TRANSFUSION MEDICINE PROTOCOLS

Blood Product Prescription, Consent and Refusal

This document should be read in conjunction with the Disclaimer

Contents

Aim

Describe the processes and responsibilities relating to the Prescription and documentation of Consent for Blood Products.

Introduction

This protocol addresses the process of prescription and informed consent required prior to the administration of fresh and fractionated blood products. **Fresh blood products** include: Red Blood Cells, Platelets, Fresh Frozen Plasma and

Cryoprecipitate. **Fractionated blood products** include: Albumex, Immunoglobulins including immunoglobulin replacement therapy (e.g. IVIg) and hyperimmune globulins, Clotting Factors (Biostate, Thrombotrol, Prothrombinex and Monofix).

Blood product prescription

The prescription of blood products is the responsibility of a doctor or midwife/ nurse practitioner licensed to prescribe blood products.

The prescription sheet shall contain the full patient identification details and specify:

- The type of blood product, including any special requirements (e.g. Irradiation, CMV Negative, etc.) Refer to Special Requirements for Blood Components within this document for more information.
- The quantity.
- The duration of transfusion.
- Any special instructions (e.g. any medication required before or during the transfusion).

The prescription constitutes the legal instruction to administer the blood product.

The prescribing clinician shall document the following in the patient's medical record:

- The transfusion decision rationale based on recognised clinical practice guidelines National Blood Authority Patient Blood Management Guidelines.
- The outcome of the transfusion including whether or not it achieved the desired effect and the occurrence and management of any adverse effects.

Informed consent

Informed consent is required for all blood products. Prior to a transfusion being administered to a patient the prescribing doctor must have a conversation with the patient/guardian. The discussion must include the following information:

Explain:

- Why are you recommending a transfusion
- What the blood product is, what it does and the expected benefits
- Risks, including both common and rare but serious
- Alternatives, including doing nothing

Ask:

- The patient/guardian is there anything else they would like to know?
- Is there anything they do not understand?

Provide:

- A **Patient consumer information leaflet**. A range of patient information leaflets are available for use at WNHS, these include:

Adults & Babies:

Blood Transfusion - KEMH Patient Information Leaflet

Blood Transfusion for your Baby - KEMH Patient Information Leaflet

Pregnant Women:

Anti D – You and Your Baby

Anti D – Information regarding Anti D for women with early pregnancy loss.

Surgical Patients:

Blood Transfusion – Intraoperative Cell Salvage

All WNHS consumer leaflets are available from Blood Bank or may be viewed on the WNHS Intranet Consumer information link

An interpreter should be provided for non-English speaking patients/guardians. There is also a Multi-cultural consent checklist with brochures available in different languages available on the ARCBS website Multi cultural consent checklist

Document the consent:

- Consent for blood products must be documented in the patient's medical notes e.g. in the progress notes, as a named risk on the consent form for a procedure, on the Generic Consent form (MR295) or on the Neonatology Consent for Blood Products form (MR417).

- Rh D Immunoglobulin (Anti D) - The woman must be informed and appropriately counselled as to the reasons for requiring Anti D. A patient information leaflet should be provided and the informed consent section on the Rh D immunoglobulin Record form (MR007) must be signed.

- In the event of the patient being unable to give consent for whatever reason, Local, State or Federal Legislation regarding consent for a medical procedure will apply.

Frequency of consent

- Acute patients**:** who are receiving a single transfusion associated with surgery or other medical condition should be consented prior to this episode of transfusion. This consent will remain valid for the remainder of the admission.
- Chronic patients: patients undergoing regular/frequent transfusion e.g. oncology, should be consented at the commencement of their treatment or as their condition evolves. This consent will remain valid for 12 months.
- Emergency transfusions: consent will be sought at the earliest opportunity.

In the event of the patient being unable to give consent, whatever reason, local, State or Federal legislation regarding consent for a medical procedure will apply. If the patient/parent REFUSES Blood Transfusion refer to Refusal of Blood Products within this document for further information.

General Risks of Transfusion

The commonest cause of transfusion reactions are fever, chills, hives and rashes. These occur in approximately 1% of all blood transfusions. Fractionated blood products derived from human plasma (e.g. immunoglobulins, albumin) include viral inactivation steps and therefore the viral risks are much lower. See Transfusion Medicine Manual ARCBS. These risks are very small compared with the risks of everyday living e.g. the chances of being killed in a road accident is about 1 in 10,000.

Description of transfusion related adverse events

Adverse reaction	Risk per unit transfused
Anaphylaxis – IgA Deficiency	1: 20,000 to 50,000
Haemolytic Reactions	Acute 1:76,000
	Delayed 1:2,500 to 11,000
Transfusion Related Acute Lung Injury (TRALI)	1: 1,200 to 190,000
Bacterial Sepsis	Platelets 1: 75,000
	Red Cells 1: 500,000
Fluid overload/cardiac failure	Up to 1% of patients receiving transfusions

Risk of transmission of viral infection

Agent and testing standard	Window period (days)	Estimate of residual risk 'per unit'
HIV	5.9	Less than 1 in 1 million
Hepatitis C	2.6	Less than 1 in 1 million
Hepatitis B	15.1	Approximately 1 in 721,000
HTLV I and II	51	Less than 1 in 1 million
Variant Creutzfeldt-Jakob Disease (vCJD) No testing		Possible. Not yet reported in Australia
Malaria (antibody)	7-14 days	Less than 1 in 1 million

Reference: ARCBS (2015) Blood Component Information Circular of Information - An extension of blood component labels.

Refusal of Blood Products

Patient choice includes the right to refuse blood components and blood products. This refusal may occur for a variety of reasons. In many instances this is a result of personal or religious beliefs. One of the religious groups who refuse blood products are the Jehovah's Witnesses.

Whatever the reason for refusal of consent for blood products, it must be discussed between the patient/ family with the Consultant responsible for care. The discussion, decisions and eventual outcome should be clearly documented in the Patient's Medical Records.

Early identification of patients with objections to receiving blood products allows an individual specific care plan to be drawn up in conjunction with the treating Clinical Specialist/ Team. **Contact the Haematology Clinical Nurse Consultant on pager 3257 for Management of Patients who Refuse Blood Products.**

The KEMH Refusal Policy is available for reference. Health professionals may also refer to the Human Tissue and Transplant Act 1982 (s21) or the Consent to Treatment Policy Appendix 7F for the legal situation that applies regarding medical practitioners performing a blood transfusion on a minor without consent. **The doctor must contact the Haematology Head of Department for advice in this situation.**

Jehovah's Witnesses WILL Usually accept:

- Dextrose
- EPO (Recombinant Erythropoietin)
- G-CSF (granulocyte colony stimulating factor)
- Recombinant Factor VIIa (NovoSeven)
- Haemaccel
- Normal Saline, Hartmann's, Ringers
- Dextran

Jehovah's Witnesses WON'T Usually accept:

- Whole Blood, Red blood cells (packed cells)
- Platelets
- Fresh Frozen Plasma
- White blood cells (i.e. Granulocytes)
- Preoperative collection and storage of autologous blood.

Individual Jehovah's Witness decision may vary:

- Immunoglobulins (e.g. Anti D CMV etc.)
- Factor VIII (i.e. Biostate)
- Clotting factors (i.e. Prothrombinex)
- Albumin
- Cryoprecipitate
- Haemodilution
- Intraoperative Cell Salvage (if continuity is maintained with the vascular system).

This guideline is for general information only. Each patient must be treated on an individual basis.

National Blood Authority Patient Blood Management Guidelines

Decision to transfuse should be based on the National Blood Authority Patient Blood Management (PBM) Guidelines. 2011 The aim of these guidelines is to improve clinical outcomes by avoiding unnecessary exposure to blood components.

- Module 1 Critical Bleeding/ Massive Transfusion https://www.blood.gov.au/pbm-module-1
- Module 2 Peri-Operative https://www.blood.gov.au/pbm-module-2
- Module 3 Medical https://www.blood.gov.au/pbm-module-3
- Module 4 Critical Care https://www.blood.gov.au/pbm-module-4
- Module 5 Obstetrics and Maternity https://www.blood.gov.au/pbm-module-5
- Module 6 Neonatal and Paediatrics https://www.blood.gov.au/pbm-module-6

Indication for red blood cells

Refer to Red Blood Cells (RBC) Administration

Indications for platelets

Refer to Platelets – Single Donor Apheresis Leucocyte Depleted Platelets Administration

Indications for fresh frozen plasma and cryoprecipitate

Refer to Fresh Frozen Plasma and Cryoprecipitate Administration

Special Requirements for Blood Components

Cytomegalovirus (CMV) negative blood products

CMV negative blood products minimise the risk of transfusion-transmitted cytomegalovirus (CMV) which is a common virus typically carried by leucocytes. CMV negative cellular blood components are available for CMV seronegative patients who are at risk of severe CMV disease. These include:

- Recipients of intra-uterine transfusion.
- Neonates less than 4 months of age.

All blood components in Australia undergo leucodepletion, which provides a significant degree of CMV risk reduction. This measure is considered adequate risk reduction for all other patients requiring transfusion (including haemopoetic stem cell and organ transplant patients and immune deficient patients without the requirement for additional CMV seronegative components. FFP, Cryoprecipitate and other plasma-derived blood components do not require CMV testing.

Irradiated blood products

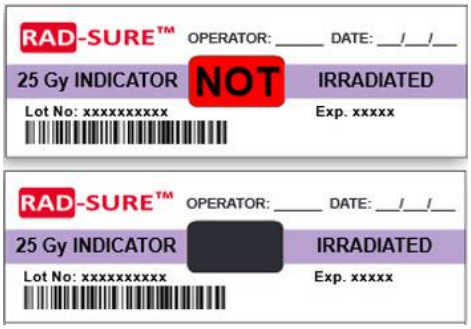
Transfusions of blood products that contain viable lymphocytes (RBC, platelets and granulocytes) to immunosuppressed patients should be irradiated to prevent the proliferation of T lymphocytes, which is the immediate primary cause of Transfusion-

Associated Graft versus Host Disease (TA-GvHD).The minimum dose is 25 Gy. Patients at risk of TA-GvHD include:

- Recipients of intrauterine transfusion (IUT) and neonatal exchange transfusion
- Neonates who have received an IUT
- Patients with congenital immune deficiencies, haematologic malignancies or receiving high dose chemotherapy
- Recipients of stem cell or bone marrow transplants
- Patients with aplastic anaemia receiving immunosuppressive therapy
- Recipients of directed donations from family members
- Recipients of HLA-matched platelets and granulocyte transfusions.

For more information on TA-GvHD refer to ANZSBT Guidelines for the Prevention of Transfusion-Associated Graft-Versus-Host Disease, 2011

Blood product irradiation is identified using the Radsure™ system. A label is applied to the blood pack prior to irradiation. The words NOT IRRADIATED are visible. Once irradiation has taken place, the word IRRADIATED remains visible.



Irradiation will reduce the shelf-life of red cells. Carefully check the expiry dates/times on the irradiated red cell blood pack label/patient compatibility label. If unsure of expiry date and time contact the Transfusion Medicine Unit (TMU).

Washed red cells

Washing red cells in 0.9% saline removes unwanted plasma proteins, including antibodies. May be indicated for patients with:

- Reactions to transfused plasma proteins e.g. Anti-IgA.
- Severe allergic reactions of unknown cause.
- Paroxysmal Nocturnal Haemoglobinurea (reacting to filtered fresh red cells).

For more information on indications for washed red cells see www.transfusion.com.au.

IgA deficient components

Rare IgA deficient fresh blood components are available from ARCBS for patients with IgA deficiency. Frozen FFP units are in stock and RBC and platelets can be collected from rare donors upon demand. In an emergency, if IgA deficient red cells are unavailable, washed red cells can be provided.

References

- Australian & New Zealand Society of Blood Transfusion (ANZSBT) & Royal College of Nursing Australia (RCNA) Guidelines for the Administration of Blood Products 2nd Edition, December 2011 http://www.anzsbt.org.au/publications/index.cfm#societyg
- ANZSBT Guidelines for Pretransfusion Testing, 4th Edition, ANZSBT, 2007 http://www.anzsbt.org.au/publications/index.cfm#societyg
- National Blood Authority – Guidance for the Provision of Cell Salvage 2014 http://www.blood.gov.au/ics#ics-guidance
- Human Tissue and Transplant Act 1982 (s21)
- Consent to Treatment Policy Appendix 7F
- British Committee for Standards in Haematology, Blood Transfusion Task Force. The Administration of blood and blood components and the management of transfused patients. Transfusion Medicine; 1999. 9: 227-238.

Related policies

- National Safety and Quality Health Service Standards, October 2012. Standard 7: Blood and Blood Products

Related WNHS policies, procedures and guidelines

- WNHS Blood Transfusion Checking Procedure
- WNHS Blood Products - Pre Transfusion Testing for Adults and Neonates
- WNHS Autologous and Direct Blood Donation
- Women & Newborn Health Service Patient Identification Policy
- WNHS Pharmacy Medication Checking and Administration
- Neonatology Clinical Care Guidelines
- Obstetrics and Gynaecology Clinical Guidelines

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Author / Reviewer:	Consultant Haematologist, Scientist in Charge Transfusion Medicine, KEMH Transfusion Coordinator		
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Standards Applicable:	NSQHS Standards: 1 Governance, 2 Consumers, 5 Patient ID/Procedure Matching, 7 Blood Products		
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