents verification/validation checking processes appropriately on prescription and Blood Bank Issue Report</li> </ul>		
	<ul style="list-style-type: none"> <li>Documents clinical observations appropriately and updates fluid balance chart as required</li> </ul>		
	<ul style="list-style-type: none"> <li>Documents procedure in the medical records</li> </ul>		
	<ul style="list-style-type: none"> <li>Aware to complete IIMS if an incident occurs</li> </ul>		
Displays appropriate hand hygiene			
Uses standard precautions as required			

<b>CLINICAL COMPETENCY OUTCOME</b>	<b>DATE:</b> _____
Name: _____ Employee Number: _____	
Participants Comments: _____ _____	
Competent <input type="checkbox"/> Not Yet Competent <input type="checkbox"/> <i>(Discuss reason and develop goals with staff member)</i>	
Assessors Comments: _____ _____	
Name, Signature and Designation of Assessor: _____	
Entered into HETI online (CSK13898 for RNs & MOs CSK13973 for ENs) on:	