Australian Red Cross
BLOOD SERVICE

# Blood Component Information

## CIRCULAR OF INFORMATION

An extension of blood component labels

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Australian governments fully fund Red Cross for the provision of blood products and services to the Australian community.

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# Introduction

The purpose of this *Blood Component Information* (Circular of Information) is to describe the blood components produced by ARCBS, including a description of the blood collection process, method of manufacture, critical manufacturing steps, clinical indications for use and administration methods. The *Blood Component Information* is considered an extension of blood and component labels as the space on these labels is very limited. Blood components are biological products and blood cells are living human tissue intended for use in the treatment of patients. Professional judgment based on clinical evaluation determines the selection of components, the dosage, the rate of administration and decisions in situations not covered in this general statement.

The ARCBS vision of "sharing life's best gift" is achieved through partnership with the Australian community to improve health outcomes, by providing sufficient, quality blood products, tissues and expert services. ARCBS complies with the regulatory framework of: the Therapeutic Goods Act, 1989; Therapeutic Goods Order *Standards for Blood Components (No 66)*; Therapeutic Goods Order *Amendment to Therapeutic Goods Order No 66 - Standards for Blood Components*; the Australian Code of Good Manufacturing Practice – Human Blood and Tissues; and the Council of Europe *Guide to the Preparation, Use and Quality Assurance of Blood Components.*

## IMPORTANT INFORMATION

Careful donor selection and available laboratory tests do NOT eliminate all potential hazards of blood transfusion. The risk of transmitting infectious agents is present, including bacteria, parasites, viruses, and the agent of variant Creutzfeldt-Jakob disease. In addition, blood components may contain immunising substances other than those indicated on the label. For example, a unit of platelets also contains residual red blood cells and white blood cells. Serious transfusion reactions are rare but may be life-threatening. Therefore, this *Blood Component Information* as a whole or in part cannot be considered or interpreted as an expressed or implied warranty of the safety or fitness of the described blood or blood components when used for their intended purpose.

Attention to the specific indications for blood components is needed to avoid inappropriate transfusion. Correctly identifying the patient, both during collection of the pre-transfusion sample and before starting the transfusion, is vital in avoiding 'wrong blood' episodes. ABO-incompatible transfusions are usually due to identification errors.

Alternatives to homologous blood transfusion, including haematinic therapy and autologous transfusion techniques, such as intra-operative cell salvage and pre-operative normovolaemic haemodilution, should be considered when appropriate, to reduce the potential risks of disease transmission and immune reactions from homologous transfusions. It should be noted, however, that autologous blood does not remove all the risks of transfusion, particularly the risks of transfusion of the "wrong blood" and bacterial contamination. The risk/benefit profile of not transfusing any product should also be considered.

This *Blood Component Information* is supplied to conform to the regulations of the Therapeutic Goods Administration (TGA).

## Blood donor selection and collection of blood

In Australia, blood and its components are collected at fixed and mobile collection centres in accordance with recommendations from the World Health Organization (WHO), International Society of Blood Transfusion (ISBT), and the International Federation of Red Cross and Red Crescent Societies, from volunteer, non-remunerated low-risk donors who have:

- satisfactorily completed a confidential interview and donor declaration about high-risk behaviour, practices, and circumstances that should cause them to refrain from donating;
- satisfactorily completed a health assessment that includes a questionnaire on past and present medical conditions;
- satisfied minimum physiological criteria; and
- been instructed to contact the blood service, even after donation, with any information that may be relevant to their health or which may affect the suitability of their donation.

Blood collection is undertaken in a manner to ensure the safety of the donor and staff whilst maintaining the safety and efficacy of the collected blood.

## Testing of donor blood

Blood donations are tested in order to:

1. Allow appropriate selection of blood for transfusion; for example, to permit ABO compatibility between donor and recipient.
2. Minimise or prevent (where possible) adverse consequences of transfusion; for example, to prevent transmission of infections that can cause disease in transfusion recipients.
3. Identify donors whose donations are not suitable for transfusion. For example, donors who carry transfusion-transmissible infections must be notified and counselled.

All tests are performed in licensed facilities, according to the principles of good laboratory and manufacturing practice, and following the manufacturers' instructions and strict ARCBS guidelines and standard operating procedures.

In Australia, mandatory tests for all blood donations are for ABO and Rh(D) blood groups, red cell antibodies, and the following infections: human immunodeficiency virus (HIV) 1 and 2, hepatitis B and C, human T-cell lymphotrophic virus (HTLV) I and II, and syphilis. Test results are checked before blood components are released for clinical use or further manufacture. Only donations that have satisfactory blood group results, are non-reactive for infectious disease screening and meet other defined specifications are released. If an infectious disease screening test is confirmed reactive, the donation is destroyed.

In order to minimise the risk of bacterial contamination of platelets, ARCBS performs screening by culture for bacterial contamination on all platelet components.

# Processing blood into components

Blood component therapy allows tailored treatment to give the patient what is required to correct a clinical problem. Components are prepared by various methods of physical separation, such as centrifugation. Component therapy makes good use of donated whole blood and other resources. The use of centralised processing facilities, harmonisation of procedures based on a pharmaceutical production model, and good manufacturing and laboratory practice (GMP/GLP) allows production of a high quality, safe, consistent product in a controlled and cost-effective manner.

# Blood component therapy

The general principles of blood component therapy include:

- clinical decisions based on a correct and specific clinical and laboratory diagnosis wherever possible; where
- transfusion therapy can provide short or long term support; to
- effectively and efficiently provide or replace missing or malfunctioning elements of the blood or immune system; while
- bearing in mind risks and benefits to the patient; and
- considering availability, costs and the importance of making good use of a valuable and limited community resource.

For these reasons, whole blood is rarely used for transfusion today and most therapy involves the transfusion or administration of specific blood components.

As with other medicinal therapies, each blood component has specific clinical indications, known benefits, and potential adverse reactions. The need for a blood component should take into account the patient's unique circumstances, and the dose should be tailored to the individual clinical situation as appropriate. The National Health and Medical Research Council (NHMRC) and the Australian Society of Blood Transfusion (ASBT) have published clinical practice guidelines for the use of blood components[1]. These are included in Appendix I.

Hospital transfusion committees should play an important role in monitoring adherence to national guidelines, developing local institutional clinical transfusion practice policies and procedures, and supervising educational, training and audit activities and the reporting of adverse reactions. *The Australian and New Zealand Society of Blood Transfusion* (ANZSBT) Guidelines for Pretransfusion Laboratory Practice provides guidance with respect to the establishment and responsibilities of hospital transfusion committees[2].

# Blood component labelling

Labels contain the following information:

- Proper name (e.g. Whole Blood or component), including any qualifications or modifications;
- Temperature range at which the component is to be stored;
- Anticoagulant and/or additive used in the preparation of the components, when appropriate, and the volume;
- Contents or volume (standard content, according to this *Blood Component Information*, is assumed unless otherwise indicated on the label);
- An identifier indicating that the collection and processing was performed by ARCBS (all communications should be addressed to ARCBS in your capital city);
- Expiry date (and time if applicable), which varies with the component, anticoagulant, additive, and method of preparation (*when the exact expiry time is not indicated, the product expires at midnight on the day of expiry*);
- Donation or pool identification number;
- When a blood component is split into two or more components, each subunit is identified with a unique split code;
- Donor's category, e.g. volunteer, autologous or directed;
- ABO blood group and Rh(D) status;
- Special handling information, as required;
- Donation tested and non-reactive for HIV I & 2, hepatitis B & C, HTLV, and syphilis;
- The following statements:
    - PROPERLY IDENTIFY INTENDED RECIPIENT;
    - DO NOT USE IF CONTENTS SHOW VISIBLE SIGNS OF DETERIORATION;
    - WARNING: THIS PRODUCT MAY TRANSMIT INFECTIOUS AGENTS;
    - SEE CIRCULAR OF INFORMATION FOR CAUTIONS & INSTRUCTIONS.

Blood component labels incorporate variable amounts of clinically important information, such as red cell phenotype, CMV antibody status and irradiation status. It is important that components should always be transfused on the basis that they are positive or negative for particular antigens (e.g. Rh(D), Rh(E), or K) or have been processed in a particular way (e.g. leucocyte depleted, irradiated) ONLY when the labels confirm the desired characteristics on the component issued for transfusion.

A list of blood component label modifier text and their explanations is provided in Appendix IV.

## Storage, transport and handling

Red cells, fresh frozen plasma, cryoprecipitate and platelet concentrates should be stored and transported at temperatures in compliance with the requirements listed in the table below.

| Component | Storage Temperature Range | Transport Temperature Range | Comments |
|---|---|---|---|
| Red Cells | 2-6ºC | 2-10°C | All blood refrigerators, including theatre and other holding refrigerators, must comply with AS3864 (1997) as amended from time to time. |
| Whole Blood – Fresh Unrefrigerated | 20-24ºC | 20-24ºC | |
| Fresh Frozen Plasma Cryo-depleted Plasma Cryoprecipitate | At or below -25ºC | At or below -25ºC | Plasma freezers must comply with AS3864 (1997) as amended from time to time. |
| Platelets | 20-24ºC | 20-24ºC | Must be stored on a platelet agitator. |

- Handling of refrigerated components outside of refrigeration should be kept to a minimum to ensure that maximum temperature requirements are not exceeded.
- Red cell components must not exceed 30 minutes at room temperature at each occasion in accordance with the AABB Technical Manual[3] as amended from time to time.
- Components should be maintained in a controlled temperature environment until administered.
- Components should be transfused as soon as possible after removal from the required storage conditions.
- Components must be handled and stored in a way that minimises the possibility of product tampering.

# Administration methods

ARCBS recommends that transfusing facilities promulgate guidelines with the support of their clinical, scientific, and other relevant staff. Institutional guidelines may be based on:

- *National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines for the Appropriate Use of Red Cells, Platelets, FFP and Cryoprecipitate[1];*
- *Australian and New Zealand Society of Blood Transfusion (ANZSBT) and Royal College of Nursing of of Australia (RCNA) Guidelines for Administration of Blood Components[4];*
- *Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for Pretransfusion Laboratory Practice[2];*
- *Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for Blood Grouping and Antibody Screening in the Antenatal and Prenatal Setting[5]; and/or*
- *Guidelines of The World Health Organization (WHO)[6], British Committee for Standards in Haematology (BCSH)[7], or other appropriate organisations.*

The ANZSBT Guidelines provide guidance especially in the areas of sample identification, compatibility testing, issue and transfusion of blood components, and investigation of transfusion reactions. All clinical staff involved in ordering, preparing, issuing, and transfusing blood components must be trained in the correct procedures, and must be familiar with the general and institutional requirements for transfusion practice.

**Identification of patient, samples, and unit(s) for transfusion**

- To ensure correct administration of blood components, the intended recipient must be properly identified at each stage of the process, from labelling of samples and request forms at the patient's bedside, through to commencement of transfusion.
- The appropriate component must be selected according to specific clinical indications. This decision should be documented on the request form and in the medical record.
- When a unit is issued or received for transfusion, patient and unit details must be confirmed according to approved procedures. This should be performed by two qualified staff.
- Transfusions must be clearly documented in the patient's medical record, including: indication for transfusion; type, number and special requirements of units requested; unique donation numbers of units transfused; starting and finishing times; periodic vital signs; and other relevant details.
- Signatures and identity of staff issuing, transporting, and administering transfusions must be recorded.
- Records should be retained for the required period.

**Inspection of components**

- Prior to issue and transfusion, components should be inspected visually. If there is any evidence of haemolysis, clot formation, a significant colour change in the blood bag as compared with the tubing segments, tampering or other suggestion that the unit is not suitable for transfusion, it must not be transfused and should be returned to the issuing blood bank or ARCBS for further evaluation.

**Administration procedures**

- Components should be mixed thoroughly by inversion before use and then transfused through an intravenous line approved for blood administration and incorporating a standard (170-200µm) filter to remove clots and aggregates.
- The container must not be compromised (e.g. entered, spiked, vented) prior to use.
- No medication or solutions should be added to or infused through the same tubing with blood components except 0.9 percent Sodium Chloride, Injection. ABO-compatible plasma, 4 percent Albumin, or other suitable plasma expanders may be used only with approval of the patient's physician. Electrolyte solutions containing calcium (such as Haemacel) must *never* be added to or administered through the same intravenous line as blood components containing citrated anticoagulant.
- Plasma thawing devices, intravenous fluid pumps and blood warmers should all be used according to the manufacturer's instructions. Their safety and appropriateness for blood components should be established prior to use. Equipment should be monitored and undergo regular maintenance.
- Blood components may be warmed during or just prior to transfusion, if clinically indicated. Only designated blood warming devices should be used and these must be operated strictly according to the manufacturer's instructions.
- Thaw frozen blood components using an approved method such as a temperature-controlled waterbath maintained between 30 and 37ºC or in an *approved* microwave device. Care must be taken to prevent contamination of entry ports. The use of watertight protective plastic over-wraps is recommended. Do not thaw components in a domestic microwave oven or under hot water directly from the tap.
- Blood components have been prepared by techniques that aid in preserving sterility up to the time of expiration. If the container is opened in a fashion that violates the integrity of the system for any reason, the component expires four hours after opening if maintained at room temperature (20-24ºC). Transfusion of a particular unit should be completed prior to component expiry or within four hours, whichever is sooner.
- Unless otherwise indicated by the patient's clinical condition, the transfusion should proceed no faster than 5mL/min for the first 15 minutes. The patient should be closely observed during this period as life-threatening reactions may occur after only a small volume of blood.
- If a transfusion reaction occurs, the transfusion should be discontinued immediately and appropriate therapy initiated. Transfusion should not resume without thorough clinical review.
- All significant adverse reactions to transfusion, including possible bacterial contamination of a blood component or suspected disease transmission, should be immediately reported to the transfusing facility's laboratory/blood bank and ARCBS.
- In the case of a transfusion reaction, the remainder of any implicated blood components should be retained for further investigation.

For more information on transfusion administration, see publications from the ANZSBT, RCNA, WHO, and AABB.

## Adverse reactions

Adverse reactions may be broadly classified as acute or delayed, and immunological or non-immunological. See Appendix II for the principal adverse reactions to blood components. Further information on aetiology, incidence, diagnosis, management, and prevention of transfusion reactions appears in:

- *ARCBS website for health professionals,* available at www.transfusion.com.au.
- *Transfusion Reactions, 3rd edition.* Popovsky M (ed). AABB Press, Bethesda, 2007.
- *Serious Hazards of Transfusion Annual Report 2007. Available at www.shotuk.org.*
- *AABB Technical Manual,* 16th edition. Roback JD (ed). AABB Press, Bethesda, 2008. Chapter 8: Infectious disease screening, and Chapter 27: Non-infectious complications of blood transfusion.
- *The Clinical Use of Blood in Medicine, Obstetrics, Paediatrics, Surgery and Anaesthesia, Trauma and Burns.* World Health Organization, Blood Transfusion Safety, Geneva, 2005.
- *Australian and New Zealand Society of Blood Transfusion (ANZSBT) and Royal College of Nursing of Australia (RCNA) Guidelines for Administration of Blood Components, 2004.*

Current risk estimates for disease transmission by blood transfusion in Australia are published periodically in *Medilink*, available at www.transfusion.com.au.

# Additives and anticoagulants

| Anticoagulants used for whole blood collections (61-69mL used for the collection of 450mL ± 10% of whole blood) | | | | |
|---|---|---|---|---|
| **Constituents in 63mL** | **CPD (Citrate Phosphate Dextrose)** | | | **CPDA-1 (Citrate Phosphate Dextrose Adenine)** |
| Manufacturer | Terumo Corporation | Pall Corporation | Fresenius | MacoPharma |
| Sodium citrate dihydrate | 1660mg | 1656mg | 1657mg | 1660mg |
| Citric acid monohydrate | 210mg | 206mg | 206mg | 210mg |
| Dextrose monohydrate | 1610mg | 1610mg | 1610mg | 2010mg |
| Sodium phosphate dihydrate | 160mg | 140mg | 158mg | 160mg |
| Adenine | 0mg | 0mg | 0mg | 17.3mg |

| Red cell additive solution (100mL used with red cells from 450mL ± 10% of whole blood) | | |
|---|---|---|
| **Constituents in 100mL** | **SAGM** | **SAGM-2** |
| Manufacturer | Fresenius<br>MacoPharma<br>Pall Corporation | Terumo Corporation |
| Dextrose monohydrate | 900mg | 0mg |
| Dextrose anhydrous | 0mg | 818mg |
| Sodium chloride | 877mg - 880mg[a] | 877mg |
| Mannitol | 525mg - 530mg[b] | 525mg |
| Adenine | 17mg | 30mg |

[a] Fresenius 877mg; MacoPharma 880mg; Pall Corporation 880mg.
[b] Fresenius 525mg; MacoPharma 530mg; Pall Corporation 525mg.

| Platelet additive solution (300mL used in each platelet pool) | |
|---|---|
| **Constituents in 300mL** | **SSP+** |
| Manufacturer | MacoPharma |
| Sodium chloride | 1215mg |
| Sodium acetate trihydrate | 1326mg |
| Sodium citrate dihydrate | 954mg |
| Sodium dihydrogenophosphate | 315mg |
| Di-sodium hydrogenophosphate | 915mg |
| Potassium chloride | 111mg |
| Magnesium chloride | 90mg |

| Apheresis plasma and platelet collection packs | |
|---|---|
| **Pack Type** | **Anticoagulant formulation** |
| Haemonetics Corporation, product 420J<br>Contains 250mL<br>Used for plasma apheresis | Sodium citrate 4% solution:<br>- 40g/L sodium citrate dihydrate<br>This is mixed ~1:16 with whole blood. |
| Baxter Healthcare, product AHB 7898<br>Contains 500mL<br>Used for platelet apheresis | ACD-A solution:<br>- 22.0g/L sodium citrate dihydrate<br>- 8.0g/L citric acid monohydrate<br>- 24.5g/L glucose<br>This is mixed ~1:8 with whole blood. |
| CaridianBCT, product 777967-900<br>Contains 750mL<br>Used for platelet apheresis | ACD-A solution:<br>- 22.0g/L sodium citrate dihydrate<br>- 7.3g/L citric acid anhydrous<br>- 24.5g/L dextrose monohydrate<br>This is mixed ~1:8 with whole blood. |

| WHOLE BLOOD Fresh Unrefrigerated Leucocyte Depleted | |
|---|---|
| **Description** | A unit of blood collected into an anticoagulant and filtered to remove most leucocytes. Whole Blood contains the red cells, platelets and plasma component of donor blood. Only Whole Blood stored for less than 24 hours at 20-24ºC can be considered a clinical source of viable platelets or therapeutic levels of labile coagulation Factors V and VIII. |
| **Indications** | Limited indications: Indicated only for those patients who have a symptomatic deficit in oxygen-carrying capacity combined with hypovolaemia of sufficient degree to be associated with shock, particularly in clinical situations where the transfusion of viable platelets and therapeutic levels of labile coagulation Factors V and VIII are also required. If only a symptomatic deficit in oxygen-carrying capacity is present, the component of choice is Red Cells. |
| **Contraindications** | Depending upon the condition of the patient, transfusion containing red cells may not be necessary even with low haemoglobin concentration. Do not use Whole Blood or other red blood cell components if anaemia can be treated with specific medications such as iron, vitamin B12, folic acid or recombinant erythropoietin and the clinical condition of the patient permits sufficient time for these agents to promote erythropoiesis. Do not use Whole Blood when blood volumes can be safely and adequately replaced with other volume expanders such as 0.9% Sodium Chloride Injection, Hartmann's Solution, or appropriate colloids. Do not use Whole Blood to correct coagulation deficiencies when they can be treated better with appropriate components and derivatives. |
| **Specification** | Volume 450mL ± 10%; Haemoglobin $\geq$ 45g/unit; Haemolysis (at expiry) $<$ 0.8%; Platelet count $>$ 60 x $10^9$/unit; Leucocyte count $<$ 1 x $10^6$/unit. |
| **Availability** | Must be requested in advance. |
| **Shelf life, storage** | 24 hours at 20-24˚C. |
| **Dosage and administration** | Each unit contains enough haemoglobin to raise the haemoglobin concentration in an average sized adult by approximately 10g/L. Whenever possible, blood of identical ABO and Rh(D) group to the recipient should be used. Transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit should be completed within four hours of commencement of transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | Phenotyped; CMV-seronegative; Irradiated. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |

| RED CELLS Leucocyte Depleted | |
|---|---|
| **Description** | The red cell component obtained by removing most of the plasma after centrifuging whole blood collected into anticoagulant. The red cells may be resuspended in other additives to prolong storage and are filtered to remove most leucocytes. |
| **Indications** | For treatment of clinically significant anaemia with symptomatic deficit of oxygen carrying capacity, and for replacement of traumatic or surgical blood loss. |
| **Contraindications** | Depending upon the condition of the patient, transfusion containing red cells may not be necessary even with low haemoglobin concentration. Do not use Red Cells if anaemia can be treated with specific medications such as iron, vitamin B12, folic acid or recombinant erythropoietin and the clinical condition of the patient permits sufficient time for these agents to promote erythropoiesis. |
| **Specification** | Volume > 200mL; Haemoglobin $\geq$ 40g/unit; Haematocrit: 0.50-0.70; Haemolysis (at expiry) < 0.8%; Leucocyte count < 1 x $10^6$/unit. |
| **Availability** | Available in group O, A, B and AB; and Rh(D) positive and negative groups. |
| **Shelf life, storage** | 42 days at 2-6°C with the appropriate additives. |
| **Dosage and administration** | Each unit contains enough haemoglobin to raise the haemoglobin concentration in an average sized adult by approximately 10g/L. Whenever possible, blood of identical ABO and Rh(D) group to the recipient should be used. However, group O red cells can be used in an emergency when the recipient's blood group is unknown. In this situation, a blood sample should be taken for blood grouping prior to commencing transfusion. Transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit should be completed within four hours of commencing transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | Phenotyped; CMV-seronegative; Irradiated. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Comments** | Time outside required storage conditions prior to commencing transfusion should not exceed 30 minutes[3]. |

| RED CELLS Paediatric Leucocyte Depleted | |
|---|---|
| **Description** | The red cell component obtained by removing most of the plasma after centrifuging whole blood collected into anticoagulant. The red cells may be resuspended in other additives to prolong storage and are filtered to remove most leucocytes. The unit is then divided into four packs of equal volume for the purpose of reducing donor exposure for small paediatric transfusions and to minimise product wastage. |
| **Indications** | For treatment of clinically significant anaemia with symptomatic deficit of oxygen carrying capacity in infants and young children. May also be used for intrauterine transfusion. |
| **Contraindications** | As for Red Cells Leucocyte Depleted (page 15). |
| **Specification** | Volume 25-100mL; Haematocrit 0.50-0.70;<br>Haemolysis (at expiry) $< 0.8\%$; Leucocyte count $< 1 \times 10^6$/unit. |
| **Availability** | Must be requested in advance, unless by local arrangement. |
| **Shelf life, storage** | 35 days at 2-6°C. |
| **Dosage and administration** | Whenever possible, blood of identical ABO and Rh(D) group to the recipient should be used. Transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit should be completed within four hours of commencement. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | Phenotyped; CMV-seronegative; Irradiated. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Comment** | Time outside required storage conditions prior to commencing transfusion should not exceed 30 minutes[3]. |

| RED CELLS Washed Leucocyte Depleted | |
|---|---|
| **Description** | Red Cells Leucocyte Depleted (page 15) are washed with 0.9% sterile isotonic saline by a manual method to remove the majority of plasma proteins, antibodies and electrolytes. The washed red cells are then resuspended in additive solution. |
| **Indications** | As for Red Cells Leucocyte Depleted (page 15). Indicated for patients who have IgA deficiency with antibodies against IgA. May reduce the incidence of severe recurrent febrile, urticarial and possible anaphylactic transfusion reactions in multitransfused patients. For further indications refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Contraindications** | As for Red Cells Leucocyte Depleted (page 15). |
| **Specification** | Volume > 130mL; Haemoglobin $\geq$ 37g/unit; Haematocrit 0.50-0.70; Haemolysis (at expiry) < 0.8%; Leucocyte count < 1 x $10^6$/unit; Last wash supernatant total protein < 0.5g/unit. |
| **Availability** | Must be requested in advance. |
| **Shelf life, storage** | 28 days at 2-6°C if resuspended in additive solution. |
| **Dosage and administration** | Whenever possible, blood of identical ABO and Rh(D) group to the recipient should be used. Transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit should be completed within four hours from commencement of transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | Phenotyped; CMV-seronegative; Irradiated. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Comment** | As there is some loss of red cells during processing, the increment in haemoglobin with this component is less than with an unwashed red cell unit. Time outside required storage conditions prior to commencing transfusion should not exceed 30 minutes[3]. |

| PLATELETS Apheresis Leucocyte Depleted | |
|---|---|
| **Description** | An adult dose of platelets prepared from anticoagulated blood which is separated into components by a suitable apheresis machine with retention of the platelets and a portion of plasma. The remaining elements may be returned to the donor. Leucocyte depletion is performed during or soon after collection. |
| **Indications** | Platelets are indicated for treatment of patients with bleeding due to severely decreased platelet production or bleeding due to functionally abnormal platelets (e.g. anti-platelet agents). Platelet transfusions are not usually effective or indicated in patients with rapid platelet destruction. They may be used in treating some bleeding patients with platelet consumption or dilutional thrombocytopenia. Platelets may be useful if given prophylactically to patients with rapidly falling or low platelet counts (usually less than $10 \times 10^9$/L secondary to cancer or chemotherapy). Platelet transfusion may also be useful in selected cases of post-operative bleeding (e.g. platelet count less than $50 \times 10^9$/L.) |
| **Contraindications** | Do not use this component if bleeding is unrelated to decreased numbers of platelets or abnormally functioning platelets. Do not use in patients with destruction of endogenous and exogenous platelets, such as in immune thrombocytopenic purpura (ITP), thrombotic thrombocytopenic purpura (TTP) or heparin-induced thrombocytopenia (HIT), unless the patient has a life-threatening haemorrhage. |
| **Specification** | Volume 100-400mL; Platelet count $> 200 \times 10^9$/unit; pH (at expiry) 6.4-7.4; Leucocyte count $< 1.0 \times 10^6$/unit. |
| **Availability** | Available in group O, A and B; and Rh(D) positive and negative groups. Group AB must be requested in advance. |
| **Shelf life, storage** | 5 days at 20-24°C. Platelets components must be agitated gently and continuously in a single layer on a platelet agitator. |

| Platelets Apheresis Leucocyte Depleted *continued* | |
|---|---|
| **Dosage and administration** | Compatibility testing is not necessary in routine platelet transfusion. Platelet components should be ABO and Rh(D) type compatible with the recipient. However, ABO-incompatible platelets may be used if ABO-compatible platelets are not available. In some patients (particularly children), plasma present in platelet units which are ABO-incompatible with the recipient's red cells may cause a positive direct antiglobulin test and possible low-grade haemolysis due to isoagglutinins present in the plasma. In situations where group O platelets are to be transfused to a non-group O recipient, use of apheresis platelets which have been tested and found to have low levels of anti-A and anti-B (low anti-A/B) or pooled platelets should be considered. Immunisation to donor red cell antigens may occur because of the presence of small but variable numbers of red cells in platelet units. When Rh(D) positive platelets are transfused to an Rh(D) negative female of child bearing potential, prevention of Rh(D) immunisation by use of Rh(D) Immunoglobulin should be considered. Usually 250 IU of Rh(D) Immunoglobulin given intramuscularly per therapeutic platelet dose provides sufficient cover. If intravenous Rh(D) Immunoglobulin administration is required, WinRho SDF™ should be used. Transfuse platelets through an intravenous line approved for blood administration and incorporating a clean standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. The number of platelet units to be administered depends on the clinical situation of each patient. One unit of Platelets Apheresis Leucocyte Depleted would be expected to increase the platelet count of a 70kg adult by 20-40 x $10^9$/L. The usual dose in an adult patient is 1 unit. For prophylaxis, this dose may need to be repeated in 1-3 days because of the short life span of transfused platelets. Both immune and non-immune mechanisms may contribute to reduced platelet recovery and survival. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | CMV-seronegative; Irradiated; HLA-compatible; Phenotyped; Crossmatch-compatible, Low anti-A/B. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Comments** | In addition to platelet-specific HPA (human platelet antigen) system antigens, platelets carry HLA class I antigens. Residual white blood cells which may be present in platelet units express both HLA class I and II antigens. Refractoriness to platelet transfusion may occur following HLA, or less commonly HPA, alloimmunisation. When transfused to a patient with an antibody specific to an expressed antigen, the survival time of the transfused platelets may be markedly shortened, and the patient may become either temporarily or permanently refractory to platelet transfusion. HLA-compatible, HPA-matched or crossmatch-compatible platelets may be indicated. |

| PLATELETS Paediatric Apheresis Leucocyte Depleted | |
|---|---|
| **Description** | Platelets prepared from anticoagulated blood which is separated into components by a suitable apheresis machine with retention of the platelets and a portion of plasma. The remaining elements may be returned to the donor. Leucocyte depletion is performed during or soon after collection. The unit is then divided into four packs of equal volume for the purpose of reducing donor exposure for small paediatric transfusions and to minimise product wastage. |
| **Indications** | As for Platelets Apheresis Leucocyte Depleted (page 18-19). |
| **Contraindications** | As for Platelets Apheresis Leucocyte Depleted (page 18-19). |
| **Specification** | Volume 40-60mL; Platelet count > 60 x $10^9$/pack; pH (at expiry) 6.4-7.4; Leucocyte count < 1.0 x $10^6$/pack. |
| **Availability** | Contact local ARCBS regarding availability. |
| **Shelf life, storage** | 5 days at 20-24ºC. Platelet components must be agitated gently and continuously in a single layer on a platelet agitator. |
| **Dosage and administration** | Compatibility testing is not necessary in routine platelet transfusion. Platelet components should be ABO and Rh(D) type compatible with the recipient. However, ABO-incompatible platelets may be used if ABO-compatible platelets are not available. In some patients (particularly children), plasma present in platelet units which are ABO-incompatible with the recipient's red cells may cause a positive direct antiglobulin test and possible low-grade haemolysis due to isoagglutinins present in the plasma. In situations where group O platelets are to be transfused to a non-group O recipient, use of apheresis platelets which have been tested and found to have low levels of anti-A and anti-B (low anti-A/B) should be considered. Immunisation to donor red cell antigens may occur because of the presence of small but variable numbers of red cells in platelet units. When Rh(D) positive platelets are transfused to an Rh(D) negative female of child bearing potential, prevention of Rh(D) immunisation by use of Rh(D) Immunoglobulin should be considered. Usually 250 IU of Rh(D) Immunoglobulin given intramuscularly per therapeutic platelet dose provides sufficient cover. If intravenous Rh(D) Immunoglobulin administration is required, WinRho SDF™ should be used. Transfuse platelets through an intravenous line approved for blood administration and incorporating a clean standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. The number of platelet units to be administered depends on the clinical situation of each patient. One unit of Platelets Paediatric Apheresis Leucocyte Depleted would be expected to increase the platelet count of an 18kg child by 20 x $10^9$/L. For prophylaxis, doses may need to be repeated in 1-3 days because of the short life span of transfused platelets. Both immune and non-immune mechanisms may contribute to reduced platelet recovery and survival. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |

| PLATELETS Paediatric Apheresis Leucocyte Depleted *continued* | |
|---|---|
| **Modifications** | CMV-seronegative; Irradiated; HLA-compatible; Phenotyped; Crossmatch-compatible, Low anti-A/B. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Comment** | As for Platelets Apheresis Leucocyte Depleted (page 18-19). |

| PLATELETS Pooled Leucocyte Depleted | |
|---|---|
| **Description** | An adult dose of platelets obtained from a pool of buffy coats from ABO identical donors and resuspended in a nutrient additive solution. The platelets are filtered to remove most leucocytes. |
| **Indications** | As for Platelets Apheresis Leucocyte Depleted (page 18-19). |
| **Contraindications** | As for Platelets Apheresis Leucocyte Depleted (page 18-19). |
| **Specification** | Volume > 160mL; Platelet count > 240 x $10^9$/pool; pH (at expiry) 6.4-7.4; Leucocyte count < 0.8 x $10^6$/pool. |
| **Availability** | Available in groups O, A and B; and Rh(D) positive and negative groups. |
| **Shelf life, storage** | 5 days at 20-24°C. Platelet components must be agitated gently and continuously in a single layer on a platelet agitator. |
| **Dosage and administration** | Compatibility testing is not necessary in routine platelet transfusion. Platelet components should preferably be ABO and Rh(D) type compatible with the recipient. However, ABO-incompatible platelets may be used if ABO-compatible platelets are not available. In some patients (particularly children), plasma present in platelet units which are ABO-incompatible with the recipient's red cells may cause a positive direct antiglobulin test and possible low-grade haemolysis due to isoagglutinins present in the plasma. However, resuspension of the platelet pools in platelet additive solution rather than plasma reduces the risk associated with transfusion of large volumes of ABO-incompatible plasma and the incidence of adverse reactions to plasma proteins. Immunisation to donor red cell antigens may occur because of the presence of small but variable numbers of red cells in platelet units. When Rh(D) positive platelets are transfused to an Rh(D) negative female of child bearing potential, prevention of Rh(D) immunisation by use of Rh(D) Immunoglobulin should be considered. Usually 250 IU of Rh(D) Immunoglobulin given intramuscularly per therapeutic platelet dose provides sufficient cover. If intravenous Rh(D) Immunoglobulin administration is required, WinRho SDF™ should be used. Transfuse platelets through an intravenous line approved for blood administration and incorporating a clean standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. The number of platelet pools to be administered depends on the clinical situation of each patient. One unit of Platelets Pooled Leucocyte Depleted would be expected to increase the platelet count of a 70kg adult by 20-40 x $10^9$/L. The usual dose in an adult patient is 1 pool. For prophylaxis, this dose may need to be repeated in 1-3 days because of the short life span of transfused platelets. Both immune and non-immune mechanisms may contribute to reduced platelet recovery and survival. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | CMV-seronegative; Irradiated. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |
| **Comments** | As for Platelets Apheresis Leucocyte Depleted (page 18-19). |

| FRESH FROZEN PLASMA | |
|---|---|
| **Description** | Fresh Frozen Plasma (FFP) is separated and frozen within eighteen hours after collection of whole blood. FFP is also prepared from anticoagulated blood which is separated into components by a suitable apheresis machine with retention of the plasma and return of the remaining elements to the donor. The apheresis plasma is then divided into two units of equal volume and freezing commenced within six hours of collection. A unit of FFP contains all coagulation factors including approximately 200 IU of Factor VIII plus the other labile plasma coagulation factor, Factor V. |
| **Indications** | FFP is indicated for patients with a coagulopathy who are bleeding or at risk of bleeding where a specific therapy such as vitamin K or factor concentrate is not appropriate or unavailable. FFP may be indicated in bleeding patients who require replacement of labile plasma coagulation factors such as in massive transfusion, cardiac bypass, liver disease or acute disseminated intravascular coagulation (DIC). It also may be indicated in cases of warfarin overdose with life threatening bleeding in addition to Prothrombin Complex Concentrates (vitamin K dependent factor concentrates e.g. Prothrombinex-VF)[8]. FFP or cryo-depleted plasma (CDP) may be indicated for patients with thrombotic thrombocytopenic purpura (TTP). |
| **Contraindications** | Do not use FFP when coagulopathy can be corrected more effectively with specific therapy, such as vitamin K, cryoprecipitate, factor VIII or other specific factor concentrates. Do not use FFP when blood volumes can be safely and adequately replaced with other volume expanders such as 0.9% Sodium Chloride Injection, Hartmann's Solution, or appropriate colloids. |
| **Specification** | Volume 250-334mL; FVIIIc $\geq$ 0.7 IU/mL. |
| **Availability** | Available in all ABO groups. |
| **Shelf life, storage** | 12 months at -25°C or below. |
| **Dosage and administration** | Compatibility tests before transfusion are not necessary. Plasma should be ABO group compatible with the recipient's red cells. However, if necessary ABO-incompatible plasma can be used with caution. Group O plasma should be restricted to known group O recipients. Group AB plasma can be safely transfused to recipients of all blood groups. Matching for Rh(D) type is not necessary. The volume transfused depends on the clinical situation and patient size, and should be guided by laboratory assays of coagulation function. Thaw using an approved method. (Refer to Administration methods, page 9-10.) Once thawed, FFP should be transfused immediately or stored at 2-6°C for up to 24 hours[9]. If used to treat coagulopathies other than Factor VIII deficiency, thawed FFP may be allocated by a medical practitioner for a designated patient under his or her care and stored at 2-6°C for up to 5 days[10]. Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | IgA deficient; Low titre anti-T; Secretor. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). |

| FRESH FROZEN PLASMA Paediatric | |
|---|---|
| **Description** | Plasma is separated from a single unit of whole blood and then divided into four packs of equal volume for the purpose of reducing donor exposure for small paediatric transfusions and to minimise product wastage. The paediatric size plasma packs are frozen within eighteen hours after collection of the whole blood. A unit of Paediatric Clinical FFP contains all coagulation factors including the labile plasma coagulation factors VIII and V. |
| **Indications** | As for Fresh Frozen Plasma (page 23). |
| **Contraindications** | As for Fresh Frozen Plasma (page 23). |
| **Specification** | Volume 63-81mL; FVIIIc $\geq$ 0.7 IU/mL. |
| **Availability** | Available in all ABO groups. |
| **Shelf life, storage** | 12 months at -25°C or below. |
| **Dosage and administration** | Compatibility tests before transfusion are not necessary. Plasma should be ABO group compatible with the recipient's red cells. Matching for Rh(D) type is not necessary. The volume transfused depends on the clinical situation and patient size, and should be guided by laboratory assays of coagulation function. Thaw using an approved method. (Refer to Administration methods, page 9-10.) Once thawed, FFP should be transfused immediately or stored at 2-6°C for up to 24 hours[9]. If used to treat coagulopathies other than Factor VIII deficiency, thawed FFP may be allocated by a medical practitioner for a designated patient under his or her care and stored at 2-6°C for up to 5 days[10]. Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | None. |

| CRYO-DEPLETED PLASMA | |
|---|---|
| **Description** | Cryo-depleted Plasma (CDP) is the supernatant remaining after cryoprecipitate has been removed from fresh frozen plasma (FFP). It contains most clotting factors in similar amounts to FFP but is deficient in Factor VIII, fibrinogen, von Willebrand Factor (VWF) (the high molecular weight multimers are more thoroughly removed than the smaller multimers), Factor XIII and fibronectin. |
| **Indications** | CDP is recommended for plasma exchange in thrombotic thrombocytopenic purpura (TTP). It may also be used as an alternative to FFP for the treatment of coagulopathy where there is no significant reduction in Factor VIII, fibrinogen, Factor XIII, or VWF, e.g. it may be used for rapid temporary warfarin reversal in patients requiring emergency surgery and in warfarin overdose with life threatening bleeding in addition to Prothrombin Complex Concentrates (vitamin K dependent factor concentrates e.g. Prothrombinex-VF). For extended warfarin reversal, vitamin K may be recommended. |
| **Contraindications** | Do not use CDP when coagulopathy can be corrected more effectively with specific therapy, such as vitamin K or specific factor concentrates. Do not use CDP when blood volumes can be safely and adequately replaced with other volume expanders such as 0.9% Sodium Chloride Injection, Hartmann's Solution, or appropriate colloids. |
| **Specification** | Volume 215-280mL. |
| **Availability** | Available in all ABO groups. |
| **Shelf life, storage** | 12 months at -25°C or below. |
| **Dosage and administration** | Compatibility tests before transfusion are not necessary. CDP should be ABO group compatible with the recipient's red cells. However, if necessary ABO-incompatible CDP can be used with caution. Group O plasma should be restricted to known group O recipients. Group AB plasma can be safely transfused to recipients of all blood groups. Matching for Rh(D) type is not necessary. The volume transfused depends on the clinical situation. Thaw using an approved method. (Refer to Administration methods, page 9-10.) Once thawed, CDP should be infused immediately or allocated by a medical practitioner for a designated patient under his or her care and stored at 2-6°C for up to 5 days (unpublished ARCBS data). Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | None. |

| CRYO-DEPLETED PLASMA Apheresis | |
|---|---|
| **Description** | Cryo-depleted Plasma Apheresis is the supernatant remaining after cryoprecipitate has been removed from apheresis fresh frozen plasma (apheresis FFP). It contains most clotting factors in similar amounts to apheresis FFP but is deficient in Factor VIII, fibrinogen, VWF (the high molecular weight multimers are more thoroughly removed than the smaller multimers), Factor XIII and fibronectin. |
| **Indications** | As for Cryo-depleted Plasma (page 25). |
| **Contraindications** | As for Cryo-depleted Plasma (page 25). |
| **Specification** | Volume 550mL $\pm$ 10%. |
| **Availability** | Contact local ARCBS regarding availability. |
| **Shelf life, storage** | 12 months at -25°C or below. |
| **Dosage and administration** | Compatibility tests before transfusion are not necessary. CDP should be ABO group compatible with the recipient's red cells. However, if necessary ABO-incompatible CDP can be used with caution. Group O plasma should be restricted to known group O recipients. Group AB plasma can be safely transfused to recipients of all blood groups. Matching for Rh(D) type is not necessary. The volume transfused depends on the clinical situation. Thaw using an approved method. (Refer to Administration methods, page 9-10.) Once thawed, CDP should be infused immediately or allocated by a medical practitioner for a designated patient under his or her care and stored at 2-6°C for up to 5 days (unpublished ARCBS data). Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | None. |

| CRYOPRECIPITATE | |
|---|---|
| **Description** | Cryoprecipitate is prepared by thawing fresh frozen plasma (FFP) between 1°C and 6°C and recovering the precipitate. The cold-insoluble precipitate is refrozen. The component contains most of the Factor VIII, fibrinogen, Factor XIII, VWF and fibronectin from the FFP. |
| **Indications** | Cryoprecipitate is indicated in the treatment of fibrinogen deficiency or dysfibrinogenaemia when there is clinical bleeding, an invasive procedure, trauma or disseminated intravascular coagulation (DIC). |
| **Contraindications** | Cryoprecipitate should not be used for the treatment of haemophilia, von Willebrand's disease or deficiencies of Factor XIII or fibronectin unless alternative therapies are unavailable. |
| **Specification** | Volume 30-40mL; Fibrinogen $\geq$ 140mg/unit; FVIIIc $\geq$ 70 IU/unit; VWF > 100 IU/unit. |
| **Availability** | Available in all ABO groups. |
| **Shelf life, storage** | 12 months at -25°C or below. |
| **Dosage and administration** | Compatibility tests before transfusion are not necessary. Preferably ABO group compatible with the recipient's red cells; however ABO-incompatible cryoprecipitate can be used with caution, particularly with large volumes. If a large volume of ABO-incompatible cryoprecipitate is used, the recipient may develop a positive direct antiglobulin test (DAT) and, very rarely, mild haemolysis. Matching for Rh(D) type is not necessary. The volume transfused depends on the clinical situation and patient size, and should be guided by laboratory assays of coagulation factors. Thaw using an approved method. (Refer to Administration methods, page 9-10). Once thawed, cryoprecipitate should be used within 6 hours if it is a closed single unit, or within 4 hours if it is an open system or units have been pooled[9]. Thawed cryoprecipitate should be maintained at 20-24°C until transfused[11]. For pooling, the precipitate in each concentrate should be mixed well with 10-15mL of diluent to ensure complete removal of all material from the container. The preferred diluent is 0.9% Sodium Chloride Injection (USP). Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. In the steady state, the half-life of fibrinogen is 3-5 days. Dosing schedules of cryoprecipitate infusions every 3 days may be appropriate for patients with congenital hypofibrinogenemia. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | None. |

| CRYOPRECIPITATE Apheresis | |
|---|---|
| **Description** | Cryoprecipitate Apheresis is prepared by thawing apheresis fresh frozen plasma (apheresis FFP) between 1°C and 6°C and recovering the precipitate. The cold-insoluble precipitate is refrozen. The component contains most of the Factor VIII, fibrinogen, Factor XIII, VWF and fibronectin from the apheresis FFP. One unit of Cryoprecipitate Apheresis is approximately equivalent to two units of whole blood derived Cryoprecipitate. |
| **Indications** | As for Cryoprecipitate (page 27). |
| **Contraindications** | As for Cryoprecipitate (page 27). |
| **Specification** | Volume 60mL ± 10%; Fibrinogen ≥ 140mg/unit; FVIIIc ≥ 70 IU/unit; VWF > 100 IU/unit. |
| **Availability** | Contact local ARCBS regarding availability. |
| **Shelf life, storage** | 12 months at -25°C or below. |
| **Dosage and administration** | Compatibility tests before transfusion are not necessary. Preferably ABO group compatible with the recipient's red cells; however ABO-incompatible cryoprecipitate can be used with caution, particularly with large volumes. If a large volume of ABO-incompatible cryoprecipitate is used, the recipient may develop a positive DAT and, very rarely, mild haemolysis. Matching for Rh(D) type is not necessary. The volume transfused depends on the clinical situation and patient size, and should be guided by laboratory assays of coagulation factors. Thaw using an approved method. (Refer to Administration methods, page 9-10). Once thawed, cryoprecipitate should be used within 6 hours if it is a closed single unit, or within 4 hours if it is an open system or units have been pooled[9]. Thawed cryoprecipitate should be maintained at 20-24°C until transfused[11]. For pooling, the precipitate in each concentrate should be mixed well with 10-15mL of diluent to ensure complete removal of all material from the container. The preferred diluent is 0.9% Sodium Chloride Injection (USP). Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration and incorporating a standard (170 to 200µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. In the steady state, the half-life of fibrinogen is 3-5 days. Dosing schedules of cryoprecipitate infusions every 3 days may be appropriate for patients with congenital hypofibrinogenemia. |
| **Adverse reactions** | Refer to Appendix II: Adverse reactions (page 35-41). |
| **Modifications** | None. |

# Appendix I: Red blood cells

Australian Government
National Health and Medical Research Council

AUSTRALASIAN SOCIETY OF BLOOD TRANSFUSION INC

## CLINICAL PRACTICE GUIDELINES

### Appropriate Use of Red Blood Cells

#### Summary of NHMRC/ASBT guidelines

This summary is derived from the National Health and Medical Research Council (NHMRC)/Australasian Society of Blood Transfusion (ASBT) *Clinical Practice Guidelines on the Use of Blood Components* (red blood cells, platelets, fresh frozen plasma and cryoprecipitate). The guidelines were produced in cooperation with the Commonwealth Department of Health and Aged Care, the Royal Australasian College of Surgeons, the Australian and New Zealand College of Anaesthetists, and other relevant groups. The coalition of organisations involved in developing the guidelines demonstrates the degree of interest across the specialties in promoting the appropriate use of blood components.

The recommendations included in this summary have been endorsed by the NHMRC and the ASBT. The recommendations aim to support:

- clinical decisions about the use of red cells; and
- quality processes to promote appropriate use of blood components and optimise patient outcomes.

The clinical recommendations are summarised overleaf. For further details, consult the NHMRC/ASBT guidelines.

#### Organisational practice

Changing organisational practice through quality improvement is as important as changing clinical practice. A quality management system that includes monitoring, assessment, action and evaluation will allow audit of usage at the local level and eventual evaluation of changes in practice and effect on health outcomes.

**Documentation used in ordering or administering blood components (eg request forms or blood administration forms) should summarise the clinical recommendations of these guidelines and collect standardised data items. Clinical and laboratory indications for blood components should be accurately recorded in that documentation and in the patient's medical record.**

As well as a record of the clinical or laboratory indications for the use of blood components, other relevant data could include: reasons for giving blood components if not in accordance with the guidelines (eg if red blood cells are given when the haemoglobin level is >100g/L); and other relevant medical history of the patient's condition.

**In all situations where blood component therapy is given, a process for clinical review should be in place to monitor the appropriateness and safety of its use and to develop systems for the implementation of these guidelines.**

Clinical review groups or 'transfusion committees' should include senior representatives of relevant clinical specialties and administration, nurses, blood bank and staff involved in quality improvement. In larger hospitals this is likely to be a separate committee. However, this is not necessary and in smaller hospitals, the role could be undertaken by the medical advisory committee or through a local geographic or organisational network.

**As part of the informed consent process, a patient should be given clear explanation of the potential risks and benefits of blood component therapy in his or her situation.**

Community concern about blood issues and the safety of blood component therapy makes the consideration of consumer issues and processes for informed consent particularly important. Change at clinical and organisational levels within hospitals will help to standardise the use of blood components. Consumers can also be important drivers of change to practice, if they are aware of the issues surrounding use of blood components and know about the risks and benefits in their own situation.

#### Contact Details

This document is one in a series of documents developed by the NHMRC/ASBT about the use of blood components. These documents are available from:

- NHMRC Website at: http: //www.nhmrc.gov.au, or
- ASBT Website at: http://www.asbt.org.au

Print copies of all documents can be obtained by emailing:

- *HEALTH ADVISORY CTTEE NHMRC@nhmrc.gov.au* or by telephoning (02) 6289 9520 (24hr answering machine) or 1800 020 103. Alternatively you can contact the ASBT by telephoning (02) 9256 5456 or emailing to the secretariat@asbt.org.au.

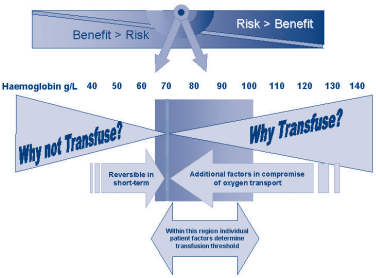
# Appendix I: Red blood cells *continued*

## Appropriate Use of Red Blood Cells

In deciding whether to transfuse red blood cells, the patient's haemogolobin level, although important, should not be the sole deciding factor. Patient factors, signs and symptoms of hypoxia, ongoing blood loss, the risk to the patient of anaemia and the risk of transfusion should be considered.

| Hb* | Considerations |
|---|---|
| <70g/L | Lower thresholds may be acceptable in patients without symptoms and/or where specific therapy is available. |
| 70–100g/L | Likely to be appropriate during surgery associated with major blood loss or if there are signs or symptoms of impaired oxygen transport. |
| >80g/L | May be appropriate to control anaemia-related symptoms in a patient on a chronic transfusion regimen or during marrow suppressive therapy. |
| >100g/L | Not likely to be appropriate unless there are specific indications. |

* The use of red blood cells for indications not listed in this table is unlikely to be considered appropriate as prophylaxis or therapy. Consult the NHMRC/ASBT guidelines for further details. Clinical and laboratory indications should be documented.




## Specific factors to consider

- Patient's cardiopulmonary reserve — if pulmonary function is not normal, it may be necessary to consider transfusing at a higher threshold.
- Volume of blood loss — clinical assessment should attempt to quantify the volume of blood loss before, during and after surgery, to ensure maintenance of normal blood volume.
- Oxygen consumption — this may be affected by a number of factors including fever, anaesthesia and shivering; if increased then the patient's need for red blood cell transfusion could be higher.
- Atherosclerotic disease — critical arterial stenosis to major organs, particularly the heart, may modify indications for the use of red blood cells.

## Prescribing blood components: checklist for clinicians

Decisions should be based on the NHMRC/ASBT *Clinical Practice Guidelines for the Use of Blood Components*, taking individual patient needs into account. Before prescribing red blood cells, ask yourself the following questions.

1. **What improvement in the patient's condition am I aiming to achieve?**
2. **Can I minimise blood loss to reduce the patient's need for transfusion?**
3. **Are there any other treatments I should give before making the decision to transfuse?**
4. **Have cross-matching and any other relevant tests been carried out?**
5. **What are the specific clinical or laboratory indications for red blood cells for this patient?**
6. **What are the risks of transmitting infectious agents through the available blood products?***
7. **Do the benefits of transfusion outweigh the risks for this particular patient?**
8. **Will a trained person monitor this patient and respond immediately if any acute transfusion reactions occur?**
9. **Have I recorded my decision to transfuse and reasons for transfusion on the patient's chart and any documentation used in the ordering or administering of blood components?**
10. **Has the patient been given a clear explanation of the potential risks and benefits of blood component therapy in his or her particular case?**

* Note that the rates of non-infective complications are probably higher than those of infective complications.

Adapted from WHO (1998) *Transfusion Today* 38: 3–6.

*Abbreviations:* Hb = haemoglobin

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# Appendix I: Platelets

Australian Government
National Health and Medical Research Council

AUSTRALASIAN SOCIETY OF BLOOD TRANSFUSION INC

# CLINICAL PRACTICE GUIDELINES

## Appropriate Use of Platelets

### Summary of NHMRC/ASBT guidelines

This summary is derived from the National Health and Medical Research Council (NHMRC)/Australasian Society of Blood Transfusion (ASBT) *Clinical Practice Guidelines on the Use of Blood Components* (red blood cells, platelets, fresh frozen plasma and cryoprecipitate). The guidelines were produced in cooperation with the Commonwealth Department of Health and Aged Care, the Royal Australasian College of Surgeons, the Australian and New Zealand College of Anaesthetists, and other relevant groups. The coalition of organisations involved in developing the guidelines demonstrates the degree of interest across the specialties in promoting the appropriate use of blood components.

The recommendations included in this summary have been endorsed by the NHMRC and the ASBT. The recommendations aim to support:

- clinical decisions about the use of platelets; and
- quality processes to promote appropriate use of blood components and optimise patient outcomes.

The clinical recommendations are summarised overleaf. For further details, consult the NHMRC/ASBT guidelines.

### Organisational practice

Changing organisational practice through quality improvement is as important as changing clinical practice. A quality management system that includes monitoring, assessment, action and evaluation will allow audit of usage at the local level and eventual evaluation of changes in practice and effect on health outcomes.

**Documentation used in ordering or administering blood components (eg request forms or blood administration forms) should summarise the clinical recommendations of these guidelines and collect standardised data items. Clinical and laboratory indications for blood components should be accurately recorded in that documentation and in the patient's medical record.**

As well as a record of the clinical or laboratory indications for the use of blood components, other relevant data could include: reasons for giving blood components if not in accordance with the guidelines (eg if platelets are given as prophylaxis when the platelet count is $>20x10^9/L$); and other relevant medical history of the patient's condition.

**In all situations where blood component therapy is given, a process for clinical review should be in place to monitor the appropriateness and safety of its use and to develop systems for the implementation of these guidelines.**

Clinical review groups or 'transfusion committees' should include senior representatives of relevant clinical specialties and administration, nurses, blood bank and staff involved in quality improvement. In larger hospitals this is likely to be a separate committee. However, this is not necessary and in smaller hospitals, the role could be undertaken by the medical advisory committee or through a local geographic or organisational network.

**As part of the informed consent process, a patient should be given clear explanation of the potential risks and benefits of blood component therapy in his or her situation.**

Community concern about blood issues and the safety of blood component therapy makes the consideration of consumer issues and processes for informed consent particularly important. Change at clinical and organisational levels within hospitals will help to standardise the use of blood components. Consumers can also be important drivers of change to practice, if they are aware of the issues surrounding use of blood components and know about the risks and benefits in their own situation.

### Contact Details

This document is one in a series of documents developed by the NHMRC/ASBT about the use of blood components. These documents are available from:

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- *HEALTH ADVISORY CTTEE NHMRC@nhmrc.gov.au* or by telephoning (02) 6289 9520 (24hr answering machine) or 1800 020 103. Alternatively you can contact the ASBT by telephoning (02) 9256 5456 or emailing to the secretariat@asbt.org.au.

# Appendix I: Platelets *continued*

## Appropriate Use of Platelets

Use of platelets is indicated for the prevention and treatment of haemorrhage in patients with thrombocytopenia or platelet function defects. The platelet count is the primary trigger for the use of platelets, with clinical risk factors for bleeding and the extent of bleeding also influencing the decision to transfuse.

Use of platelets is likely to be **appropriate as prophylaxis** for:

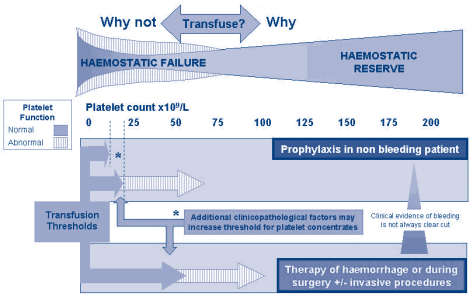
| Indication* | Considerations |
|---|---|
| **Bone marrow failure** | At a platelet count of $<10x10^9$/L in the absence of risk factors and $<20x10^9$/L in the presence of risk factors (eg fever, antibiotics, evidence of systemic hemostatic failure). |
| **Surgery/invasive procedure** | To maintain platelet count at $>50x10^9$/L. For surgical procedures with high risk of bleeding (eg ocular or neurosurgery) it may be appropriate to maintain at $100x10^9$/L. |
| **Platelet function disorders** | May be appropriate in inherited or acquired disorders, depending on clinical features and setting. In this situation, platelet count is not a reliable indicator. |

Use of platelets is likely to be **appropriate as therapy** for:

| Indication* | Considerations |
|---|---|
| **Bleeding** | May be appropriate in any patient in whom thrombocytopenia is considered a major contributory factor. |
| **Massive haemorrhage/ transfusion** | Use should be confined to patients with thrombocytopenia and/or functional abnormalities who have significant bleeding from this cause. May be appropriate when the platelet count is $<50x10^9$/L ($<100x10^9$/L) in the presence of diffuse microvascular bleeding). |

* The use of platelets for indications not listed in these tables is unlikely to be considered appropriate as prophylaxis or therapy. Consult the NHMRC/ASBT Guidleines for further details. Clinical and laboratory indications should be documented.

**Factors to consider in deciding whether or not to use platelets as therapy**




## Contraindications

Use of platelets is not generally considered appropriate in the treatment of:

- immune-mediated platelet destruction
- thrombotic thrombocytopenic purpura
- haemolytic uraemic syndrome or
- drug-induced or cardiac bypass thrombocytopenia without haemorrhage.

## Prescribing blood components: checklist for clinicians

Decisions should be based on the NHMRC/ASBT *Clinical Practice Guidelines for the Use of Blood Components*, taking individual patient needs into account. Before prescribing platelets, ask yourself the following questions.

1. **What improvement in the patient's condition am I aiming to achieve?**
2. **Can I minimise blood loss to reduce the patient's need for transfusion?**
3. **Are there any other treatments I should give before making the decision to transfuse?**
4. **What are the specific clinical or laboratory indications for platelets for this patient?**
5. **What are the risks of transmitting infectious agents through the available blood products?***
6. **Do the benefits of transfusion outweigh the risks for this particular patient?**
7. **What other options are there if no platelets are available in time?**
8. **Will a trained person monitor this patient and respond immediately if any acute transfusion reactions occur?**
9. **Have I recorded my decision to transfuse and reasons for transfusion on the patient's chart and any documentation used in the ordering or administering of blood components?**
10. **Has the patient been given a clear explanation of the potential risks and benefits of blood component therapy in his or her particular case?**

* Note that the rates of non-infective complications are probably higher than those of infective complications.

Adapted from WHO (1998) *Transfusion Today* 38: 3–6.

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# Appendix I: Fresh frozen plasma and cryoprecipitate

Australian Government
National Health and Medical Research Council


## CLINICAL PRACTICE GUIDELINES

### Appropriate Use of Fresh Frozen Plasma and Cryoprecipitate

#### Summary of NHMRC/ASBT guidelines

This summary is derived from the National Health and Medical Research Council (NHMRC)/Australasian Society of Blood Transfusion (ASBT) *Clinical Practice Guidelines on the Use of Blood Components* (red blood cells, platelets, fresh frozen plasma and cryoprecipitate). The guidelines were produced in cooperation with the Commonwealth Department of Health and Aged Care, the Royal Australasian College of Surgeons, the Australian and New Zealand College of Anaesthetists, and other relevant groups. The coalition of organisations involved in developing the guidelines demonstrates the degree of interest across the specialties in promoting the appropriate use of blood components.

The recommendations included in this summary have been endorsed by the NHMRC and the ASBT. The recommendations aim to support:

- clinical decisions about the use of fresh frozen plasma and cryoprecipitate; and
- quality processes to promote appropriate use of blood components and optimise patient outcomes.

The clinical recommendations are summarised overleaf. For further details, consult the NHMRC/ASBT guidelines.

#### Organisational practice

Changing organisational practice through quality improvement is as important as changing clinical practice. A quality management system that includes monitoring, assessment, action and evaluation will allow audit of usage at the local level and eventual evaluation of changes in practice and effect on health outcomes.

**Documentation used in ordering or administering blood components (eg request forms or blood administration forms) should summarise the clinical recommendation of these guidelines and collect standardised data items. Clinical and laboratory indications for blood components should be accurately recorded in that documentation and in the patient's medical record.**

As well as a record of the clinical or laboratory indications for the use of blood components, other relevant data could include: reasons for giving blood components if not in accordance with the guidelines (eg if fresh frozen plasma is given when there is no evidence of bleeding or abnormal coagulation); and other relevant medical history of the patient's condition.

**In all situations where blood component therapy is given, a process for clinical review should be in place to monitor the appropriateness and safety of its use and to develop systems for the implementation of these guidelines.**

Clinical review groups or 'transfusion committees' should include senior representatives of relevant clinical specialties and administration, nurses, blood bank and staff involved in quality improvement. In larger hospitals this is likely to be a separate committee. However, this is not necessary and in smaller hospitals, the role could be undertaken by the medical advisory committee or through a local geographic or organisational network.

**As part of the informed consent process, a patient should be given clear explanation of the potential risks and benefits of blood component therapy in his or her situation.**

Community concern about blood issues and the safety of blood component therapy makes the consideration of consumer issues and processes for informed consent particularly important. Change at clinical and organisational levels within hospitals will help to standardise the use of blood components. Consumers can also be important drivers of change to practice, if they are aware of the issues surrounding use of blood components and know about the risks and benefits in their own situation.

#### Contact Details

This document is one in a series of documents developed by the NHMRC/ASBT about the use of blood components. These documents are available from:

- NHMRC Website at: http: //www.nhmrc.gov.au, or
- ASBT Website at: http://www.asbt.org.au

Print copies of all documents can be obtained by emailing:

- *HEALTH ADVISORY CTTEE NHMRC@nhmrc.gov.au* or by telephoning (02) 6289 9520 (24hr answering machine) or 1800 020 103. Alternatively you can contact the ASBT by telephoning (02) 9256 5456 or emailing to the secretariat@asbt.org.au.

# Appendix I: Fresh frozen plasma and cryoprecipitate *continued*

## Appropriate Use of Fresh Frozen Plasma and Cryoprecipitate

Fresh frozen plasma is frequently used inappropriately, either in respect of the particular indication or in excessive quantity for a given indication. There are also a number of clinical situations in which the use of fresh frozen plasma has been advocated but has not been shown to be of benefit or alternative therapies are equally satisfactory or safer.

As there is little scientific evidence regarding the effectiveness of cryoprecipitate in improving clinical outcomes, and specific factor concentrates are now widely available, its use should be limited to selected indications.

Use of **FFP** is likely to be appropriate for:

| Indication* | Considerations |
|---|---|
| **Single factor deficiencies** | Use specific factors if available. |
| **Warfarin effect** | In the presence of life-threatening bleeding. Use in addition to vitamin-K-dependent concentrates. |
| **Acute DIC** | Indicated where there is bleeding and abnormal coagulation. Not indicated for chronic DIC. |
| **TTP** | Accepted treatment. |
| **Coagulation inhibitor deficiencies** | May be appropriate in patients undergoing high-risk procedures. Use specific factors if available. |
| **Following massive transfusion or cardiac bypass** | May be appropriate in the presence of bleeding and abnormal coagulation. |
| **Liver disease** | May be appropriate in the presence of bleeding and abnormal coagulation. |

* The use of fresh frozen plasma or cryoprecipitate for indications not listed in these tables is unlikely to be considered appropriate. Consult the NHMRC/ASBT guidelines for further details. Clinical and laboratory indications should be documented.

*Note:* Abnormal coagulation is defined here as greater than 1–1.5 times normal range.

Use of **cryoprecipitate** is likely to be appropriate for:

| Indication* | Considerations |
|---|---|
| **Fibrinogen deficiency** | May be appropriate where there is clinical bleeding, an invasive procedure, trauma or DIC. |
| **DIC** | Fibrinogen deficiency is commonly encountered in DIC. At fibrinogen levels lower than 1.0g/L and where there is clinical bleeding, use of cryoprecipitate to keep fibrinogen levels above 1.0g/L may be indicated. |

## Contraindications

The use of **fresh frozen plasma** is generally not considered appropriate in cases of

- hypovolaemia,
- plasma exchange procedures or
- treatment of immunodeficiency states.

Unless alternative therapies are unavailable, the use of **cryoprecipitate** is not generally considered appropriate in the treatment of:

- haemophilia
- von Willebrand's disease, or
- deficiencies of factor XIII or fibronectin.

## Prescribing blood components: checklist for clinicians

Decisions should be based on the NHMRC/ASBT *Clinical Practice Guidelines for the Use of Blood Components*, taking individual patient needs into account. Before prescribing fresh frozen plasma or cryoprecipitate, ask yourself the following questions.

1. **What improvement in the patient's condition am I aiming to achieve?**
2. **Can I minimise blood loss to reduce the patient's need for transfusion?**
3. **Are there any other treatments (such as specific or combined factor concentrates) that would be more appropriate and safer?**
4. **What are the specific clinical or laboratory indications for fresh frozen plasma or cryoprecipitate for this patient?**
5. **What are the risks of transmitting infectious agents through the available blood products?***
6. **Do the benefits of transfusion outweigh the risks for this particular patient?**
7. **What other options are there if no fresh frozen plasma or cryoprecipitate is available in time?**
8. **Will a trained person monitor this patient and respond immediately if any acute transfusion reactions occur?**
9. **Have I recorded my decision to transfuse and reasons for transfusion on the patient's chart and any documentation used in the ordering or administering of blood components?**
10. **Has the patient been given a clear explanation of the potential risks and benefits of blood component therapy in his or her particular case?**

* Note that the rates of non-infective complications are probably higher than those of infective complications.

Adapted from WHO (1998) *Transfusion Today* 38: 3–6.

*Abbreviations:* DIC = disseminated intravascular coagulation; TTP = thrombotic thrombocytopenic purpura

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# Appendix II: Adverse reactions

| Adverse reaction | Clinical considerations |
|---|---|
| **Allergic** | ***Usual aetiology:*** Allergy to plasma proteins, rarely to donor medication etc.<br>***Incidence:*** 1-3% of transfusions[3,12].<br>***Main clinical features:*** Usually pruritic urticarial lesions, but may also include wheezing or angioedema.<br>***Investigation:*** Usually none.<br>***Intervention:*** Stop or slow transfusion. Give antihistamine. In severe cases consider corticosteroids or adrenaline. Transfusion can be continued at a slower rate when the reaction abates. Consider premedication and/or washed cells if recurrent. |
| **Anaphylactoid reactions or anaphylaxis** | ***Usual aetiology:*** The majority of these reactions have been reported in IgA deficient patients who have antibodies against IgA of the IgE class. Also IgE-mediated allergy to other plasma proteins, rarely to donor medication etc.<br>***Incidence:*** 1:20,000-50,000 transfusions[3,12].<br>***Main clinical features:*** May be fatal. Onset characterised by coughing, bronchospasm, laryngospasm, respiratory distress, vascular instability, nausea, abdominal cramps, vomiting, diarrhoea, shock and loss of consciousness.<br>***Investigation:*** Check recipient pre-transfusion sample for IgA deficiency and presence of antibodies against IgA.<br>***Intervention:*** Stop transfusion immediately. Maintain airway and intravenous line. Administer adrenaline and corticosteroids. Treat hypotension. Inform ARCBS. Where appropriate, use autologous, washed or components from IgA deficient donors if future transfusion required. |
| **Circulatory overload (often referred to as transfusion-associated circulatory overload (TACO))** | ***Usual aetiology:*** Volume overload usually due to rapid or massive transfusion of blood in patients with diminished cardiac reserve or chronic anaemia.<br>***Incidence:*** Up to 1% of patients receiving transfusions[3,12].<br>***Main clinical features:*** Dyspnoea, orthopnea, cyanosis, tachycardia, increased blood pressure and pulmonary oedema.<br>***Investigation:*** Clinical assessment.<br>***Intervention:*** Stop transfusion and treat symptoms with oxygen, diuretic therapy and upright position. In susceptible patients, transfusion should be administered slowly and in the most concentrated form possible. |

(Continued next page)

# Appendix II: Adverse reactions *continued*

| Adverse reaction | Clinical considerations |
|---|---|
| **Febrile non-haemolytic transfusion reaction** | ***Usual aetiology:*** Alloimmunisation to donor HLA or other antigens. Cytokine accumulation during storage.<br>***Incidence:*** : 0.1-1% of transfusions with universal leucocyte depletion[3]. Most frequently in patients previously alloimmunised by transfusion or pregnancy.<br>***Main clinical features:*** Temperature rise of $\geq$1ºC during or shortly after transfusion and in the absence of any other pyrexic stimulus. Chills, rigors and headache.<br>***Investigation:*** Clinical assessment.<br>***Intervention:*** Consider and exclude other causes. Give antipyretic. |
| **Haemolysis: acute intravascular** | ***Usual aetiology:*** Immunologic destruction of transfused red cells, nearly always due to incompatibility of antigen on the transfused cells with antibody in the recipient circulation. Most common cause is transfusion of ABO-incompatible blood. Rarely due to physical or chemical damage to transfused red cells e.g. effects of drugs co-administered with transfusion, effects of bacterial toxins, thermal injury due to freezing or overheating or transfusion of red cell antibodies.<br>***Incidence:*** Variably reported for ABO incompatibility as 1:12,000-77,000[12].<br>***Main clinical features:*** Characteristically begins with an increase in temperature and pulse rate; symptoms may include chills, dyspnoea, chest or back pain, abnormal bleeding or shock. Instability of blood pressure is frequent. In anaesthetised patients, hypotension and evidence of DIC may be the first sign.<br>***Investigation:*** Clinical assessment. Clerical check of ABO typing of patient and unit. Perform direct antiglobulin test (DAT) and indirect antiglobulin test (IAT), renal function, tests for haemolysis (e.g. urinary haemoglobin) etc.<br>***Intervention:*** Stop transfusion immediately. Maintain blood pressure and renal output. Seek urgent assistance. Inform the laboratory responsible for dispensing blood for transfusion. Inform ARCBS. |

(Continued next page)

## Appendix II: Adverse reactions *continued*

| Adverse reaction | Clinical considerations |
|---|---|
| **Haemolysis: delayed (usually extravascular)** | ***Usual aetiology:*** Usually occurs in previously red cell alloimmunised patients in whom antigens on transfused red cells provoke anamnestic production of red cell antibody. Usual timeframe is 2-14 days after transfusion.<br>***Incidence:*** 1:4,000-9,000[12].<br>***Main clinical features:*** Signs may include unexplained fever, development of a positive DAT, jaundice and unexplained decrease in haemoglobin.<br>***Investigation:*** DAT and IAT. Liver function tests. Markers of haemolysis (urinary haemosiderin, haptoglobin etc.).<br>***Intervention:*** Most delayed haemolytic reactions have a benign course and require no treatment. Perform antibody identification and provide antigen negative blood if further transfusion is needed. Inform ARCBS. |
| **Immune modulation (often referred to as transfusion-related immune modulation (TRIM))** | ***Usual aetiology:*** Exact mechanism yet to be elucidated. Possibly mediated by donor white cells or plasma.<br>***Incidence:*** Not known.<br>***Main clinical features:*** Unproven. Suggested increased risk of infection and cancer recurrence.<br>***Investigation:*** Not known.<br>***Intervention:*** Not known - possibly leucocyte depletion. |

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## Appendix II: Adverse reactions *continued*

| Adverse reaction | Clinical considerations |
|---|---|
| **Infection - bacterial** | ***Usual aetiology:*** Bacteria may enter the blood during collection or preparation of components. Occasionally bacteria may enter due to contamination of ports during thawing of frozen products in a waterbath. Both Gram positive and Gram negative organisms have been identified. Organisms capable of multiplying at low temperatures and those using citrate as a nutrient are most often associated with red cell contamination, especially Yersinia enterocolitica. Greatest risk is for platelets stored at room temperature. In order to minimise the risk of bacterial contamination of platelets, ARCBS performs screening by culture for bacterial contamination on all platelet components.<br>***Incidence:*** For clinically apparent reactions, variously reported in the international literature to be at least 1:75,000 for platelets[3,13] and at least 1:500,000 for red cells[3,14].<br>***Main clinical features:*** Can be acute, severe and life-threatening. May be fatal. Onset of high fever, severe chills, hypotension or circulatory collapse during or soon after transfusion should suggest the possibility of bacterial contamination and/or endotoxin reaction. More common with platelets (stored at room temperature), previously frozen components thawed by immersion in a waterbath and red cell components stored for several weeks.<br>***Investigation:*** Clinical assessment. Blood cultures from the patient. Culture and Gram stain of blood component. Keep blood bag and giving set (sealed) for further investigation.<br>***Intervention:*** Stop transfusion immediately if suspected. Start broad spectrum antibiotics once cultures have been taken. Cardiovascular support. Inform ARCBS. |
| **Infection - malaria** | ***Usual aetiology:*** Although rare, transfusion transmitted malaria continues to pose a risk. In order to minimise this risk, all potential blood donors are subjected to stringent screening procedures, including collection of a comprehensive medical and travel history as part of the donor assessment process. ARCBS also performs malarial antibody screening on donors with a potential malarial exposure risk.<br>***Incidence:*** Estimated residual risk per unit for malaria is 1: 4.9 million-10.2 million[15].<br>***Main clinical features:*** As per malarial infection.<br>***Investigation:*** Clinical assessment. Laboratory investigation.<br>***Intervention:*** Treat specific diagnosis. Inform ARCBS. |
| **Infection - other** | ***Usual aetiology:*** Infectious agents for which there are no routinely available tests to predict or prevent the disease. All potential blood donors are subjected to stringent screening procedures to minimise the risk that they will transmit infectious agents. Possible causes may include, but are not limited to, Dengue Fever, West Nile Virus, Chagas Disease and Parvovirus B19.<br>***Incidence:*** Variable.<br>***Main clinical features:*** Features of specific clinical infection.<br>***Investigation:*** Clinical assessment. Microbiological investigation.<br>***Intervention:*** Treat specific diagnosis. Inform ARCBS. |

(Continued next page)

# Appendix II: Adverse reactions *continued*

| Adverse reaction | Clinical considerations |
|---|---|
| **Infection – variant Creutzfeldt-Jakob Disease (vCJD)** | ***Usual aetiology:*** Risk of vCJD is possible; not yet reported in Australia. There are currently no routinely available tests to predict or prevent vCJD. In Australia, as a precaution, people who have spent a cumulative period of six months in the UK between 1 January 1980 and 31 December 1996 and/or had a transfusion in the UK between 1 January 1980 and the present time are not accepted as blood donors.<br>***Incidence:*** To date, there have been no reported cases of vCJD in Australia. In the UK, there have been a small number of reported cases of putative transfusion transmission since 2004. There have been no reported cases of transmission by transfusion of classical Creutzfeldt-Jakob Disease (cCJD), and retrospective studies suggest that the possibility of such transmission of cCJD is remote.<br>***Main clinical features:*** As per vCJD infection.<br>***Investigation:*** Clinical assessment. Immediate consultation with experts.<br>***Intervention:*** Seek expert advice. Inform ARCBS. |
| **Infection - viral** | ***Usual aetiology:*** Transfusion transmitted viral infections, such as hepatitis and HIV which may occur due to window period transmissions.<br>***Incidence:*** ARCBS estimates of residual risk of transfusion-transmitted infection are based on published models[16]. The values listed below have been recently updated and represent the median risk estimate derived using 3 models. The risk per unit for HIV is approximately 1 in 5.4 million; the risk for hepatitis C is approximately 1 in 2.7 million; the risk for hepatitis B is approximately 1 in 739,000 and the risk for HTLV I/II is approximately 1 in 17.5 million. The HIV, HCV and HBV risk estimates are based on ARCBS data from 1 January 2007 to 31 December 2008. The HTLV risk estimate is based on data from 1 January 2004 to 31 December 2008. Refer also to Appendix V: Residual risk estimates for transfusion-transmitted infection (page 47-48).<br>***Main clinical features:*** Variable severity from asymptomatic to fatal. Features of specific clinical infection.<br>***Investigation:*** Clinical assessment. Liver function tests. Specific testing for viral markers.<br>***Intervention:*** Treatment for specific diagnosis, if available. Reduction in the risk of CMV transmission by CMV-seronegative or leucocyte depleted blood components. Inform ARCBS. |

(Continued next page)

# Appendix II: Adverse reactions *continued*

| Adverse reaction | Clinical considerations |
|---|---|
| **Iron overload** | ***Usual aetiology:*** Long-term complication of repeated red cell transfusions with iron deposition in organs. Each transfusion contributes about 250mg of iron.<br>***Incidence:*** Not known, typically after > 100 red cell units[3], but should be considered with multiple transfusions, especially > 20 units.<br>***Main clinical features:*** Symptoms and signs of organ damage or failure; especially liver, cardiac and arthropathy.<br>***Investigation:*** Serum ferritin and transferrin saturation. Organ imaging and liver biopsy.<br>***Intervention:*** Iron chelating agents for treatment and for prevention where anticipated. |
| **Metabolic complications including hypothermia** | ***Usual aetiology:*** Rapid infusion of large volumes of cold blood can depress the body temperature and result in metabolic complications such as acidosis, hyperkalaemia, hypocalcaemia etc. Rarely seen outside the massive transfusion setting.<br>***Incidence:*** Variable.<br>***Main clinical features:*** Depends on clinical situation. Risk of cardiac arrhythmia or cardiac arrest. Symptoms of hypocalcaemia.<br>***Investigation:*** Electrolyte analysis. Cardiac monitoring.<br>***Intervention:*** Slow rate of infusion. Use of blood warmer where appropriate. Use of fresh blood. |
| **Post-transfusion purpura** | ***Usual aetiology:*** Alloimmunisation to platelet-specific antigens, most often Human Platelet Antigen 1a (HPA-1a).<br>***Incidence:*** Rare.<br>***Main clinical features:*** Development of dramatic, sudden and self-limiting thrombocytopenia, typically 7-10 days after a blood transfusion in a patient with a history of sensitisation by either pregnancy or transfusion. While the immune specificity may be to a platelet-specific antigen the patient lacks, both autologous and allogeneic platelets are destroyed.<br>***Investigation:*** Demonstrate anti-platelet antibody.<br>***Intervention:*** Intravenous immunoglobulin. Antigen-negative platelets may be indicated if platelet transfusion is required but this is controversial. Inform ARCBS. |

(Continued next page)

# Appendix II: Adverse reactions *continued*

| Adverse reaction | Clinical considerations |
|---|---|
| **Transfusion associated graft-versus-host disease** | ***Usual aetiology:*** Viable T lymphocytes in the transfused component engraft in the recipient and react against tissue antigens in the recipient.<br>***Incidence:*** Rare. Severely immunocompromised recipients are at greatest risk. Has been reported in immunologically normal recipients heterozygous for a tissue antigen haplotype for which the donor is homozygous, especially directed donations from family members.<br>***Main clinical features:*** Fever, rash, liver function abnormalities and pancytopenia. Usually fatal.<br>***Investigation:*** Skin biopsy. Demonstrate donor leucocyte engraftment.<br>***Intervention:*** Supportive care. Prevention by gamma irradiation. Inform ARCBS. |
| **Transfusion related acute lung injury (TRALI)** | ***Usual aetiology:*** Specific mechanism of action is not clear. HLA or granulocyte antibodies in donor plasma reacting with recipient HLA or granulocyte antigens may play a role. Rarely, the reverse may be the case.<br>***Incidence:*** Variably reported. 1:5,000-190,000 transfusions[3].<br>***Main clinical features:*** Onset of fever, tachycardia, hypotension, hypoxia and pulmonary oedema within six hours of transfusion.<br>***Investigation:*** Clinical assessment and investigation (e.g. chest x-ray, oxygen saturation and laboratory investigations). TRALI is a clinical diagnosis. Diagnosis may be supported by demonstration of HLA or granulocyte antibodies in donor/recipient serum together with a positive crossmatch.<br>***Intervention:*** Stop transfusion immediately. Provide cardiovascular and respiratory support. Inform ARCBS. |

# Appendix III: Clinical indications for modified blood components

| Modification | Clinical considerations |
|---|---|
| **CMV-seronegative**<br>**- Red Cells**<br>**- Platelets**<br>**- Whole Blood** | ***Description:*** CMV-seronegative blood is selected by performing testing for antibodies to CMV, using a CMV test approved for donor screening. Transmission of CMV disease is associated with cellular blood components. FFP, cryoprecipitate and other plasma-derived blood components do not require special testing.<br>***Clinical indication:*** For CMV-seronegative recipients who are at risk for severe CMV disease.<br>***Patient groups:*** CMV-seronegative recipients of allogeneic or autologous stem cell, bone marrow or solid organ transplants. CMV-seronegative recipients of highly immunosuppressive chemotherapy e.g. leukaemia, lymphoma. Recipients of intrauterine red cell transfusions. Premature (< 1500g) or immunocompromised neonates. Pregnant women who require transfusion, regardless of CMV status. Refer to ANZSBT Guidelines for pretransfusion laboratory practice, 5th edition, March 2007 – Section 2.6.<br>***Comment:*** For indications where CMV-negative blood components are required, the following is recommended: 1. Select CMV-seronegative components whenever possible. 2. If not available, leucocyte depleted components are considered to offer a high level of safety in preventing CMV transmission, but are not universally believed to be equivalent to CMV-seronegative components. 3. Careful monitoring for CMV infection and disease in high risk patients. The additional benefit of leucocyte depletion in preventing transfusion transmitted CMV infection, in the context of the sole use of CMV-seronegative components, is unknown.<br>***References:*** ANZSBT. Guidelines for pretransfusion laboratory practice, 5th edition, March 2007. ASBT. Guidelines for leucocyte depletion of blood and blood products, 1996. Bowden RA, et al. A comparison of filtered leucocyte-reduced and cytomegalovirus seronegative blood products for the prevention of transfusion-associated CMV infection after marrow transplant. Blood 1995; 86: 3598-3603. Nichols WG et al. Transfusion-transmitted cytomegalovirus infection after receipt of leukoreduced blood products. Blood 2003; 101: 4195-4200. Vamvakas EC. Is white blood cell reduction equivalent to antibody screening in preventing transmission of cytomegalovirus by transfusion? A review of the literature and meta-analysis. Transfusion Medicine Reviews 2005; 19(3): 185-199. |

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# Appendix III: Clinical indications for modified blood components *continued*

| Modification | Clinical considerations |
|---|---|
| **Frozen storage**<br>**- Red Cells (rare)** | ***Description:*** Frozen red cells are prepared by adding glycerol to red cells as a cryoprotective agent before freezing. Frozen red cells may be stored for up to 10 years, and for longer intervals if there is a particular need for specific units. Prior to transfusion, the glycerol must be removed from the thawed component by washing the cells with sodium chloride. The washed red cells are then resuspended in additive solution.<br>***Clinical indication:*** For red cells with unusual phenotypes and for autologous collections when liquid-preserved blood cannot fulfil demands.<br>***Patient groups:*** For patients with rare red cell phenotypes, or multiple red cell antibodies. |
| **Irradiation**<br>**- Red Cells**<br>**- Platelets**<br>**- Whole Blood**<br>**- Granulocytes** | ***Description:*** Blood components that contain viable lymphocytes may be irradiated to prevent the proliferation of T-lymphocytes, which is the immediate cause of Transfusion-Associated Graft versus Host Disease (TA-GVHD). The minimum dose achieved in the irradiation field should be 25Gy, with no part receiving greater than 50Gy. Red cells may be irradiated at any time up to 14 days after collection, and thereafter stored for a further 14 days from irradiation. Platelets can be irradiated at any stage in their five day storage and thereafter can be stored up to their normal shelf life of five days after collection. Granulocytes for all recipients should be irradiated as soon as possible after production, and thereafter transfused with minimal delay.<br>***Clinical indication:*** For the prevention of TA-GVHD.<br>***Patient groups:*** Recipients of intrauterine transfusion. Neonates who have previously received intrauterine transfusions. Patients with congenital immune deficiencies, Hodgkin's disease or receiving purine analogue drugs. 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-compatible single donor platelets and granulocyte transfusions.<br>***Side effects and hazards:*** Gamma irradiation of red cells increases the rate of efflux of extracellular potassium. In considering the clinical significance of this, both the speed and volume of the transfusion, as well as the age of the blood, must be taken into account. Blood for intrauterine and exchange transfusion should be used within 24 hours of irradiation. Blood for paediatric transfusion should be used within 48 hours of irradiation.<br>***References:*** ANZSBT, ARCBS, NZBS. Guidelines for gamma irradiation of blood components, May 2003.<br>Available at: www.anzsbt.org.au/publications/index.cfm#societyg |

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# Appendix III: Clinical indications for modified blood components *continued*

| Modification | Clinical considerations |
|---|---|
| **Paediatric size**<br>**- Red Cells**<br>**- Platelets**<br>**- FFP** | ***Clinical indication:*** For small volume transfusions in infants and children.<br>***Patient groups:*** Infants and children, as requested. |
| **Phenotyping**<br>**- Red Cells**<br>**- Platelets** | ***Clinical indication:*** For patients requiring specific antigen-negative components due to alloimmunisation.<br>***Patient groups:*** Prevention or management of alloimmunisation to red cell or platelet antigens. |
| **Washing**<br>**- Red Cells** | ***Description:*** Washing removes unwanted plasma proteins, including antibodies. There will be some loss of red cells.<br>***Clinical indication:*** For patients requiring red cells with a low protein supernatant.<br>***Patient groups:*** Patients with reactions to transfused plasma proteins e.g. IgA deficiency. Patients with severe allergic reactions of unknown cause. May also be considered for severe reactions despite leucocyte depletion; patients with paroxysmal nocturnal haemoglobinuria (PNH) who experience reactions despite group-specific leucocyte depleted fresh red cells; rarely, for patients with T-activation when units from donors with low anti-T titres are not available or severe autoimmune haemolytic anaemia where excess complement may worsen destruction.<br>***References:*** American Society of Anesthesiologists Task Force on Blood Component Therapy. Practice guidelines for blood component therapy. Anesthesiology 1997; 84: 732-47. |

# Appendix IV: Explanation of blood component label modifier text

| Modifier Text | Explanation |
|---|---|
| **Irradiated** | The component has been irradiated and the expiry has been reduced accordingly. Refer to Appendix III: Clinical indications for modified blood components (page 42-44). The component will also have a RADSURE label to indicate that irradiation was performed. |
| **Irradiated NEONATAL** | The component has been ordered for a neonatal transfusion and has been irradiated. The expiry has been reduced to 48 hours post-irradiation. The component will also have a RADSURE label to indicate that irradiation was performed. |
| **Hyper concentrated** | The supernatant has been removed from the red cell component and the expiry reduced to 48 hours post-hyper concentration. |
| **Directed** | A directed component is one that has been collected from a selected donor known to the patient, usually a close relative of the patient. The component is reserved for that patient. Such components are always irradiated. They will also have a blue label with the patient details attached. |
| **Hyper concentrated/ irradiated** | The supernatant has been removed and the component has been irradiated. The expiry is reduced to 24 hours post-hyper concentration/irradiation. |
| **Irradiated for IUT** | The component has been ordered for an intrauterine transfusion and has been irradiated. The expiry is reduced to 24 hours post-irradiation. |
| **For intrauterine transfusion** | The component has been ordered for an intrauterine transfusion. Therefore the expiry has been reduced to 48 hours post-application of the modifier (e.g. washing). |
| **CMV-negative** | The originating donor sample/donation has been tested for CMV antibody and is negative. |
| **Not NAT tested** | Due to extenuating circumstances (e.g. machine failure or specific clinical demand), this component has been released without NAT (nucleic acid technology) testing being performed. A disclaimer form will accompany these components. |
| **Low anti-T** | The originating donor sample/donation has been tested and anti-T was not detected. |
| **IgA deficient** | The originating donor sample/donation has been tested and is IgA deficient. |
| **Secretor plasma Le(b+)** | The component is from a Le (a-b+) donor and, as such, is suitable for absorption of Lewis antibodies. Suitable for transfusion. |

(Continued next page)

# Appendix IV: Explanation of blood component label modifier text *continued*

| Modifier Text | Explanation |
|---|---|
| **Not for neonatal use** | The component has been deemed unsuitable for neonatal use due to the presence of red cell antibodies (low titre only). It should not be transfused to a neonate. |
| **Phenotype reserve** | The originating donor sample/donation or previous testing of donor has had an extended phenotype performed and forms part of a panel of cells reserved for patients with antibodies or where antigen negative blood is otherwise specifically required. |
| **Low anti-A/B** | The originating donor sample/donation has low levels of anti-A and anti-B. |
| **Autol release - see disclaimer** | This autologous component has tested positive for one or more viral markers but has been released upon request by the patient's physician. A disclaimer form will accompany these components. |

# Appendix V: Residual risk estimates for transfusion-transmitted infection

ARCBS publishes estimates of the residual risks of transfusion-transmitted infections as a service to clinicians to guide transfusion decision-making and informed consent processes.

The viral risk estimates presented in Table 1 (below) have recently been revised based on ARCBS data from 1 January 2007 to 31 December 2008. ARCBS estimates of residual risk of transfusion-transmitted viral infection are based on published models and represent the median risk estimate derived using 3 models. These estimates are updated annually. It should be noted that, as the order of magnitude of these risks is very small, the calculated median risk estimate may fluctuate from year to year.

**Table 1** - Residual risk estimates for transfusion-transmitted infections

| Agent and testing standard | Window Period (Days) | Estimate of residual risk 'per unit' [a] |
|---|---|---|
| **HIV (antibody + NAT)** | 9 | Approximately 1 in 5.4 million |
| **HCV (antibody + NAT)** | 5.4 | Approximately 1 in 2.7 million |
| **HBV (HBsAg)** | 38 | Approximately 1 in 739,000 |
| **HTLV I & II (antibody)** | 51 | Approximately 1 in 17.5 million |
| **Variant Creutzfeldt-Jakob Disease (vCJD) [No testing]** | | Possible. Not yet reported in Australia. See section below. |
| **Malaria (antibody)** | N/A | 1 in 4.9 million to 1 in 10.2 million |

[a] HIV, HCV, HBV risk estimates are based on ARCBS data from 1 January 2007 to 31 December 2008. HTLV risk estimate based on data from 1 January 2004 to 31 December 2008. For other agents refer below.

Viral estimates: Seed CR, Kiely P and Keller AJ. Residual Risk of Transfusion Transmitted Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and Human T Lymphotrophic Virus. Intern Med J 2005; 35(10): 592-8.

Malaria: Seed CR. Residual Risk Estimates for Transfusion Transmitted Malaria (TTM). ARCBS DPARC: November 9/10 2005 meeting.

There have been no reported cases of transmission by transfusion of classical Creutzfeldt-Jakob Disease (cCJD), and retrospective studies suggest that the possibility of such transmission of cCJD is remote.

To date, there have been no reported cases of vCJD in Australia. In the UK, there have been a small number of reported cases of putative transfusion transmission since 2004. In Australia, as a precaution, people who have spent a cumulative period of 6 months in the UK between 1 January 1980 and 31 December 1996 and/or had a transfusion in the UK between 1 January 1980 and the present time are not accepted as blood donors.

# Appendix V: Residual risk estimates for transfusion-transmitted infection *continued*

When considering the significance of specific risks, it is often useful to compare them to the risks associated with everyday living. The risk estimates listed above are very small when compared to everyday risks (refer to the Calman scale in Table 2 below). The chance of dying in a road accident, for example, is about 1 in 10,000 per year.

**Table 2 -** The Calman Chart (Calman 1996*) for explaining risk (UK risk per 1 year)

| | |
|---|---|
| **Negligible** | < 1,000,000 e.g. death from a lightning strike |
| **Minimal** | 1:100,000 - 1:1,000,000 e.g. death from a train accident |
| **Very low** | 1:10,000 - 1:100,000 e.g. death from an accident at work |
| **Low** | 1:1000 - 1:10,000 e.g. death from a road accident |
| **Moderate** | 1:100 - 1: 1000 e.g. death from smoking 10 cigarettes per day |
| **High** | > 1:100 e.g. transmission of chickenpox to susceptible household contacts |

* Calman K. The Health of the Nation. Br J Hosp Med 1996; 56: 125-6.

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# Notes

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