Blood - Management of Fresh Blood Components

**Summary** This Policy Directive applies to clinicians (medical practitioners, nurses and midwives), hospital transfusion service staff, staff of hospital blood banks, pathology providers and health service managers who are involved with the collection, storage and transfusion of fresh blood and fresh blood components and provides guidance in areas central to the provision of transfusion therapy.

Please Note: A link to the BloodSafe e-Learning website has been inserted on page 1 of the policy (2 May 2012).

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**Distributed to** Public Health System, Divisions of General Practice, Government Medical Officers, Health Associations Unions, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

**Audience** All staff involved with the provision of transfusion therapy

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Secretary, NSW Health

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
POLICY STATEMENT

MANAGEMENT OF FRESH BLOOD COMPONENTS

PURPOSE

The purpose of this Policy Directive is to provide clinicians (medical practitioners, nurses and midwives), hospital transfusion service staff, hospital blood bank staff, pathology providers and health service managers who are involved with the collection, storage and transfusion of fresh blood and blood components with guidance in areas central to the provision of transfusion therapy.

MANDATORY REQUIREMENTS

- All staff involved with the provision of transfusion therapy must adhere to the provisions of this Policy Directive. It is recognised that some of the requirements in this policy such as the role of the Local Health Districts are not applicable to private health facilities. However, private health facilities are expected to comply with the general principles described in the Policy Directive in compliance with the Private Health Facilities Act 2007 and Regulation 2010.

- Each health facility in NSW that provides transfusion therapy must have effective systems and procedures in place to enable compliance with this Policy Directive. In particular, the facility must have a process for the review of transfusion issues. This may be through an existing committee or through the establishment of a specific hospital transfusion committee. The process must include monitoring, quality improvement in the care of blood and transfusion practices and staff education. As a minimum requirement, all staff who are involved in transfusion-related activities must have completed the BloodSafe e-Learning program (www.BloodSafelearning.org.au)

IMPLEMENTATION

Chief Executives must ensure that:

- the principles and requirements of this policy are applied, achieved and sustained;
- all staff are made aware of their obligations in relation to the Policy Directive;
- all staff receive appropriate training to enable them to carry out their obligations in relation to this Policy Directive; and
- documented procedures are in place to support the Policy Directive.

Clinicians (medical practitioners, nurses and midwives), Hospital Blood Bank staff, Pathology Providers and Hospital Transfusion Service staff

- must comply with this Policy Directive.

REVISION HISTORY

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<tr>
<th>Version</th>
<th>Approved by</th>
<th>Amendment notes</th>
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<td>March 2012</td>
<td>Deputy Director-General, Population Health</td>
<td>Updated policy. Replaces PD2005_261</td>
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<td>October 2002</td>
<td>Deputy Director-General, Population Health</td>
<td>Guidelines for the Management of Fresh Blood Components originally issued as Circular 2002/92</td>
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INTRODUCTION

In line with the Australian Health Ministers’ Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products¹ (Attachment A), this Policy Directive provides clinicians (medical practitioners, nurses and midwives), hospital transfusion service staff, hospital blood bank staff, pathology providers, and health service managers who are involved with the collection, storage and transfusion of fresh blood and blood components with guidance in areas central to the provision of transfusion therapy.

1 TRANSFUSION-RELATED ISSUES

1.1 Safe and effective transfusion therapy

Safe and effective transfusion therapy requires the following elements:

- a clearly defined indication and evidence for the likely benefit of transfusion;
- the accurate identification of the patient for compatibility testing;
- a request for the appropriate blood component and quantity required;
- the identification of possible transfusion hazards and the likelihood of their occurrence;
- communication of the benefits and risks to the patient and/or family/carers;
- identification and appropriate management of high risk patients;
- appropriate handling, administration and monitoring of transfused components;
- early recognition and prompt action in relation to adverse events of transfusion, including feedback to the hospital transfusion service;
- appropriate documentation; and
- participation in quality improvement programs.

1.2 Blood components – Clinical Practice Guidelines

Compliance with the current and any subsequent National Health & Medical Research Council / Australasian Society of Blood Transfusion Clinical Practice Guidelines on the Use of Blood Components and summary Clinical Practice Guidelines² is required.

1.3 Consent for treatment

As part of the informed consent to medical treatment, a patient must be given a clear explanation of the potential risks and benefits of blood component therapy, and the patient’s consent to receiving a blood transfusion³ must be obtained and documented. Where treatment involves the administration of blood components / products over a period of time or a series of patient visits e.g. administration of clotting products to patients with haemophilia, the patient should be provided with advice about the treatment together with advice about material risks and benefits and consent should be obtained and documented in the normal way prior to commencing the treatment. It is not necessary to seek the patient’s consent for each of the

¹ Statement endorsed by the Australian Health Ministers’ Conference, 12 November 2010
² NHMRC/ANZSBT, Clinical Practice Guidelines on the Use of Blood Components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate), 2001 at: www.nhmrc.gov.au
³ NSW Health, Policy Directive (PD2005_406) – Consent to Medical Treatment – Patient Information
subsequent stages of the treatment program. However, the patient’s consent is required and should be documented if a new treatment is proposed which was not previously explained to the patient or where alternative treatments become available or if new risks associated with the treatment are identified.

1.4 Pre-transfusion sample collection and labelling of blood specimens

The staff member collecting the blood sample must be trained in collection procedures. The person collecting the sample must label the specimen tube at the time the blood is collected from the patient. At the time of collection, two people, one of whom may be the patient, must check the name of the person from whom the sample was collected against the name written on the specimen tube to ensure that they are identical. If the patient is unconscious, irrational or unable to respond to direct questioning, the patient’s responsible person (as defined in the NSW Ministry for Health’s Policy Directive (PD2005_406) – Consent to Medical Treatment – Patient Information or a second staff member must confirm the patient’s identity.

Labelling procedures in the laboratory must ensure that the correct sample is being tested. All blood tubes must be adequately labelled and laboratory staff must check the label each time the tube is handled.

1.5 Transfusion verification procedure

In the presence of the patient two people must independently check the details of the patient’s identity, the blood pack and the accompanying documentation when the transfusion is being set up. The two people must have knowledge of the transfusion verification procedure and the patient must be involved, if appropriate.

1.6 Reason for transfusion to be recorded

The reason for a patient requiring a blood transfusion should be recorded in the records relating to the patient.

1.7 Blood for Rh (D) - negative patients

Rh (D)-negative patients requiring blood transfusion must normally be given Rh (D)-negative blood. If there is a shortage of Rh (D)-negative blood, Rh (D)-positive blood may be given to Rh (D)-negative males and post menopausal females who have no anti-D antibodies. If large quantities of O Rh (D)-negative blood are required, irrespective of the patient’s age, Rh (D)-positive blood may have to be given.

Small health care facilities must not store O Rh (D)-negative blood. If local clinicians believe that blood is warranted at these sites, O Rh (D)-positive blood must be stored instead.

In this Policy Directive a small health care facility is defined in the public health system as a facility that is a member of one of the following groups - community acute, community non-acute facilities, multi-purpose services and hospices.

If usage of O Rh (D)-negative blood is very low at any health care facility the Australian Red Cross Blood Service (Blood Service) may consider providing O Rh (D)-positive blood in place of O Rh (D)-negative blood to that facility.

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4 ANZSBT Royal College of Nursing Guidelines for the Administration of Blood Products, 2011
5 ANZSBT Guidelines for Pretransfusion Laboratory Practice 2007
6 ANZSBT Royal College of Nursing Guidelines for the Administration of Blood Products, 2011
2 TRANSPORTATION AND STORAGE OF BLOOD AND BLOOD COMPONENTS

The transportation and storage of blood components must comply with the relevant Australian Standards and ANZSBT Guidelines for the Administration of Blood Products7,8.

2.1 Transportation

Blood products must be transported according to the specifications of the supplier and the receiving facility. The acceptance of products into the inventory of the receiving facility should be conditional on evidence of suitable storage and handling whilst in transit. Products should not be used for transfusion if there is any doubt regarding the conditions of storage during transport. Table 1 sets out the requirements for the safe transportation of blood and blood components.

Table 1

<table>
<thead>
<tr>
<th>Step</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Service delivery to designated point</td>
<td>Use a validated transport vehicle or validated transport system</td>
</tr>
<tr>
<td>Transport between sites a regional health centre to a health facility</td>
<td>Use a validated transport vehicle or a validated transport system</td>
</tr>
<tr>
<td>Transport products at the following temperature range</td>
<td>Red blood cells: 2 to 6°C</td>
</tr>
<tr>
<td></td>
<td>Fresh frozen plasma, cryoprecipitate: at or below -25°C</td>
</tr>
<tr>
<td></td>
<td>Platelets: 20 to 24°C (with gentle agitation)</td>
</tr>
<tr>
<td>Transport to patient</td>
<td>FFP and platelets should be commenced as soon as possible after receipt in the clinical setting.</td>
</tr>
<tr>
<td></td>
<td>The transfusion of red blood cells must commence within 30 minutes of removal from storage. The procedures set out in the ANZSBT Guidelines for the Administration of Blood Products 2011 should be followed where:</td>
</tr>
<tr>
<td></td>
<td>(1) red cells have been out of controlled storage for less than 30 minutes and not transfused 9 or</td>
</tr>
<tr>
<td></td>
<td>(2) where red blood cells are out of controlled storage for longer than 30 minutes 10</td>
</tr>
</tbody>
</table>

2.2 Storage – minimum requirements

Storage equipment for blood and blood products must comply with the relevant provisions of Australian Standard AS 3864-1997 Medical refrigeration equipment – For the storage of blood and blood products. Table 2 sets out the storage temperature and shelf life for blood and blood components stored under optimal conditions Table 2

7 Australian Standard AS 3864, Medical Refrigeration Equipment –for the storage of blood and blood products (1997) or any Standard that supersedes this.
8 ANZSBT Guidelines for the Administration of Blood Products 2011
9 Ibid (see section 5.5.1)
10 Ibid (see section 5.5.2)
2.3 Labelling of blood components

Labelling procedures in the laboratory must ensure that the correct sample is being tested. All blood tubes must be adequately labelled and laboratory staff must check the label each time the tube is handled, in accordance with National Pathology Accreditation Advisory Council Requirements for Transfusion Laboratory Practice\textsuperscript{15}.

Sometime in the future, in line with international practice, the Australian Red Cross Blood Service (the Blood Service) will be changing its bar coding system for blood components to the ISBT Code 128 bar code. Under this system donation identification numbers will be unique, as the year of collection will be encoded into the donation number. This will eliminate the problems associated with the recycling of donation numbers under the previous ABC Codabar system. During the change over period the barcode readers will be expected to be able to read both the ABC Codabar and the Code 128 bar code formats.

### 3 CLINICAL GOVERNANCE ISSUES

The following sets out the respective roles of the Blood Service and Local Health Districts in the provision and follow up of transfusions in health care facilities across the state.

#### 3.1 Role of the Blood Service

The Blood Service provides various blood components to the NSW health system. The Blood Service operates a 24 hour, 7 day a week phone line (Tel. 1300 478 348) for advice and consultation on urgent clinical matters including untoward transfusion reactions.

Significant reactions and near-miss incidents relating to the use of fresh blood components must be reported (1) via the Incident Information Management System (IIMS) in accordance with NSW Ministry for Health Policy Directive (PD2007_061) –Incident Management\textsuperscript{16} and (2) to the Blood Service. Examples of matters to be reported include:

\begin{tabular}{|l|l|l|l|}
\hline
Blood component & Temperature range and conditions & Shelf life & Comments \\
\hline
Whole Blood & 2 to 6\textdegree{}C & 35 days & Refrigerators must comply with AS 3864 (1997)\textsuperscript{11} \\
Red Cells & 2 to 6\textdegree{}C & 42 days & Refrigerators must comply with AS 3864 (1997)\textsuperscript{12} \\
Platelet & 20 to 24\textdegree{}C & 5 days & Must be stored on a reciprocating concentrate rocker \\
Frozen Plasma & At or below -25\textdegree{}C & 365 days & Refrigerators must comply with AS 3864 (1997)\textsuperscript{13} \\
Cryoprecipitate & At or below -25\textdegree{}C & 365 days & Refrigerators must comply with AS 3864 (1997)\textsuperscript{14} \\
\hline
\end{tabular}

\textsuperscript{11} Australian Standard AS 3864, Medical Refrigeration Equipment –for the storage of blood and blood products (1997) or any Standard that supersedes this.

\textsuperscript{12} Ibid.

\textsuperscript{13} Ibid.

\textsuperscript{14} Ibid.

\textsuperscript{15} National Pathology Accreditation Advisory Council (2008). Requirement for Transfusion Laboratory Practice.

\textsuperscript{16} NSW Health, Policy Directive (PD2005_634) – Reportable Incident Definition under Section 20L of the Health Administration Act.
• ABO incompatibility;
• wrong blood in tube;
• incorrect blood component transfused;
• transfusion-associated graft versus host disease (GVHD);
• transfusion related acute lung injury (TRALI);
• suspected bacterial contamination;
• anaphylaxis;
• post transfusion purpura;
• other suspected transfusion transmitted infections.

3.2 Role of the Local Health Districts

Establishing and implementing a quality improvement system for the clinical use of blood and blood components requires the commitment and cooperation of executive staff, health service managers, hospital transfusion service staff, hospital blood bank staff, pathology providers, quality improvement staff, clinicians and patients. The recommendations for a quality management system are set out in the NHMRC/ANZSBT, Clinical Practice Guidelines on the Use of Blood Components17.

Each health care facility that undertakes transfusion therapy must establish a process for the review of transfusion issues. This may be through an existing committee or through the establishment of a specific committee such as a hospital transfusion committee. The process should ensure clear arrangements for responsibility for education (including training in relation to the transfusion verification procedure), monitoring and quality improvement in the care of blood/blood components and transfusion practices.

The Local Health District must ensure that each of its health care facilities has appropriate arrangements in place to enable the development of local transfusion therapy policies that are consistent with state-wide policies and which address any problems that have been identified. Specific matters to be addressed include the following:

• monitoring the safety, adequacy and reliability of the supply of blood, blood components and alternatives to transfusion;
• monitoring the usage of blood components in the health care facility;
• reviewing incidents of severe adverse effects or errors associated with transfusion;
• developing systems and procedures for the implementation of the policy within the health care facility;
• promoting the effective implementation of the policy through the education and training of clinicians and blood bank staff involved in the transfusion process;
• monitoring the implementation of the policy in the health care facility and take appropriate action to overcome any factors hindering its effective implementation.

Each health care facility must have clear lines of reporting blood and blood transfusion issues to the authority responsible for blood transfusion. In particular, all adverse events relating to blood or blood transfusion must be reported. In the NSW public health system the relevant authority must report to the Local Health District Clinical Governance Unit.

17 NHMRC/ANZSBT. Clinical Practice Guidelines on the Use of Blood Components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate), 2001 at: www.nhmrc.gov.au
3.3 Reporting of infections

Local Health Districts must notify the local Public Health Unit and the Blood Service whenever a patient is suspected of having developed a transfusion-transmitted infection. Local Health Districts must allow Blood Service staff access to patients’ records to enable the Blood Service to collect and assess data relating to the units of blood and/or blood components that may be implicated in the transmission of infectious agents.

4 RETENTION OF RECORDS

It is essential that health records be retained for designated periods of time to facilitate both donor and patient follow up.

Health facilities in the public sector should follow the requirements for the retention of records set out in the General Retention and Disposal Authority - Public Health Services: Patient /Client Records (GDA 17) 2004 of the State Records Authority of New South Wales. In particular health facilities should refer to:

4.4.0 Blood Bank and blood collection services (includes autologous and homologous);
4.4.2 Laboratory records of blood donations and administration of blood & blood products;
4.4.3 Registers of blood products. Recorded details of fresh and pooled blood products

4.1 Patient and component information

The following information must be retained for a minimum of 20 years\(^{18},^{19}\)

- donation or batch number and description of all blood components and manufactured blood components
- ABO/Rh (D) group if relevant
- date and time received
- expiry date and time
- fate of the component or blood component (issued, expired, transferred)
- patient’s family name, given name/s in full, hospital record or national health number or date of birth.
- date and time of transfusion

4.2 Donor records

The Human Tissue Regulation 2010\(^{20}\) sets out the period for the retention of a donor’s records as not less than 10 years from the date on which the record relating to the medical suitability of the donor was signed.

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\(^{18}\) General Retention and Disposal Authority - Public Health Services: Patient /Client Records (GDA 17) 2004

\(^{19}\) National Pathology Accreditation Advisory Council, Requirements for the Retention of Laboratory Records and Diagnostic Material, 2009 at: www.health.gov.au

5 ATTACHMENT

ATTACHMENT A

AUSTRALIAN HEALTH MINISTERS’ CONFERENCE STATEMENT ON NATIONAL STEWARDSHIP EXPECTATIONS FOR THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

The Australian Health Ministers’ Conference (AHMC) has determined that a clear statement is needed on governments’ stewardship expectations for the providers of blood and blood products within the health sector. Stewardship, in this context, means responsible, sustainable and appropriate use of blood and blood products.

Blood and blood products are provided under the National Blood Agreement 2003 to which all Commonwealth, State and Territory Governments are signatories. Achieving a blood supply that can meet the growing needs of an ageing population at an affordable cost requires the commitment from blood donors to be matched by an equal commitment from other parties in the supply chain.

All governments are committed to:

• Providing an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services; and
• Promoting safe, high quality management and use of blood products, blood related products and blood related services in Australia.

A key component of the blood sector and one which plays an invaluable part is that of the health providers of blood and blood products. Hospitals, doctors, laboratories and other health providers serve a vital role in ensuring these key resources reach the patients in need.

In fulfilling this role, Ministers expect that these health providers will contribute to the sustainability of the blood supply by adopting these stewardship measures for their own organisation and requiring their adoption by any other party to whom they supply blood.

Blood Stewardship Principles

Blood should be managed in ways that ensure:

• All blood products are used in a clinically appropriate manner in accord with relevant professional guidelines and standards;
• Informed patient consent procedures are implemented for all patients;
• Processes, programs and facilities are in place to minimise the wastage of blood products;
• Facilities are accredited with the appropriate bodies to meet all quality and safety obligations; and
• Transfusion related adverse event information is collected and managed according to jurisdictional requirements.

National blood product planning, management and governance are supported by:

• Health providers having an ordering and receipt verification process in place which provides adequate financial accountability as required by governments; and
• Inventory data is provided on a regular and timely basis to assist in supply and demand planning, especially in times of national shortages.

Governments and the National Blood Authority will continue to manage the Australian blood supply to meet the needs of the community. Health providers play a vital role in making sure that products are available to meet clinical need, when and where required. The contribution of these health providers to safe and appropriate use, including minimisation of cost and wastage in the supply, is equally important. Ministers look to health providers to increase their efforts in these areas to ensure that Australia has a sustainable and affordable blood supply into the future.

Statement Approved by the Australian Health Ministers’ Conference, 12 November 2010.