

Guideline for the Management of Fresh Blood Components

NSW DEPARTMENT OF HEALTH

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Introduction

The guideline sets out the obligations of a health care facility to ensure the safe and appropriate use of fresh blood and blood components. The guideline should be read in conjunction with Circular 2002/92. The circular sets out the mandatory requirements of the public health system.

The guideline is divided into three sections that relate to the three groups that are essential for the good management of blood in the health care facility – clinicians (medical practitioners and nurses), hospital transfusion service staff and health service managers.

It is essential during all stages of the transfusion process – from collection to transfusion – that appropriate documentation is maintained.

A summary of the responsibilities of a clinician is set out in Appendix A – Clinical Care.

Clinician responsibilities in transfusion therapy

Homologous blood transfusion is supportive therapy and the patient's problem must be correctly and accurately identified. Transfusion therapy is generally required for haematological deficiencies for the prevention of problems or until the basic disease process can be corrected. Homologous transfusion in the perioperative setting should not be regarded as the first line of therapy for patients with haemopoietic defects and for many patients it is possible to minimise requirements for homologous blood components. Clearly, a patient must never be exposed to the potential hazards of a transfusion when there is unlikely to be significant benefits.

The following table provides guidance for the clinician in balancing the risk and benefits in relation to transfusion therapies.

Transfusion therapy	Evidence for benefit if adhering to guidelines	Potential for harm
Red cell concentrates	+++ Positive	+/-
Platelets	+++ Positive	+
Fresh Frozen Plasma	+ Equivocal	+
Cryoprecipitate	+ Equivocal	+
Factor concentrates	+++ Positive	+/-
Preoperative autologous deposit	+/- Negative	+
Perioperative haemodilution	+/- Equivocal	+/-
Intraoperative salvage	+ Positive	+/-

Safe and effective transfusion therapy

Safe and effective transfusion therapy requires the following elements:

- clearly define the indication and evidence for likely benefit of transfusion
- accurately identify the patient for compatibility testing
- request the appropriate blood component and quantity required
- identify possible transfusion hazards and the likelihood of their occurrence
- communicate the benefits and risks to the patient and/or family/carers
- identify and appropriately manage 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
- participate in quality improvement programs.

Blood components – Clinical Practice Guidelines

The NHMRC/ASBT, *Clinical Practice Guidelines on the Use of Blood Components* and summary *Clinical Practice Guidelines* provide information on the appropriate circumstances for the use of red blood cells, platelets, fresh frozen plasma and cryoprecipitate.

The *Clinical Practice Guidelines* provide a list of circumstances under which the use of fresh blood components could be accepted as appropriate therapy. The recommendations contained in the guidelines are not applicable to most acute situations, and specialty areas such as paediatrics and obstetrics.

Red blood cells

The guidelines apply to patients who are haemodynamically stable. In emergency situations there may not be time to determine the patient's haemoglobin level. The decision to transfuse or not to transfuse patients who are haemodynamically unstable with blood loss must be based on clinical judgement.

Fresh frozen plasma

The standardised sizes of fresh frozen plasma units are 150mL and 300mL.

The dosage of fresh frozen plasma depends upon the clinical situation and underlying disorder, but 12–15mL/kg is a generally accepted starting dose. Then measure the effect.

Blood for Rh negative patients

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

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

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

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

Leucodepleted blood and blood components

The presence of leucocytes in blood components has been shown to be detrimental to the quality of the product and responsible for many of the adverse side effects of transfusion including viral transmission, non haemolytic transfusion reactions and the initiation of immune responses.

Leucocyte depletion filters are the only practical method for minimising exposure to leucocytes.

NHMRC – National Health and Medical Research Council

ASBT – Australasian Society of Blood Transfusion

The guidelines can be found at www.health.gov.au/nhmrc/advice/blooduse.htm

British Committee for Standards in Haematology, Working Party of the Blood Transfusion Task Force: Contreras, Ala, Greaves et al, *Guidelines for the use of fresh frozen plasma*, Transfusion Med 1992;2:57-63

Refer to the *NSW Health Services Comparison Data Book* for an explanation of the facility terms

ASBT, *Guidelines for Leucocyte Depletion of Blood and Blood Components*

ASBT Guidelines for Irradiated Blood Products

ARCBS Guidelines on Gamma Irradiation of Blood Component

Homologous blood transfusion is the transfusion of blood between members of the same species

AHMAC, Review of the Alternative to Homologous Blood Donation, A report by the Blood and Blood Products Committee, June 2000

ASBT, Guidelines for Preoperative Autologous Blood Collection

NHS (UK), Circular 1998/224 – Better Blood Transfusion

Irradiated blood and blood components

Cellular blood components are irradiated to reduce the risk of graft versus host disease (GVHD).

Transfusion of the patient's own blood

For many years blood transfusion using donated (homologous) blood has been accepted medical therapy for blood loss and severe anaemia. However, growing recognition of the adverse effects of homologous transfusion and community concern about the safety of donated blood has led to the rise of alternatives to homologous blood transfusion.

Predeposit autologous blood collection

Predeposit autologous blood (PAD) collection is a procedure whereby a patient's own blood is collected and stored to meet their transfusion needs during elective surgery.

Although PAD is an attractive concept, there is no evidence yet that it either reduces adverse events or significantly reduces demand for donated blood. However, despite costs, difficult organisational logistics and some wastage, the practice may have benefits in certain circumstances. Where appropriate and available, patients need to be aware that it is a possible alternative to receiving donor blood.

Intraoperative red cell salvaging

Cell salvage is a term that covers a range of techniques that scavenge or drain blood from operative fields and re-infuse the blood back into the patient to reduce homologous red cell needs.

The procedure is indicated in operations where blood loss is anticipated to be more than two litres. It is therefore applicable to a few elective operations such as cardiac surgery and major orthopaedic surgery, and a number of emergency situations such as ruptured spleen or liver and ruptured aortic aneurysm.

Acute normovolaemic haemodilution

Acute normovolaemic haemodilution (ANH) is a procedure where autologous blood is donated immediately before surgery and then replaced by an equal volume of fluid, usually a crystalloid solution. The autologous blood is then re-infused into the patient after significant blood loss has stopped.

The value of the practice of ANH as a means of saving blood remains unproven. This is potentially useful technique that also needs continued careful research and evaluation.

The main use for this procedure is during cardiac bypass.

Pharmacological agents for enhancing haemostasis

There is a range of pharmacological agents available for minimising the use of homologous blood during surgery. These include erythropoietin, aprotinin, epsilon aminocaproic acid and tranexamic acid, and desmopressin 1-desamine-8-D-arginine vasopressin.

AHMAC, *Review of the Alternatives to Homologous Blood Donation*, A report by the Blood and Blood Products Committee, June 2000

Directed blood donation

There are highly specific indications for the use of directed donors such as during transplantation procedures. There is no evidence that the risk of viral transmission (or any other risk of transfusion) is reduced when homologous blood is collected from a directed donor as opposed to an anonymous volunteer. In fact, there is evidence to suggest that directed donations can result in a net increase in transfusion risk.

Directed donation is defined as a homologous donation collected from a specified donor designated for a specified patient

Pretransfusion testing

At the time of specimen collection ensure adequate documentation and accurate identification of the patient and the specimen to eliminate clerical error and patient misidentification.

ARCBS – NSW/ACT Directed Donation Policy

Double checking of the specimen and patient at the time of sample collection by either one staff member and patient, if appropriate, or two staff members. At least one staff member must be trained in specimen collection procedures.

ASBT Guidelines for Pretransfusion Testing

The staff member must label the specimen at the time of its collection from the patient.

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.

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.

NSW Health, Circular 99/16, *Patient Information and Consent to Medical Treatment*

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.

Transfusion equipment

Blood components must be administered through the appropriate equipment that is licensed for the specific purpose.

All equipment to be used during the transfusion process must be used according to the manufacturer's instructions.

While the rapid transfusion of large volumes of refrigerated blood carries a risk that the heart temperature could be lowered to a point where ventricular fibrillation could occur it is generally considered unnecessary to warm blood.

Warming of blood is only necessary under appropriate situations including the following cases:

- cardiac bypass
- exchange transfusion of infants
- patients with cold agglutinations when recommended by the haematologist
- rapid transfusion, particularly in the setting of pre-existing hypothermia or potential hypothermia, when it is anticipated that large amounts of fluid/blood will be required (eg a patient with multi-trauma).

Obligations of the Hospital Transfusion Service

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Processing, inventory and distribution of blood and blood components

The delivery of a safe product to patients is vital. The care of blood and blood components, according to established protocols, from collection to transfusion will ensure a safer product is provided to the patient. The transportation and storage of blood components must comply with the terms of the Memorandum of Understanding between the health facility and the ARCBS.

A summary of the responsibilities of a hospital transfusion service is set out in Appendix 2 – Hospital Transfusion Service

Transportation

The aim is to transport blood and blood components within the designated storage conditions (refer to Storage on page 8). The following sets out the requirements for the safe transportation of blood and blood components.

Step	Requirement
ARCBS delivery to designated point	Use a validated transport vehicle or validated transport system
Transport between sites a regional health centre to a health facility	Use a validated transport vehicle or a validated transport system Transport products at the following temperature range Red blood cells: 2 to 6°C Fresh frozen plasma, cryoprecipitate: at or below -25°C Platelet concentrates: 20 to 24°C
Transport to patient	FFP and platelets should be commenced as soon as possible after receipt in the clinical setting. The transfusion of red blood cells must commence within 30 minutes of removal from storage. If the transfusion has not been/will not be commenced within 30 minutes, the red blood cells must be returned to the laboratory or to the validated transport system

ASBT Pretransfusion Testing Guidelines

Australian Standard AS 3864, Medical refrigeration equipment – For the storage of blood and blood products, 1997

The following documentation must accompany blood or blood components that are transported between health care facilities:

- health care facility from which the blood or blood component is being transferred
- date of transfer
- type of component eg platelets, red blood cells
- time the blood component was packaged
- person responsible for the packaging and their contact details including phone number.

Storage – minimum requirements

To ensure that the quality of the blood component to be transfused is of the highest standard appropriate storage equipment that complies with the relevant provisions of Australian Standard AS 3864-1997 *Medical refrigeration equipment – For the storage of blood and blood products* should be used.

The following table sets out the storage temperature and shelf life for blood and blood components stored under optimal conditions.

Australian Standard
AS 3864, *Medical
refrigeration
equipment –
For the storage
of blood and blood
products*, 1997

Blood component	Temperature range and conditions	Shelf life	Comments
Whole Blood	2 to 6°C	35 days	Refrigerators must comply with AS 3864 (1997)
Red Cells	2 to 6°C	42 days	Refrigerators must comply with AS 3864 (1997)
Platelet	20 to 24°C	5 days	Must be stored on a reciprocating concentrate rocker
Frozen Plasma	At or below -25°C	365 days	Refrigerators must comply with AS 3864 (1997)
Cryoprecipitate	At or below -25°C	365 days	Refrigerators must comply with AS 3864 (1997)

A plan is required to ensure that there is a **clear chain of responsibility** for responding to the alarm, initiating appropriate response/s and taking corrective action. Owners of equipment are responsible for the correct functioning of the equipment, that is the clinical and engineering staff must respond to identified problems of the equipment.

Inventory management

To ensure an acceptable expiry rate pathology services must:

- rotate blood and blood components so that the oldest (within date) product is used first
- rotate unused blood and blood components (from the ARCBS) back to the ARCBS (any blood product that does not meet the **storage and transportation requirements** must be discarded)
- measure the expiry rates of red blood cells, FFP and platelets if received, each month.

If the health care facility or pathology service has losses of blood products that are clearly their fault then the ARCBS may reclaim the costs involved through either the facility/service or the Treasury Managed Fund.

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.

The ARCBS 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.

*ASBT, Guidelines for
Pretransfusion Testing*

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.

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Obligations under Clinical Governance

The following sets out the respective roles of the ARCBS–NSW and health services in the provision and follow up of transfusions in health care facilities across the state.

Role of the ARCBS

The ARCBS–NSW provides various human blood components to the NSW health system.

The ARCBS–NSW operates a 24 hour, 7 day a week phone line (Tel. 02 9229 4444) for advice and consultation on urgent clinical matters including untoward transfusion reactions.

The ARCBS has the primary responsibility for the investigation of cases when blood and blood components have been implicated in the transmission of any infectious agent including HIV, hepatitis B and hepatitis C.

Significant reactions to fresh blood components should be reported to the ARCBS–NSW. These reactions include:

- ABO incompatibility
- graft versus host disease (GVHD)
- transfusion related acute lung injury (TRALI).

Role of the health service

NHMRC/ASBT, *Clinical Practice Guidelines on the Use of Blood Components*, September 2001

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, quality improvement staff, clinicians and patients. The recommendations for a quality management system are set out in the NHMRC/ASBT, *Clinical Practice Guidelines on the Use of Blood Components*.

Each health care facility that has 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 committee must be responsible for education (including training for the transfusion verification procedure), monitoring and quality improvement in the care of blood/blood components and transfusion practices.

The committee must have the authority within the health care facility to develop local policy in relation to transfusion therapy that is consistent with statewide policies and resolve any problems that have been identified.

Specific roles of the committee can include the following:

- monitor the safety, adequacy and reliability of the supply of blood, blood components and alternatives to transfusion
- monitor the usage of blood components in the health care facility
- review incidents of severe adverse effects or errors associated with transfusion
- develop systems and procedures for the implementation of the policy within the health care facility

- promote the effective implementation of the policy through the education and training of clinicians and blood bank staff involved in the transfusion process
- monitor the implementation of the policy in the health care facility and take appropriate action to overcome any factors hindering its effective implementation.

In each health care facility there must be clear lines of reporting blood and blood transfusion issues to the blood transfusion committee. In particular, all adverse events relating to blood or blood transfusion must be reported to the committee.

In the NSW public health system the blood transfusion committee must report to the Area Quality Council.

An adverse event is an unintended injury or complication that results in disability, death or prolonged hospital stay and is caused by health care management.

Reporting of infections

Health services must notify the ARCBS-NSW whenever a patient is suspected of having developed an infection through blood or blood components and allow access of staff from the ARCBS-NSW to assist in the collection and assessment of data relating to the units of blood and/or blood components that may be implicated in the transmission of infectious agents.

Retention of records

It is essential that health records be retained for designated periods to facilitate both donor and patient follow up. The following sets out the periods for retention of certain records and information that will facilitate this process.

Public sector

Health facilities in the public sector should follow the requirements for the retention of records set out in the General Disposal Authority 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 and blood products.

Private sector

Donor records

The Human Tissue Regulation 2000 sets out the periods for the retention of donor's records:

- for donors who are at least 20 years of age at the time of donation, the records must be retained for at least 10 years.
- for donors who are less than 20 years of age at the time of the donation, the records must be retained for a minimum of 20 years or until that donor would have reached 30 years of age, whichever is the longer.

Human Tissue
Regulation, 2000

National Pathology
Accreditation Advisory
Council, *Retention of
Laboratory Records
and Diagnostic
Material*, 1998.

Patient and component information

The following information must be retained for at least 20 years:

- donation or batch number and description of all blood components and manufactured blood components
- ABO/Rh(D) group if relevant
- fate of the component or blood component (issued, expired, transferred)
- patient's family name, given name/s in full, and medical record number or date of birth.

Health facilities in the private sector may also refer to the General Disposal Authority of the State Records Authority of New South Wales for further information.

References

4

ARCBS, *Guidelines on Gamma Irradiation of Blood Component*. Refer to the latest edition.

ARCBS-NSW/ACT, *Directed Donation Policy*, August 2000.

ASBT, *Guidelines for Irradiated Blood Products*. Refer to the latest edition.

ASBT, *Guidelines for Leucodepleted Blood Products*. Refer to the latest edition.

ASBT, *Guidelines for Preoperative Autologous Blood Collection*. Refer to the latest edition.

ASBT, *Guidelines for Pretransfusion Testing*. Refer to the latest edition. This document provides guidelines for pretransfusion testing and safe transfusion practice.

Australian Health Ministers' Advisory Council, *Review of the Alternatives to Homologous Blood Donation*. A report by the Blood and Blood Products Committee, June 2000.

Australian Standard AS 3864-1997 *Medical refrigeration equipment – For the storage of blood and blood products*, 1997. Also refer to Australian Code of Good Manufacturing Practice for Human Blood and Tissue, Therapeutic Goods Administration, June 2000.

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NHMRC/ASBT, *Clinical Practice Guidelines on the Use of Blood Components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate)*, September 2001 at: www.health.gov.au/nhmrc/publications/synopses/cp77syn.htm

NHMRC/ASBT, *Clinical Practice Guidelines: Appropriate Use of Red Blood Cells*, October 2001 at: www.health.gov.au/nhmrc/publications/synopses/cp77syn.htm

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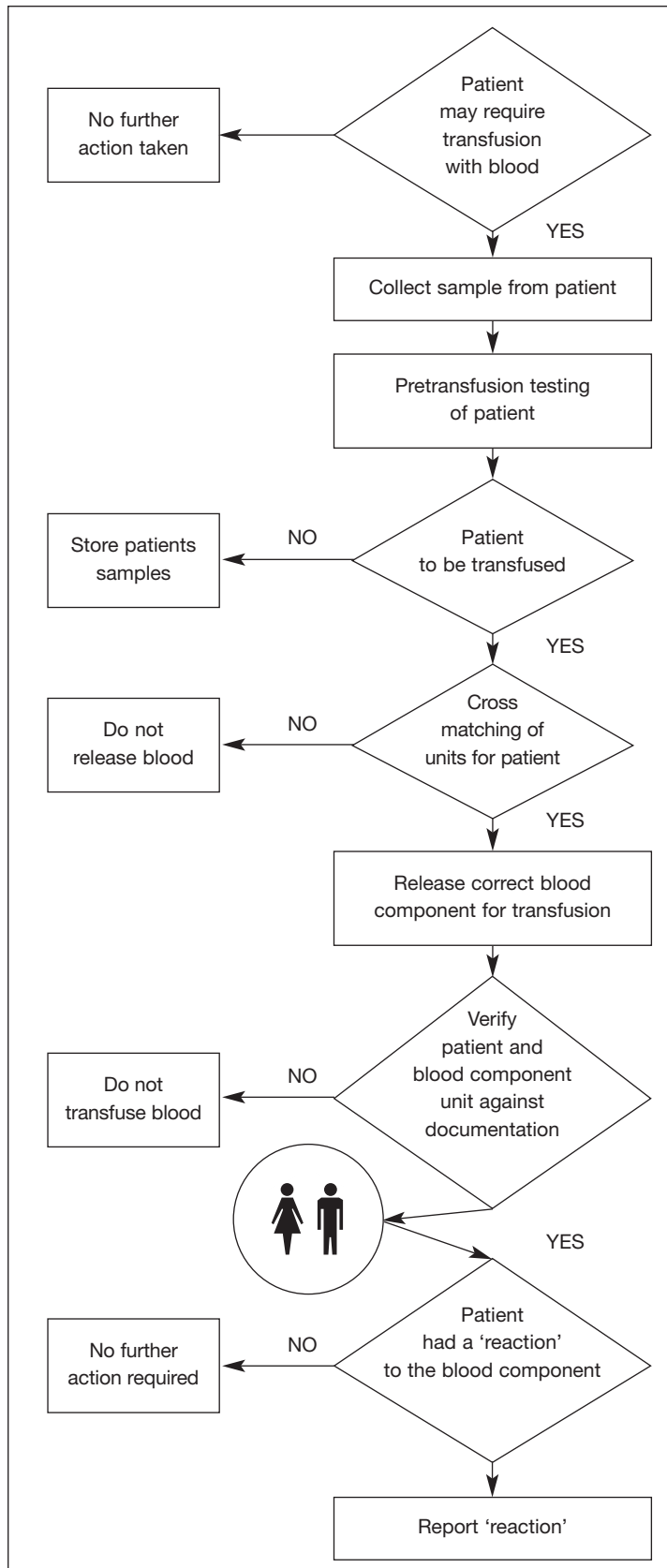
NHMRC/ASBT, *Clinical Practice Guidelines: Appropriate Use of Platelets*, October 2001 at: www.health.gov.au/nhmrc/publications/synopses/cp77syn.htm

NHMRC/ASBT, *Blood Components: A Guide for Patients*, February 2002 at:
www.health.gov.au/nhmrc/publications/synopses/cp77syn.htm

NSW Health, Circular 2000/74 – *Human Tissue Regulation 2000: new medical certificates for donors of blood and semen*, 2000. The Circular details the certificates that must be obtained from all blood donors.

NSW Health, Circular 99/16 – *Patient Information and Consent to Medical Treatment*, 1999.

Appendix A - Clinical Care



Ensure appropriate documentation at all stages

Clinically assess for the appropriate use of red blood cells, platelets, fresh frozen plasma and cryoprecipitate.

Ensure adequate documentation and accurate identification to eliminate clerical error and patient misidentification.

Double checking at the time of sample collection by either one staff member and patient (if appropriate) or two staff members.

At least one staff member must be trained in specimen collection procedures.

Label the specimen at the time of its collection from the patient by the person collecting the specimen.

Determine the patient's ABO group, Rh(D) group and antibody screen.

Document reason/s for transfusion

Obtain patient's consent. Provide a clear explanation of the potential risks and benefits of blood component therapy.

A patient's blood type, including ABO and Rh group, must be compatible with the donor's blood type.

Attach patient's cross match details to blood component unit.

Before release of the blood component ensure that all appropriate cross matching and verification procedures have been performed.

Document the release of the blood component in the blood bank inventory.

In the presence of the patient two people must independently verify the patient's identity and blood component against the documentation before commencing a transfusion.

The two people must have knowledge of the transfusion verification procedure.

Appropriately monitor the patient during the transfusion.

If the blood component is not used it must be returned to the blood bank and the appropriate entry made in the inventory.

THE PATIENT

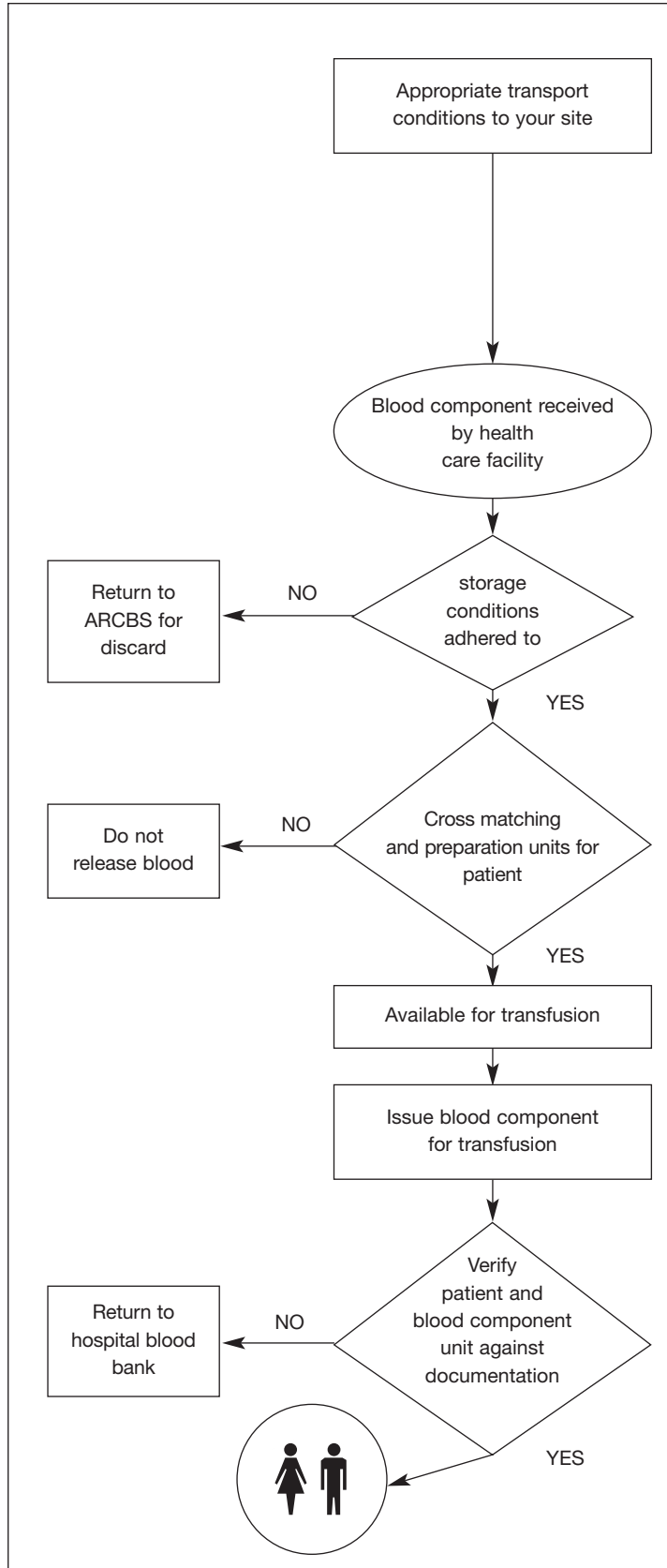
As a minimum the 'reaction' must be reported to:

- clinician responsible for the patient
- local blood transfusion committee if an adverse event
- ARCBS if possible transmission of an infectious agent. Other significant reactions such as ABO incompatibility, GVHD and TRALI must be reported to the ARCBS.

Document in the patient's medical record.

B

Appendix B – Hospital Transfusion Service



Ensure appropriate documentation at all stages

Transport from the ARCBS to designated point by a validated transport vehicle.

Transport from a designated point such as a regional centre to a health facility or from one site to another within the health facility by a validated transport vehicle or a validated transport system.

Products to be transported at the following temperature range

- Red blood cells: 2 to 6°C
- Fresh frozen plasma, cryoprecipitate: ≤ -25°C
- Platelet concentrates: 20 to 24°C

Enter details of blood component's unique identification number and expiry data into the blood bank inventory.

Refrigerate according to AS 3864-1997

- Red Blood Cells: 2 to 6°C
- Platelet Concentrate: 20 to 24°C
- Frozen Plasma: ≤ -25°C
- Cryoprecipitate: ≤ -25°C

Rotate stock to ensure that oldest (within date) is used first.

Return unused blood components to ARCBS.

A patient's blood type, including ABO and Rh group, must be compatible with the donor's blood type.

Attach patient's cross match details to blood component unit.

Component to be issued with appropriate documentation that allows verification against the patient and blood component unit.

In the presence of the patient two people must independently verify the patient's identity and blood component against the documentation before commencing a transfusion.

The two people must have knowledge of the transfusion verification procedure.

Appropriately monitor the patient during the transfusion.

THE PATIENT

