Australian and New Zealand Society of Blood Transfusion Ltd Royal College of Nursing Australia

2nd Edition, December 2011

GUIDELINES FOR THE ADMINISTRATION OF BLOOD PRODUCTS





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<u>Disclaimer</u>: Institutions using these guidelines should formulate their own policies according to their patient population and availability of irradiated components. By necessity, these policies may need to be broader than those in this document.

Foreword

ANZSBT Council is pleased to publish the second edition of the *Guidelines for the Administration of Blood Products*.

The current guidelines were developed by the ANZSBT Clinical Practice Improvement Committee (CPIC), the Australian Specialist Practitioners of Transfusion (AUS SPOT), Royal College of Nursing Australia (RCNA) and supersede the previous *Guidelines for the Administration of Blood Components* 1st edition (2004).

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Summary Of Changes To The 2004 Guidelines

Although significant changes from the first edition are highlighted below, it is recommended that the document is reviewed in its entirety to support the validity of, and maintain consistency with, established health service policy and protocols. In addition, this second edition attempts to capture the wealth of transfusion-related resources and tools now established in use throughout Australia and New Zealand as a result of increasing interest and investment in infrastructure supporting transfusion.

Information from existing guidelines and standards, for example related to pretransfusion laboratory practice, patient identification and refrigeration, have purposely not been reproduced within this document to avoid inconsistency and the need to synchronise content as each independent document is updated. The reader is instead provided with the links and references for the necessary information where applicable.

Table 1: Summary of major changes from the first (2004) edition of the guidelines

No.	Change Details	1 st Edition	2 nd Edition
1	The order of presentation has been changed to reflect the sequential nature of the administration process.	Х	✓
2	The title has been changed from "Guidelines for the administration of blood components" to "Guidelines for the administration of blood products" to reinforce that policy and procedures for administration apply both to fractionated products and fresh blood components.	X	√
3	Review and modification of the directive terms, "must, "should" and "may". Given the lack of a clear evidence base for many areas of transfusion practice, the use of these terminologies through the document reflects the need to defer to expert opinion and observed current clinical practice.	X	✓
4	Provision of further guidance for the process of informed consent, refusal of blood products and inclusion of a section about consent and the Jehovah's Witness.	C2	2
5	Inclusion of the date and time of the transfusion in the prescription in addition to the request form.	C1	3.1
6	Removal of the recommendation that the staff member receiving blood for transfusion e.g. in the clinical area should sign the blood collection slip, including the time of delivery, as this is considered neither practical nor routine practice.	D2	Х
7	The manner in which a blood collection slip is retained may now be defined by the hospital transfusion service.	D2	5.3
8	Addition of guidance for health service management of emergency group O red cells to support critical bleeding.	Х	5.4

No.	Change Details	1 st Edition	2 nd Edition
9	Clarification and expansion of the requirements and responsibilities of the local transfusion service provider for validation of packing configurations for transportation of blood products.	D2	5.6
10	The duration before changing the blood administration set has been increased from 8 to 12 hours in the absence of evidence that this is less safe. This aligns the document with the BCSH <i>Guideline on the Administration of Blood Components</i> 2009. However as individual product information varies between administration sets, the manufacturer's guidelines must be followed.	A2	6.2.4
11	A change to the number of units recommended to be transfused per blood administration set. The first edition stated 2-4 units, depending on urgency. The current edition does not limit the number of units as long as flow is maintained and the manufacturer's recommendations are followed.	A2	6.2.4
12	Changes to bedside filtration policy due to the introduction of universal pre-storage leucodepletion and a common acceptance of the redundancy of microaggregate filters.	А3	6.3
13	The current formulation of Gelofusine® has been removed as an incompatible fluid, even though this is not consistent with the BCSH <i>Guideline on the Administration of Blood Components</i> 2009. The manufacturer confirms negligible calcium content and the product has not been shown to be incompatible through current and common experience. This exception does not suggest the expert group authorise or condone the use of other forms of IV fluids not listed as compatible.	B1	6.6.1
14	Update of patient identification requirements in line with national guidelines including the current Australian Commission on Safety and Quality in Health Care (ACSQHC) <i>Standards</i> and New Zealand Blood Service (NZBS) <i>Transfusion Medicine Handbook 2008</i> .	D4	6.9
15	Clarification and expansion of staff who can perform the patient and product identity checks before hanging the blood product. The new wording accommodates current national regulations in both Australia and New Zealand.	D4	6.9.2.1
16	Addition of typical infusion rates for blood products rather than a generic infusion rate.	C4	6.10
17	The "four hour rule" received considerable attention. International guidelines and clinical practice show some variation in their interpretation of the point at which this period commences, i.e. from "removal from controlled storage" or from "penetration of the port".	D5	6.10.1

No.	Change Details	1 st Edition	2 nd Edition
	There are no recent and conclusive evidence-based studies to indicate risk with regard to bacterial contamination or product viability.		
	The expert group concluded that the product SHOULD be infused within four hours of leaving controlled storage. In certain clinical situations such as transfusion of neonates, where a slow infusion rate is indicated, transfusion MUST be completed within four hours of commencement and no longer than four-and-a-half (4½) hours following release of the product from controlled storage.		
	This exception to standard practice must be documented in a hospital or health service policy/procedure. This acknowledgment aligns these guidelines with the BCSH <i>Guideline on the Administration of Blood Components</i> (2009).		
18	More extensive directions about frequency of monitoring during transfusion. Of note is the additional recommendation that patient observations be recorded at 15 minutes after commencement of the transfusion, with the caveat that continuous visual observation for that time period may suffice in specialist areas with transfusion expertise. Furthermore, the expert group advise that patients should still be under close observation up to 30 minutes after commencement of transfusion in line with the BCSH <i>Guideline on the Administration of Blood Components (2009)</i> .	C4	6.11
19	Removal of the need to record transfusion observations separately, as this is considered neither practical nor routine practice.	C4	х
20	Retention of empty bags or bottles after transfusion is no longer recommended other than to be returned to the transfusion service in the event of an acute transfusion reaction. This change reflects the lack of value of microbiological investigation on inadequately stored blood product containers and associated occupational health and safety concerns.	D5	6.13
21	Addition of a new and detailed section on paediatric transfusions.	Х	7.2

Comments on these guidelines and suggestions for revision for inclusion in the next update are welcomed and can be forwarded to:

Australian and New Zealand Society of Blood Transfusion Ltd 145 Macquarie Street Sydney NSW 2000 Australia

Introduction

The aim of the *Guidelines for the Administration of Blood Products* is to provide guidance on the appropriate storage and collection of blood products as well as the safe administration and management of transfused patients. This document should be utilised as a tool to create policy rather than a clinical procedural document. To aid this process additional links to relevant tools and guidelines have been incorporated into the body of the document. These guidelines must also be considered in conjunction with the ANZSBT *Guidelines for Pretransfusion Laboratory Practice* and the NPAAC *Requirements for Transfusion Laboratory Practice*.

The areas covered by this document are:

- 1. The decision to transfuse.
- 2. Consent for blood products.
- Prescription of blood products.
- 4. Requests for blood products and pretransfusion blood sampling
- 5. Storage, collection and transport of blood products.
- 6. Administration of blood products.
- 7. Special transfusion circumstances.
- 8. Management of transfusion reactions and other transfusion-related adverse events.
- 9. Clinical governance.

In this edition of the guidelines the following directive terms are used:

- **Must** Indicates a practice which is considered mandatory based on this committee's expert opinion, following review of available evidence.
- Should Indicates a practice which is recommended and where compliance would be expected for good clinical practice, but for which alternative practices may also be acceptable. Individual organisations may elect to increase the level of compliance to mandatory by substituting "must" within their own policies and guidelines.
- May Indicates a practice which is permissible within the limits of these guidelines.

The term "the Blood Service" is used throughout the document and refers to the Australian Red Cross Blood Service and New Zealand Blood Service (NZBS) in their respective countries.

The term "blood product" has been used generically in the title and throughout the document to describe blood components and plasma-derivatives. Where the term "blood components" is specifically used it is referring to red cells, platelets, fresh frozen plasma, cryoprecipitate, cryosupernatant, whole blood or granulocytes. "Plasma derivatives" and "plasma-derived" are used to refer to plasma proteins fractionated from large pools of human plasma under pharmaceutical conditions, for example coagulation factors, albumin and immunoglobulins.

Whilst the general principles of these guidelines apply to the administration of plasma-derived blood products, relevant product information and local procedures/protocols for specific guidance on fractionated and recombinant products must be consulted.

Please refer to the glossary on pages 51-53 for further information regarding definitions.

Summary Of Recommendations

Table 2: Summary of recommendations made in the guidelines

Section	Section 1: Decision To Transfuse			
R1	The decision to transfuse, and the consideration of other blood management strategies, must be based on a thorough clinical assessment of the patient and his/her individual needs.			
R2	The indication for transfusion or the chosen alternative must be documented in the patient's medical/clinical record.			

Section 2: Consent For Blood Products

R3 Health services must have a transfusion consent policy for both adults and children for:

- Acquisition and documentation of informed consent for blood products.
- The period of time that consent remains valid.
- Refusal of blood products, including policy for Jehovah's Witnesses.
- When consent is unable to be obtained.

Section	Section 3: Prescription Of Blood Products		
R4	The prescription must give a clear, legible instruction.		
R5	The prescription must be available to check at the patient's side when the transfusion takes place.		
R6	The prescription must be retained within a patient's medical/clinical record following completion of a transfusion.		

Section	Section 4: Requests For Blood Products And Pretransfusion Blood Sampling		
R7	Pretransfusion sample collection must include positive patient identification processes.		
R8	The blood product request must include positive patient identification processes and provide a clear communication to the transfusion service provider as to the product, urgency and dose required.		
R9	The blood product request must include the clinical indication for the transfusion and any special blood product requirements for the patient.		

Section	Section 5: Storage Collection And Transport Of Blood Products			
R10	Health services must have a policy for the storage, collection, transport and receipt of blood products including the associated documentation and checking procedures.			
R11	The policy for collection of blood products must clearly define staff responsibilities and their education, training and competency requirements.			

Section 5: Storage Collection And Transport Of Blood Products continued

R12 Health services must have a policy and protocol for requesting and obtaining blood in a critical bleeding scenario.

Section 6: Administration Of Blood Products

- R13 Health services must have a policy for patients receiving transfusion of blood that defines:
 - Positive identification of the patient.
 - Selection of the appropriate location and timing for the transfusion.
 - Validation of equipment employed in transfusion.
 - Administration procedures for components, compatible fluids and medications.
 - Optimal observation, care and monitoring of the patient.

Section 7: Special Transfusion Circumstances

- R14 Health services providing out-of-hospital transfusion services must have defined policy and protocols to determine staff responsibilities and best practice in all aspects of the out-of-hospital transfusion.
- **R15** Health services providing transfusion support to paediatric and neonatal populations must ensure policy and protocols recognise the special needs and requirements of this patient population.

Section 8: Management And Reporting Of Adverse Events

- R16 Health services must have a policy for the management and reporting of adverse events and near miss events relating to blood product therapy that includes:
 - Education, training and assessment of competency of staff to ensure recognition and appropriate response to adverse events.
 - Requirements for documentation of observations and the subsequent management of an adverse event.
 - Guidelines for management of transfusion reactions.
 - The procedure for reporting adverse and near miss events in local incident management systems, state or national haemovigilance systems.
 - The mechanism for review of adverse events and near misses.
 - Requirements for reporting to the transfusion service provider, and/or Blood Service or manufacturer.

Section 9: Clinical Governance

- R17 All health services performing transfusion must have a committee responsible for clinical governance of the transfusion process.
- **R18** All health services performing transfusion must implement appropriate policy and procedures governing all aspects of local transfusion practice.

Section	Section 9: Clinical Governance continued			
R19	A designated staff member should be appointed by the health service to be responsible for local policies for blood transfusion and for organising the training of staff involved in transfusion.			
R20	Health services should maintain documentation of dedicated transfusion training and competency assessment of their staff involved in the transfusion process.			

Section 1

The Decision To Transfuse

The decision to transfuse, and the consideration of other blood management strategies, must be based on a thorough clinical assessment of the patient and his/her individual needs. The indication for transfusion, or other blood management strategies chosen, must be documented in the patient's medical/clinical record.

The NHMRC/ASBT Clinical Practice Guidelines on Fresh Blood Components (2001) are under review at the time of production of these guidelines. Module 1 of the new national Patient Blood Management Guidelines (critical bleeding/massive transfusion) was released in March 2011 with subsequent modules due for sequential release from late 2011 onwards.

It is not the intent of this document to provide further detail on appropriate use of blood products, but current resources which may inform the decision are provided below.

1.1 Additional resources

ANZSBT. Guidelines for Pretransfusion Laboratory Practice (2007) http://www.anzsbt.org.au/publications/documents/PLP Guidelines Mar07.pdf

ANZSBT/RANZCOG. Guidelines for Blood Grouping & Antibody Screening in the Antenatal & Perinatal Setting (2007)

http://www.anzsbt.org.au/publications/documents/Antenatal Guidelines Mar07.pdf

Australian Health Ministers Advisory Council (AHMAC). Evidence-based clinical practice guidelines for the use of recombinant and plasma-derived FVIII and FIX products (2006) http://www.nba.gov.au/pubs/pdf/fviii-gls-2006.pdf

Australian Health Ministers' Conference. Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia (2007)

http://www.nba.gov.au/ivig/pdf/criteria.pdf

Australian Red Cross Blood Service. Blood Component 'Circular of Information' An extension of blood component labels 2009

http://www.transfusion.com.au/sites/default/files/BCI%202009.pdf

Australian Red Cross Blood Service. Transfusion practice, products and safety information http://www.transfusion.com.au

Baker RI et al: Warfarin Reversal. Consensus guidelines, on behalf of the Australasian Society of Thrombosis and Haemostasis. MJA 2004; **181** (9): 492-497 (currently under review) http://www.mja.com.au/public/issues/181 09 011104/bak10441 fm.html

NBA. Patient Blood Management Guideline Development http://www.nba.gov.au/guidelines/review.html

NBA. Patient Blood Management Guidelines Module 1 - Critical Bleeding / Massive Transfusion http://www.nba.gov.au/guidelines/module1/index.html

NHMRC/ASBT. Clinical Practice Guidelines on the Use of Blood Components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate) (2001) (currently under review) http://www.nhmrc.gov.au/ files nhmrc/file/publications/synopses/cp78.pdf

NHMRC/NBA. Guidelines on the prophylactic use of Rh D immunoglobulin (anti D) in obstetrics (2003) http://www.nba.gov.au/pubs/pdf/glines-anti-d.pdf

NZBS. Transfusion Medicine Handbook 2008 http://www.nzblood.co.nz/Clinical-information/Transfusion-medicine/Transfusion%20medicine%20handbook

UK Blood Transfusion & Tissue Transplantation Services. Handbook of Transfusion Medicine http://www.transfusionguidelines.org.uk/index.aspx?Publication=HTM

WHO. World Health Organization Handbook: The Clinical Use of Blood http://www.who.int/bloodsafety/clinical_use/en/Handbook_EN.pdf

Reco	mmendations
R1	The decision to transfuse, and the consideration of other blood management strategies, must be based on a thorough clinical assessment of the patient and his/her individual needs.
R2	The indication for transfusion or the chosen alternative must be documented in the patient's medical/clinical record.

Section 2

Consent For Blood Products

All elements of the consent process should reflect prevailing local, state, territory or national requirements, and include:

- Variations in requirements by blood product type e.g. blood components versus plasma-derived products.
- Variations in documentation e.g. generic or dedicated transfusion consent form versus documentation in the patient's medical/clinical record.
- A The period of time that consent is valid e.g. a single prescription or an episode of care.
- The patient's capacity to give consent.
- △ The age of consent.

2.1 Obtaining informed consent

Informed consent for transfusion means a documented dialogue has occurred between the patient and a prescriber and which includes:

- The reason for the proposed blood product transfusion.
- The nature of the proposed blood product transfusion.
- The risks and benefits of the blood product as well as the risks or consequences of not receiving the product.
- The availability and appropriateness of any other blood management strategies.
- An opportunity to ask questions.
- Use of a competent interpreter when the patient is not fluent in English.
- Use of written information or diagrams where appropriate.

Consideration of the patient's language and cognitive ability should influence the written information provided. A range of written information for the Australian and New Zealand context, including in languages other than English, and specific information for parents and children is available.

2.1.1 Additional resources

ANZSBT. Publications List

http://www.anzsbt.org.au/publications/index.cfm

BloodSafe. Prescribing blood and blood components

http://www.health.sa.gov.au/bloodsafe/Default.aspx?tabid=53

Blood Watch. Blood Transfusion - patient information

http://www.cec.health.nsw.gov.au/resources

Health and Disability Commissioner Act 1994

http://www.legislation.govt.nz/act/public/1994/0088/latest/viewpdf.aspx

New Zealand Bill of Rights Act 1990

http://www.legislation.govt.nz/act/public/1990/0109/latest/viewpdf.aspx

NHMRC. Blood Components: A Guide for Patients

http://www.nhmrc.gov.au/ files nhmrc/file/publications/synopses/cp85.pdf

2.2 Documentation of consent

Consent must be documented by the prescriber in the patient's medical record either:

- On a generic or transfusion-specific consent form.
- In the progress notes.

2.3 Documentation of refusal

Refusal of consent, whether for religious or personal reasons, must be documented in the patient's medical/clinical record in either the progress notes or on a specific document produced for this purpose.

Where a patient refuses consent to transfusion of specific blood products, both those not to be administered and alternatives acceptable for administration should be clearly documented.

2.4 Inability to give consent

Wherever possible the patient him/herself must consent to treatment. The local, state, territory or national legislation regarding consent for a medical procedure must apply where consent cannot be obtained e.g. temporary or long term intellectual impairment, inability to communicate consent or loss of consciousness. This may include consideration of "Advanced directives" or "Medical/Welfare Power Of Attorney".

2.5 Jehovah's Witnesses

For many Jehovah's Witnesses, blood transfusion is forbidden. This includes whole blood or its components.

- Individual Witnesses may or may not agree with the use of albumin, immunoglobulins or coagulation factors.
- Most Witnesses do not allow preoperative autologous blood deposition.
- Acute normovolaemic haemodilution or dialysis may be acceptable according to personal conscience, if no other person's blood is used and the extracorporeal circulation is continuous with body circulation.
- There is a group of Witnesses (AJWRB) who believe that the decision to refuse or accept blood transfusions is a personal matter which should be decided individually.

In all circumstances, the wishes of the individual Jehovah's Witness must not be assumed. Consent must be sought in a thorough and confidential manner, be established with certainty and documented clearly in the patient's medical/clinical record.

The following should be clearly documented in the patient's medical/clinical record:

- As a member of the religious body of Jehovah's Witnesses, the patient refuses the use of blood components during surgery/treatment.
- The specific blood therapies which are or are NOT acceptable to the patient should be listed.
- The patient is aware that the planned procedure/treatment may entail a higher risk in the event of bleeding complications; in extreme situations, where there are no alternatives to medical transfusion, death may result.
- A checklist may be helpful in major surgery as this may often involve multiple disciplines (e.g. the surgeon, anaesthetist, and haematologist).

Regardless of the patient's choice of blood therapy, strict confidentiality must be maintained.

2.5.1 Unconscious adult Jehovah's Witness patient

Many baptised Witnesses carry a "Medical Directive / Advanced Directive / Health Care Directive / Alert Card"; alternatively, this may be available from their relatives.

- This is a form of living will which states the patient's wishes and alerts medical staff to his/her treatment preferences.
- A This is usually signed by two other Witnesses, commonly a family member and a religious elder.
- △ This document relieves medical staff of legal liability arising from not transfusing an adult Witness.

If there is an unambiguous written statement from an adult patient that he/she is a Jehovah's Witness and refuses blood under any circumstances, respect for the patient's autonomy requires that this wish be respected, just as if it had been expressed verbally. A copy should be filed in the medical/clinical record.

In the absence of a "Directive", an unconscious Jehovah's Witness should be given lifesaving treatment, including blood transfusion. However, attempts to seek an alternative person legally entitled to provide consent should be made prior to any blood transfusion, unless in an emergency.

The Hospital Liaison Committee for Jehovah's Witnesses should be contacted. Refer to the additional resources below if contact details not available through the health service.

2.5.2 Emergency transfusion of children of Jehovah's Witnesses

Where a parent or guardian refuses consent to administer blood products in the emergency treatment of a child (less than 16 years of age) prevailing local, state, territory or national legislation or guidelines should apply.

2.5.3 Additional resources

Associated Jehovah's Witnesses for Reform on Blood (AJWRB) www.ajwrb.org

Jehovah's Witnesses Website - Watchtower Society (WTS) www.watchtower.org

Recommendations	Re	co	m	me	en	da	11	O	ns
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R3 Health services must have a transfusion consent policy for both adults and children for:

- Acquisition and documentation of informed consent for blood products.
- The period of time that consent remains valid.
- Refusal of blood products including policy for Jehovah's Witnesses.
- When consent is unable to be obtained.

Section 3

Prescription Of Blood Products

The prescription is the written authorisation to administer the blood product. It must be available at the patient's side when the transfusion commences and must be retained within the patient's medical/clinical record when the transfusion is complete.

In New Zealand, blood products that are prescribed are classified as medicines. In Australia, blood products apart from immunoglobulins (e.g. intravenous immunoglobulin, Rh D immunoglobulin) are exempt from this classification (scheduling).

The prescription of blood products is the responsibility of the medical officer, midwife, nurse practitioner or other healthcare professional licensed or accredited to prescribe blood products.

The prescriber is responsible for ensuring:

- △ The blood product transfusion is clinically appropriate.
- △ The expected benefits outweigh the potential hazards.
- Informed patient consent has been obtained and documented.
- (Linical staff caring for the patient are informed that the blood product has been prescribed.
- A Patient risk factors are identified, and special requirements are documented.

3.1 Requirements for blood product prescription

Prescription charts for intravenous fluids or specific transfusion prescription charts intended for blood product transfusion must be used to maintain consistency with all medical prescribing according to local, state or territory legislation.

The prescription must be legible and contain:

- A Patient identification details: family name, given name, gender, date of birth (DOB) and unique patient identification number if available.
- Date, timing and urgency of the transfusion.
- Appropriate and consistent terminology for the blood product to be administered.
- Special blood product requirements e.g. irradiated, CMV seronegative.

Note: special blood product requirements must be communicated to the transfusion service provider as soon as they become known to allow a record to be made in the laboratory information system. The special requirements must also be documented on the prescription each time the product is administered.

- The route of administration.
- The number of units / dose of blood product to be given, using appropriate terminology specific to the product (e.g. number of packs, mL, units or grams); blood component volumes should be stated in mL for paediatric patients.
- The duration over which the blood product is to be administered.
- Special instructions e.g. use of blood warmer, any medication required before or after the transfusion.

- Legibly written name and signature of the prescriber, and a contact telephone number / pager number / Medicare provider number in accordance with health service policies; the prescriber must be clearly identifiable to minimise delays if the prescription needs clarification.
- The patient's known allergies, history of adverse drug reactions and previous transfusion reactions.

Standardised terminology for blood components is not yet agreed nationally but prescribers should be encouraged to avoid acronyms that may be ambiguous or misleading.

Prescriptions for plasma-derived blood products and recombinant products should include the brand name. The need for recombinant products should be clearly defined on the prescription.

Recommendations			
R4	The prescription must give a clear, legible instruction.		
R5	The prescription must be available to check at the patient's side when the transfusion takes place.		
R6	The prescription must be retained within a patient's medical/clinical record following completion of a transfusion.		

Section 4

Requests For Blood Products And Pretransfusion Blood Sampling

The request constitutes the mechanism of communication with the transfusion service provider(s), asking them to prepare and issue the blood product for administration.

Failure to correctly identify the patient at the time of sample collection, in addition to errors related to prescribing the wrong product or transfusion of the wrong patient, remain a significant cause of patient morbidity and mortality.

It is essential that patients are positively identified and that labelling of samples occurs at the patient's side. If not, a "wrong blood in tube" (WBIT) event could result which may compromise safety in two ways:

As a precursor to transfusion of the incorrect, and possibly incompatible, blood product.

By leading to inappropriate therapy due to incorrectly allocated results (Jeffcott et al, 2010).

It is not the intent of this document to provide extensive detail on requests, request forms or sample collection. The reader is referred to current resources available for this purpose as indicated in 4.1 below.

4.1 Additional resources

ANZSBT. Guidelines for Pretransfusion Laboratory Practice (5th Edition, March 2007) http://www.anzsbt.org.au/publications/documents/PLP Guidelines Mar07.pdf

NPAAC. Requirements for Transfusion Laboratory Practice (1st Edition, 2008) http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-transfusion.htm

Recommendations			
R7	Pretransfusion sample collection must include positive patient identification processes.		
R8	The blood product request must include positive patient identification processes and provide a clear communication to the transfusion service provider as to the product, urgency and dose required.		
R9	The blood product request must include the clinical indication for the transfusion and any special blood product requirements for the patient.		

Section 5

Storage, Collection And Transport Of Blood Products

Preservation of blood product viability is mandatory to maximise the efficacy of transfusion while minimising any risk to the patient from functional deterioration or contamination of the product. This is achieved by maintaining an appropriate cold chain and ensured by monitoring and recording the movement of the blood product from receipt to issue.

In addition, appropriate checking procedures, at each point of product transit, lessens the risk of transfusion of the wrong product to the wrong patient – a significant source of error identified by haemovigilance programs.

It is not the intent of this document to reiterate the requirements of the health service or the transfusion service provider with regard to storage and collection, documentation, or validation of pneumatic tubes where used. The reader is directed to the additional resources provided in 5.7

5.1 Storage of blood products

The current Australian standard relating to the storage of blood products (AS 3864-1997 *Medical refrigeration equipment - For the storage of blood and blood products*) specifies that red cells must only be stored in temperature-controlled, dedicated blood refrigerators and not in ward or domestic refrigerators. Other blood products must also be stored according to their specific requirements.

Controlled storage refrigerators must have an uninterruptable power supply and should be appropriately sited to allow the required ventilation, rapid access by designated staff and protection from access by the general public.

There must be a policy and protocol for a 24-hour/day immediate response to a refrigeration failure in order to maintain blood product viability and continued support for patient transfusion requirements.

Where a controlled storage refrigerator is located at a remote site, i.e. one not situated within the laboratory of the transfusion service provider, that refrigerator must be controlled and maintained according to current standards. The ownership and responsibility for the maintenance and monitoring of this refrigerator and accompanying registers must be documented by the health service concerned.

Movement of blood products into or out of a controlled storage refrigerator must be documented in a register or electronic system designated for this purpose. Documentation must include the product type, donation/batch number, patient name and MRN/NHI number if available, otherwise patient name and DOB, staff member's identification and the time and date the blood product was removed from (or returned to) storage for each unit removed (or returned).

5.2 Collection of blood products for transfusion from a controlled storage refrigerator

Before collection, both patient and staff must be adequately prepared to commence the transfusion process without delay. Requirements for administration are detailed in section 6. Refer to the checking steps given in 6.9 before blood product is collected.

Where a patient is haemodynamically stable, only one unit of red cells should be removed at a time from a controlled storage refrigerator to avoid wastage.

5.3 Checking procedures

Staff collecting blood products from the transfusion service provider, or remotely-located controlled storage refrigerator, must provide appropriate documentation in the form of a blood collection slip, prescription chart or patient's medical record, identifying the patient for whom the blood product is required as well as the specific blood product details. The documentation must comply with existing national standards for patient identification as listed in the references.

The staff member collecting the blood product from the transfusion service provider or removing the blood product from the remote, controlled storage refrigerator is responsible for verifying the patient identification details, blood product type and the blood product identification details.

The following information must be verified:

- The patient identification and blood product details on the compatibility label attached to the blood product.
- The patient identification and blood product details on the blood collection slip or blood transfusion compatibility report form (where used).
- △ The blood product type.

After completion of the checking procedure, removal of the product from storage must be documented in the register or electronic system for the purposes of tracking (see 5.1).

On its arrival at the clinical area, an appropriately trained staff member should confirm that the correct blood product has been delivered.

Where a blood collection slip is used, the health service or transfusion service provider should define how this documentation is retained or electronically stored.

5.4 Emergency red cells

In critical bleeding, and at the discretion of the treating clinician, there may be insufficient time to undertake full compatibility testing. It may be necessary to provide emergency group O red cells which may not be specifically labelled for the patient.

The decision to use uncrossmatched blood components must balance the patient's clinical need against the risk of potential adverse events such as a transfusion reaction due to pre-existing antibodies.

Where a health service determines the need for an inventory of emergency group O red cells, policies must clearly define:

- △ The transfusion service provider responsible for initial provision and replacement of emergency products.
- The procedure to obtain the available emergency group O red cells.
- The procedure to obtain clinical advice to facilitate appropriate acute patient management with regard to blood product use.

The inventory of emergency group O red cells must be controlled by the transfusion service provider and should be stored in an area of the refrigerator separate from crossmatched units labelled for specific patients. Storage and transport conditions are the same as for crossmatched red cells.

The issue of emergency group O red cells must be documented so a full audit trail is maintained. The transfusion service provider must be informed immediately if emergency group O red cells are required or removed from the controlled refrigerator. This assists traceability, allows replenishment of emergency group O red cells and commences a dialogue on obtaining a specimen from the patient for rapid grouping/screening and subsequent move to group-specific/crossmatched red cells.

Where the use of whole blood from emergency donor panels is authorised, this procedure must be governed in accordance with local, state, territory or national policies.

5.5 Transport of blood products to clinical areas

Once issued, blood must be transported **immediately** to the requesting clinical area or to a temperature-controlled remote refrigerator.

Institutions using a pneumatic tube system to transport blood products must validate the system for this purpose before implementation. A system must be in place to ensure the prompt collection of transported products, including a mechanism to notify requesting staff of the dispatch and arrival of the product. As transport systems are usually communal, due care and appropriate checking procedures must be instituted to avoid incorrect allocation of blood products to the incorrect location/patient.

Duration of storage of blood products within designated transport containers, including boxes and insulated ice boxes (e.g. "Eskys" or "chilly bins"), is defined and validated by the transfusion service provider, and dependent on appropriate and correct packing configuration. If blood products are received from the transfusion service provider in a designated transport box and are not able to be transferred to a dedicated, temperature-controlled, remote refrigerator, defined storage times must not be exceeded.

Before opening the container check the date and time by which the container is to be unpacked.

Once the storage container is opened, or as soon as the validated storage time is exceeded:

- All enclosed blood components SHOULD be transfused within the subsequent four hours (refer to 6.10.1).
- If multiple components are required for transfusion over a time period greater than four hours after opening the storage container, consider the need to transport the blood components in separate, validated transport boxes. This will maintain the cold chain of all transported components while some of the components are transfused.

5.5.1 "30-minute rule" for red cells

If any delay is encountered, blood components must be returned to the transfusion service provider as soon as possible, or placed back into a controlled storage refrigerator and the transfusion service provider informed accordingly. The time of return must be documented in the register.

Red cell units which have been out of controlled storage for <u>less than 30 minutes</u> and not transfused can, at the discretion of the transfusion service provider, be accepted back into the blood bank inventory for later re-issue either to the same or a different patient.

5.5.2 Red cells out of controlled storage longer than 30 minutes

Once a unit of red cells has been out of controlled storage for **more than 30 minutes**, one of the following must apply:

- Transfusion of the unit must be completed (as per 6.10.1).
- The unit must be appropriately marked as "unsuitable for use" by a designated method and either returned directly to the transfusion service provider or returned to the remote blood refrigerator, the time of return documented in the register and the transfusion service provider informed.

5.6 Transport of blood products between health services

A local transfusion service provider may choose to use Blood Service shippers for transporting blood products between health services, or when returning blood products from the health service to their inventory. If the Blood Service's shipper configurations are used by the local transfusion service provider, the responsibility for ensuring appropriate cold chain compliance rests with the local transfusion service provider.

A local transfusion service provider must also validate any packing configurations other than those published by the Blood Service if there is an intention to transport products between health services, or when returning blood products from the health service to the local transfusion service provider. Staff, both clinical and those of the local transfusion service provider, must be trained and competent in transport of blood products, including packing configurations, if participating in transfer of product between health services or transfusion service providers.

Packing scheme permutations must take into consideration:

- The product type.
- The ambient temperature.
- The numbers of products.
- △ The distance and time of travel required.

Where blood is transferred between health services, e.g. with a patient, the receiving health service must confirm that the product is suitable for clinical use by assuring that the cold chain has not been breached. This may require assessment of the time of packing, review of the packing configuration and assessment of the temperature of the products. This is best facilitated by notifying the receiving health service's transfusion service provider of the receipt of blood.

5.7 Additional resources

For additional information refer to the following references:

AABB. Guidelines for Pneumatic Tube Delivery Systems: Validation and Use to Transport Blood Components.

ACHS. Standards EQuIP 5

http://www.achs.org.au/EQUIP5

ANZSBT. Guidelines for Pretransfusion Laboratory Practice (section 4.5, 5th Edition, March 2007) http://www.anzsbt.org.au/publications/documents/PLP Guidelines Mar07.pdf

NPAAC. Requirements for Transfusion Laboratory Practice (section 9, 1st Edition, 2008) http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-transfusion.htm

NZBS. Transfusion Medicine Handbook 2008

http://www.nzblood.co.nz/Clinical-information/Transfusion-

<u>medicine/Transfusion%20medicine%20handbook</u>NZBS. The time interval between removal of blood from storage and subsequent infusion

 $\frac{\text{http://www.nzblood.co.nz/content/download/629/4024/file/Time\%20Interval\%20between\%20Storag}{e\%20and\%20Infusion\%20111l031.pdf}$

Standards Australia. AS 3864-1997 Medical refrigeration equipment - For the storage of blood and blood products

http://www.saiglobal.com/PDFTemp/Previews/OSH/As/as3000/3800/3864.pdf

Recommendations			
R10	Health services must have a policy for the storage, collection, transport and receipt of blood products including the associated documentation and checking procedures.		
R11	The policy for collection of blood products must clearly define staff responsibilities and their education, training and competency requirements.		
R12	Health services must have a policy and protocol for requesting and obtaining blood in a critical bleeding scenario.		

Section 6

Administration Of Blood Products

6.1 Venous access

IV access cannula size must be large enough to maintain an adequate flow rate for the transfusion. 18-20G or larger is recommended for non-emergency transfusion in adults. Smaller gauge devices can be used but may restrict the flow rate of the transfusion and result in a much longer time to infuse a component. 22-24G or larger is recommended for paediatric patients. However, the individual clinical context of the patient requiring transfusion will determine the size and type of IV access.

- In the critical bleeding / massive transfusion setting, large diameter IV access may be required to achieve adequate flow rates to resuscitate the patient. Additional IV access points may also be required if blood products need to be administered concurrently.
- In paediatric patients, and in adults with fragile or difficult veins, a smaller gauge cannula may only be possible with a resultant slower administration rate.

Most central venous access devices (CVAD), i.e. peripherally inserted central catheters (PICC), implanted ports and central venous catheters (CVC) have an adequate diameter to allow suitable flow. They may be used with an approved volumetric infusion device.

6.2 Equipment

6.2.1 Blood administration sets

- Blood components must be transfused using an administration set approved for this purpose. This must incorporate a standard filter which removes clots and small clumps of debris that may form during collection and storage. The recommended filter pore size is 170-200 micron.
- When blood is being administered by syringe to small infants or neonates, the blood must be drawn into the syringe via a 170-200 micron filter.
- A Platelets must be transfused through a new blood administration set unless administered in the setting of massive/rapid transfusion when platelets and plasma may need to be transfused through the same administration set.
- Platelets must not be transfused through a blood administration set which has been used for red cells, as red cell debris may trap infused platelets.
- A Red cells may follow platelets through the same blood administration set, but not precede platelets.
- Albumin and intravenous immunoglobulin formulations that do not require reconstitution may be administered via either a standard IV administration set without a filter, or a blood administration set.
- A Refer to individual product information for other plasma-derived blood products.

6.2.2 Priming and connecting blood administration sets

- The blood product should be mixed thoroughly by gentle inversion before use.
- The blood administration set may be primed with 0.9% sodium chloride (normal saline) or the blood product.

- The manufacturer's recommendations must be followed when priming the blood administration set.
- Blood administration sets must not be "piggy-backed" into other lines.
- Attachment to extension tubing on an IV cannula is acceptable.
- When administering blood products through a multi-lumen venous access device, other lumens can be used concurrently for medications and infusion of fluids. Refer to 6.6 for further information regarding co-administration of medications and fluids.

6.2.3 Flushing blood administration sets

- Priming or flushing blood administration sets with a small amount of 0.9% sodium chloride (normal saline) between red cell packs is not evidence-based and may be unnecessary. However 0.9% sodium chloride (normal saline) may be required to maintain access if the next red cell unit is not readily available.
- Compatible blood products can be administered sequentially and in critical bleeding this is the usual practice. However, platelets must not be transfused through a blood administration set which has been used for red cells (see 6.2.1).
- At completion of the transfusion episode, blood administration sets may be flushed with 0.9% sodium chloride (normal saline) to ensure that the patient receives the entire blood product. The minimum volume of 0.9% sodium chloride (normal saline) required to completely clear the IV line should be used, taking into account the individual circumstances of the patient, for example in neonates, some paediatric patients or in those at risk of fluid overload or on fluid restrictions.

6.2.4 Changing blood administration sets

- The blood administration set must be changed when transfusion is completed or every 12 hours if the transfusion episode is not yet complete. This is intended to reduce the risk of bacterial growth occurring.
- Any number of red cell units may be transfused during a 12-hour period provided the flow rate remains adequate. However specific manufacturer's recommendations defining the maximum number of units per blood administration set must not be exceeded.
- A new blood administration set should be used if infusion of another fluid, medication or platelets is to continue after the current transfusion (refer to 6.2.1). This is intended to reduce the risk of incompatible fluids or drugs causing haemolysis of residual red cells in the administration set or drip chamber.

6.3 Additional filters

6.3.1 Leucocyte depletion filters

All red cells and platelets issued by the Blood Service are leucocyte depleted and therefore additional bedside leucocyte depletion filters are not required.

In rare cases when blood components have been collected within a local health service, e.g. autologous units or directed donation, bedside leucocyte depletion filters may be indicated. This must be verified with the provider / local health service policy. Product information on the correct use of these filters must be followed.

Note: Granulocyte, stem cell or bone marrow infusions MUST NEVER be infused through a leucocyte depletion filter.

6.3.2 Microaggregate filters

Microaggregate filters (pore size 20-40 microns) are intended to remove microscopic debris from stored red blood cells. There is no evidence from controlled trials that they offer clinical benefit and their use is not generally recommended (Woodfield, 2003).

6.3.3 Other filters

Local or manufacturer policies and product information may apply where other filters are used in settings such as intra-operative or post-operative cell salvage etc.

In addition the following guidelines may be of assistance in creating local health service policy:

ANZSBT. Guidelines for Autologous Blood Collection (2002)

http://www.anzsbt.org.au/publications/documents/2002 Vol9 2.pdf

Association of Anaesthetists of Great Britain and Ireland (AAGBI). Blood Transfusion and the Anaesthetist – Intra operative cell Salvage

http://www.aagbi.org/sites/default/files/cell%20 salvage 2009 amended.pdf

Better Blood Transfusion. Learn Cell Salvage

http://www.transfusionguidelines.org.uk/index.aspx?Publication=BBT&Section=22&pageid=974

National Institute for Health and Clinical Excellence (NICE). Intraoperative Blood Cell Salvage in Obstetrics

http://www.nice.org.uk/guidance/IPG144

6.4 Infusion devices

Local health service policy should indicate whether volumetric infusion and external pressure or rapid infusion devices can be used, including in which situations they are appropriate. The device must be validated by the manufacturer for the administration of blood products and used exactly as specified by the manufacturer.

The manufacturer of the device or model chosen for transfusion must be able to demonstrate that it does not cause haemolysis or damage to red cells, granulocytes or platelets, as appropriate, and specify the maximum infusion rate and pressure setting at which safety was demonstrated.

6.4.1 Volumetric infusion pumps

Used to deliver blood products when:

- Controlled flow rates are required for specific patients, for example paediatric patients, or those at risk of fluid overload.
- Infusion of blood products via gravity is unreliable e.g. via PICC or small gauge cannula.

May be used to deliver products via:

- Peripheral lines.
- CVAD.

6.4.1.1 Checklist for volumetric infusion pumps

- When infusing blood components through a volumetric infusion pump, a blood administration set incorporating a 170-200 micron filter must be used.
- If a 170-200 micron filter is to be added to the administration set as a separate item, it must be compatible with all other equipment used in the transfusion process.
- Staff using volumetric infusion pumps must demonstrate knowledge and competency in their use according to health service policy.

- The checking procedure prior to spiking and hanging the blood must include a check of the device and device settings as well as the standard blood product and identity checks.
- A Both pump settings and volume delivered must be monitored hourly throughout the infusion to ensure that expected volume is delivered.
- Any adverse outcome as a result of using a pump to transfuse blood must be notified to the appropriate authority as per hospital guidelines.
- Volumetric infusion pumps must undergo a regular maintenance program e.g. by the health service biomedical provider.

6.4.2 External pressure devices (bags) and rapid infusion devices

External pressure devices (bags) and rapid infusion devices are used to assist infusion of large volumes of red cells in the setting of critical bleeding; they usually also warm the red cells.

External pressure bags are occasionally used in the absence of critical bleeding to assist controlled infusion by gravity rather than a volumetric pump although this practice is discouraged.

In critical bleeding a large gauge peripheral cannula or CVAD MUST be used.

In non-critical bleeding, when an external pressure bag is used to improve flow rates, the blood product can be delivered via a peripheral line or CVAD as above. External pressure devices should:

- Exert pressure evenly over the entire bag.
- Have a gauge to measure the pressure.
- Not exceed 300mm Hg of pressure.
- Be monitored at all times when in use.

6.4.3 Syringe drivers

Syringe drivers are devices in which a standard syringe is placed in a housing that depresses the plunger at a controlled rate. They may be useful for continuous infusion of coagulation factors such as Factor VIII or Factor IX or for transfusion in the paediatric setting (see 7.2).

If a syringe driver is used, the configuration must ensure that blood products pass through a 170-200 micron blood filter. The clinical policy must include the importance of aseptic technique, only withdrawing from (spiking) the primary bag once and labelling of the syringe (if detached from the bag) to ensure correct patient identification and optimum product viability.

6.5 Blood warmers

Local health service policy should indicate whether blood warmers can be used, including in which situations they are appropriate. The device must be validated by the manufacturer for the administration of blood products and used exactly as specified by the manufacturer.

6.5.1 Indications for blood warmers

A blood warmer is indicated for:

- Large volume rapid transfusions of >50 mL/kg/hour in adults or >15 mL/kg/hour in children.
- Exchange transfusions.
- Plasma exchange for therapeutic apheresis in adults.
- Intrauterine transfusions, at the discretion of the feto-maternal specialist.
- Patients with clinically significant cold agglutinins.

6.5.2 General recommendations

- A Red cells should only be warmed as they flow through a blood administration set using a specifically designed, approved commercial device with a visible thermometer and audible warning alarm.
- Blood warmers must undergo a regular maintenance program e.g. by the health service biomedical provider.
- The operating temperature of the commercial blood warmer must be recorded on the patient's infusion record when used to warm red cells.
- A Red cells must not be warmed above the set point temperature of the approved device, commonly 41°C.
- Blood administration sets used with warmer must be primed as for other blood administration sets prior to use.
- Due to the risk of contamination from infected water baths, it is recommended that these types of devices be replaced with dry heat blood warming equipment.
- Improvised warming such as putting the pack in hot water, in a microwave oven or on a radiator must NEVER be used. These methods may damage red cells and cause harm to the patient.

6.5.3 Additional resources

AABB. Primer of Blood Administration (available to individual and institutional AABB members) http://www.aabb.org/development/education/material/Pages/default.aspx

BCSH. Guideline on the Administration of Blood Components

http://www.bcshguidelines.com/documents/Admin blood components bcsh 05012010.pdf

BCSH. Guidelines on the management of massive blood loss

http://www.bcshguidelines.com/documents/massive bloodloss bjh 2006.pdf

NHS Blood and Transplant Services. A Drop of Knowledge: Guidance for New and Developing Transfusion Practitioners

http://www.transfusionguidelines.org.uk/docs/pdfs/bbt-01 ADOKV5-July09.pdf

NZBS. Transfusion Medicine Handbook 2008

http://www.nzblood.co.nz/Clinical-information/Transfusion-

medicine/Transfusion%20medicine%20handbook

6.6 Concurrent fluids and medications

Intravenous fluid solutions must not be co-administered with blood components unless there are sufficient data to ensure compatibility.

A multi-lumen access device is generally safe for continuous co-administration of other therapeutic solutions, allowing for rapid dilution in the blood stream. In the absence of a multi-lumen access device, a second IV access device must be inserted if a continuous IV infusion is required.

Administering two different types of blood components concurrently via separate IV access lines is not recommended in routine practice, since in the event of an adverse reaction it is difficult to ascertain which component is responsible. However, this situation may arise in the setting of critical bleeding.

6.6.1 Compatible fluids

The only IV fluid universally compatible with blood components is 0.9% sodium chloride (normal saline).

- Red cells are compatible with ABO-compatible plasma and 4% albumin.
- For fluids compatible with plasma-derived and recombinant products refer to the individual product information.
- The current formulation of Gelofusine® (available in Australia) contains negligible calcium, and is considered compatible based on common experience and current practice, particularly by anaesthetists, in the absence of data to the contrary and as quoted by the manufacturer. http://www.bbraun.com/cps/rde/xchg/bbraun-com/hs.xsl/products.html?level=3&id=00020742770000000152

6.6.2 Incompatible fluids

- Electrolyte and colloid solutions containing any calcium (e.g. Haemaccel®, Hartmann's solution, lactated Ringer's solution or Gelafusal® [available in New Zealand]) should not be administered with blood components collected in an anticoagulant containing citrate as they may cause clotting of the infusion line.
- 5% dextrose in water or hypotonic sodium solutions may cause red cells to haemolyse.

6.6.3 Medications

Medication must NOT be added to the blood bag or blood administration set / IV line prior to, or during transfusion.

Medication may interact with the anticoagulant, additive solutions, or the blood component contained in the bag. A break in the integrity of the infusion line may also increase the risk of bacterial contamination of the component. Furthermore, if a reaction occurs, it is difficult to ascertain whether the medication or the blood component was responsible for the adverse effect.

In multi-lumen CVAD, separate lumens can be used to simultaneously administer blood components and medications. However, caution should be exercised if:

- It is the first time a medication has been administered.
- The medication is associated with adverse effects (such as amphotericin).

Medications administered intermittently rather than continuously may be administered via the same IV line according to the following procedure:

- Stop the transfusion.
- Elush the line, via the injection port, using 0.9% sodium chloride (normal saline) to clear blood from the IV port and tubing.
- Administer the medication.
- A Flush the line with 0.9% sodium chloride (normal saline) before restarting the transfusion.

Note: this procedure should not result in the infusion time exceeding four hours.

In the absence of a multi-lumen CVAD, and when medications or fluids require administration without interruption of concurrently transfused blood products, additional IV access should be obtained.

Co-administration of morphine, pethidine and/or ketamine diluted ONLY in 0.9% sodium chloride (normal saline) for patient controlled analgesia or continuous side arm infusion, via a non-reflux valve has been shown not to adversely affect red cells (Birch, 2001). Local hospital protocols should define the procedure for co-administration of patient-controlled analgesia and blood products.

Further evidence from clinical studies is required to inform clinical practice on the safety and efficacy of co-administration of other medications and blood components.

6.6.4 Additional resources

Hanan M, Yousef R F, Padmore D, Neurath D & Rock G A The effect of patient-controlled analgesia on co administered red blood cells. Transfusion 2006; **46**: 372-376

Murdock J, Watson D, Dorée C J, Blest A, Roberts MM & Brunskill S J. Drugs and blood transfusions: dogma or evidence-based practice? Transfusion Medicine 2009; **19**: 6–15

6.7 Location and timing of the transfusion

Transfusion must only take place when it is appropriately resourced, i.e. enough trained staff are available to monitor the patient, where the patient can be observed and where emergency medical support is readily available. Overnight/out-of-hours transfusion should be avoided unless clinically indicated.

- The transfusion must begin as soon as the blood component is delivered to the clinical area, following removal from the designated transport box / controlled storage.
- The commencement time of the transfusion must be recorded.

6.8 Checklist before a blood product is issued by / collected from the transfusion service provider / remote refrigerator

Before requesting issue of, or collecting the blood product, the following should be checked by clinical staff:

- The prescription has been satisfactorily completed.
- Informed consent has been obtained and the indication for transfusion has been documented in the patient's medical/clinical record.
- The patient has been assessed to determine whether it is appropriate to undertake the transfusion at the planned time.
- Intravenous access is appropriate and patent.
- Any pre-medication prescribed for the patient has been administered, and at a suitable time before the transfusion commences to allow it to be effective.
- Appropriately trained and competent staff are available for the duration of the transfusion, including two staff to perform the blood product and patient identity checks at the patient's side.

6.9 The pre-administration identity check of patient and blood product

The final check at the patient's side is a vital step in preventing transfusion error. Staff must be vigilant in the checking procedure to ensure that the right blood is administered to the right patient.

Information regarding patient identification and patient identification bands is obtained from the Australian Commission on Safety and Quality in Health Care (ACSQHC) *Standards* and NZBS *Transfusion Medicine Handbook* which are current at time of production of these guidelines, as referenced below.

Flippin' Blood also contains this information and is a useful resource for clinical areas.

http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PatientID-Resources-NatStd Bands.

http://www.nzblood.co.nz/Clinical-information/Transfusion-medicine/Transfusion%20medicine%20handbook

http://www.health.sa.gov.au/bloodsafe/Portals/0/flippn'bloodchartSept06.pdf

Information regarding patient identification on compatibility labels and reports is obtained from the ANZSBT *Guidelines for Pretransfusion Laboratory Practice* 5th Edition, March 2007 (currently under review).

6.9.1 Identification bands (ID bands)

All patients receiving a blood product, whether inpatient, outpatient or day patient MUST be positively identified and SHOULD have an identification band attached to their body that complies with Australian and New Zealand standards/guidelines.

The following *minimum* core patient identifiers are mandatory:

- FAMILY NAME and Given Name(s) Family and given names should be clearly differentiated. Family name should appear first in UPPER case text followed by given name(s) in "Title" case. That is, FAMILY NAME, Given Name(s); for example, SMITH, John Paul.
- Medical record number (MRN), National Health Index (NHI) number or equivalent.
- **DOB** ("date of birth" written as DD/MM/YYYY).

Individual hospitals / health services should determine how they meet the specifications for identification bands. Issues that will need to be determined locally at the hospital / health service level include:

- Inclusion of additional identifiers, such as barcodes or the patient's gender.
- Inclusion of substitute identifiers, in the instance that one or more of the mandatory identifiers listed above is unknown (e.g. DOB).
- Use of cultural naming conventions or use of preferred names rather than correct names.

6.9.1.1 Neonates

Neonates must be identified and have an identity band attached immediately at birth. The same patient identifiers, as specified in 6.9.1, should also apply to neonates.

Local operational policy may stipulate that neonates wear two identification bands at all times, i.e. same details on two different limbs.

6.9.1.2 Unconfirmed identity and name changes

When a patient's identity cannot be reliably confirmed, e.g. temporary or long-term intellectual impairment, inability to communicate or loss of consciousness, they must be registered according to the documented hospital procedure as, e.g. "Unknown Male" or "Unknown Female" using an emergency MRN or NHI number.

- Once the patient is identified, patient information should be updated and a new identification band attached.
- Change of identity details should only occur when the period of critical medical management, e.g. initial resuscitation, has ended.
- Local operational policy must stipulate procedures to ensure that such patients can be correctly identified throughout their admission, particularly in relation to the reconciliation of samples/investigations including those related to pretransfusion testing.

In the event that core patient identification details (family name and given names, DOB) are legitimately changed or updated (e.g. unknown patient, baby name change, typographical errors):

- Patient details must be updated in the Patient Administration System (MRN or NHI number must not change).
- A new identification band must be attached to the patient.

The transfusion service provider must be notified immediately if pretransfusion testing has been undertaken.

6.9.2 Checking procedure

- A The patient's identity must **always** be confirmed prior to transfusion.
- The patient's full name (family and given name), MRN/NHI number and/or DOB, must be checked and found to be identical on the patient's identification band, the compatibility label attached to the blood product and the blood product prescription.

It is acknowledged that the MRN/NHI number will not be available on a compatibility label/report as a third patient identifier in some circumstances e.g. pretransfusion testing requested as an outpatient prior to admission, MRN/NHI number not provided to a private pathology transfusion service by a health service. Where provided or recorded, the MRN/NHI number should be considered as a third patient identifier and must be consistent on the documentation and patient identification band.

6.9.2.1 Staff responsibility

In the absence of evidence to support a change, the current recommendation is that two members of staff must undertake the identity check of the patient and blood product **at the patient's side** immediately prior to administration. Each of these two staff is responsible for the accuracy of the checking procedure. Although commonly performed co-operatively, consideration should be given to independent checking.

- The staff performing the identity check must be medical officers, registered nurses or midwives, anaesthetic technicians or other staff authorised and appropriately trained by their health service.
- The two individuals carrying out the check must both sign the relevant documentation confirming the patient and product check has occurred, and is correct and compatible.
- The person spiking/hanging the blood product must be authorised and appropriately trained by their institutions to spike/hang the product, and must be one of the two staff members who have undertaken the blood and patient identity check. The pack should not be spiked until the identity check of patient and blood product is complete. The pack must be spiked and commenced immediately after the check has been completed. If there is a delay, the checking process must be repeated.
- Lt is the responsibility of the person spiking or hanging the blood product to ensure it is appropriate to undertake the transfusion at that time. This may include an assessment of patient clinical status and confirmation with the prescriber.

6.9.2.2 Confirmation of patient identity

The identification band checking procedure must include the following steps:

- Check the identification band is securely attached to the patient.
- Ask the patient (if conscious and rational) to state and spell their family name and given name in full, and DOB (whenever possible); ensure that the stated full name and DOB are identical to those on the identification band and confirm correct spelling of names.
- If the patient is unable to state and spell their name, ask a parent, guardian or carer (if present and able to do so) to verify the patient's identity; ensure the stated full name and DOB are identical to those on the identification band.

The blood transfusion compatibility report form, where used, should NOT form part of the final patient identity check at the patient's side, but may be used to check blood component information once identity has been established.

6.9.2.3 Blood product checklist

The blood product checking procedure must ensure the following:

- The patient's full name (family and given name), DOB, and MRN/NHI number (if included), are identical to those on the compatibility label attached to the blood product and the blood product prescription.
- The blood product type is the same on the prescription, on the product and the laboratory compatibility label.
- The blood product is checked for compliance with any special requirements on the prescription (e.g. irradiated, CMV seronegative).
- The blood group and donation/batch number on the compatibility label are identical to that information on the product from the supplier.
- The blood group on the blood component is compatible with the blood group of the patient as indicated on the compatibility label attached to the pack; if the blood group of the blood component and the patient are not identical, the transfusion service provider must make a specific comment to indicate that it is compatible (or most suitable available).
- The blood component/product has not passed its crossmatch expiry or unit/product expiry date and time.
- The integrity of the blood product is confirmed by excluding:
 - Any leaks at the ports and pack seams.
 - Any evidence of haemolysis, unusual discoloration or turbidity.
 - The presence of any large clots.
 - Broken or leaking bottles or vials.

If a discrepancy is found while performing the checking procedure at the patient's side, that is not covered by a comment by the issuing transfusion service provider, the blood must not be transfused until the discrepancy is resolved with the transfusion service provider.

If there is any concern regarding the integrity of the product, it must not be used and should be returned to the issuing transfusion service provider.

6.10 Infusion rates and precautions

The infusion rate for blood products depends on the clinical context, age and cardiac status of the patient. In stable, non-bleeding adult patients typical administration durations are:

A Red cells 60-180 minutes per unit.

A Platelets 15-30 minutes (Australia) / 30-60 minutes (New Zealand) per

standard adult equivalent dose.

Fresh frozen plasma 30 minutes per unit (i.e. 10-20mL/kg/hr).

Cryoprecipitate 30-60 minutes per standard adult dose (i.e. 10-20mL/kg/hr).

Granulocytes Infusion rates should follow local protocols.

Plasma-derived products Infused in a timeframe in accordance with product-specific

instructions.

For patients at risk of circulatory overload e.g. cardiac failure, it is usually necessary to transfuse more slowly with frequent monitoring. Concomitant use of diuretics should also be considered.

Patients with acute bleeding or who are in hypovolemic shock require blood components to be transfused rapidly. The use of a blood warmer is recommended in critical bleeding / massive transfusion situations.

For information on paediatric and neonatal transfusion practices refer to 7.2.

Start each pack slowly, where possible and clinically appropriate. The rate of infusion may then be increased, usually after 15 minutes, to the maximum infusion rate defined in accordance with the prescription, as long as there are no signs or symptoms of an adverse reaction.

Specific guidance regarding rates for administration of plasma-derived blood products should be obtained from the relevant product information and included in local hospital procedures/protocols. *Flippin' Blood* also contains this information and is a useful resource for clinical areas.

6.10.1 Maximum duration for transfusion

The transfusion should normally be completed within four hours of the product leaving approved controlled storage (or sooner if specified on the pack / transfusion report).

Note: In certain clinical situations such as transfusion of neonates, where a slow infusion rate is indicated, the hospital or health service may instead permit completion of transfusion within four hours of **commencement**. This is to accommodate transport time of the product to the clinical area of up to 30 minutes.

This exception to standard practice must be documented in a hospital or health service policy/procedure. Transfusion **must** be completed within four hours of commencement <u>and no longer than four-and-a-half (4½) hours</u> following release of the product from controlled storage.

6.11 Observations and monitoring

The following recommendations relate specifically to transfusion of blood components. While the general principles apply to the infusion or administration of plasma-derived products, refer to relevant product information and local procedures or protocols for specific guidance.

- Patients receiving transfusions must be monitored for signs of potential complications of the transfusion, and any suspected problems dealt with promptly.
- A Prior to commencement of the transfusion, patients should be appropriately educated and advised to report to staff immediately any adverse effects that they may experience during or after the transfusion.
- Transfusion must only take place when enough trained staff are available to monitor the patient and where the patient can be readily observed and emergency support is available.
- The commencement time of the transfusion must be documented.
- The patient MUST be closely observed for the first 15 minutes after commencement of each unit and SHOULD be closely observed from the start of each individual blood component pack throughout the transfusion, to detect any adverse effects.
- Serious and life threatening reactions (anaphylaxis, transfusion-related acute lung injury [TRALI], haemolysis and sepsis) can occur unpredictably and progress rapidly, therefore further indicating the need for close observation throughout the transfusion.
- Where the patient is not in an open area that allows continuous visual observation, consideration should be given to attending the patient for the first 30 minutes of the transfusion. Previous Serious Hazards Of Transfusion (SHOT) reports (www.shotuk.org) highlighted that two thirds of reactions occur within the first 30 minutes after commencement, and a third of reactions occur later than 30 minutes and even after completion of transfusion.
- As a **minimum**, the vital signs of temperature, pulse, respiration rate and blood pressure MUST be measured and recorded as follows:
 - Prior to the start of each individual blood component pack administered.
 - 15 minutes after commencing administration of each blood component pack.

- When administration of each blood component pack is completed.
- Measurement of vital signs SHOULD be undertaken and recorded 15 minutes after commencement and compared with baseline. However, individual institutions may consider continuous visual observation for the first 15 minutes, with vital sign measurement directed by the clinical status of the patient, a reasonable alternative in appropriate specialist areas with transfusion expertise.
- There is no consensus on subsequent frequency of routine vital sign measurement during transfusion, however many institutions stipulate hourly measurements, after the initial 15 minute period, until completion of the transfusion. Regular visual observation throughout the transfusion is however essential.
- Additional vital sign measurements during the transfusion, including oxygen saturation, are at the discretion of each clinical area / hospital policy. The frequency and recording of vital signs must be adjusted according to the individual patient's clinical condition. More frequent monitoring may be required based on underlying comorbidities and intercurrent factors, e.g. if the patient has congestive heart failure, bleeding, increased intracranial pressure, renal dysfunction or is unable to respond or shows signs or symptoms of a reaction.
- Assessment of skin condition, prior to and during transfusion i.e. for the presence/absence of rash, can assist recognition of a transfusion related allergic reaction.
- All observations must be recorded in the patient's medical/clinical record.

6.11.1 Children, unconscious or anaesthetised patients

- A Routine observation patterns must be applied, however closer observation should take place for infants, unaccompanied children and patients who are unable to verbalise symptoms or use the call bell due to mental or physical limitations.
- Unconscious or anaesthetised patients require increased monitoring and vigilance for signs of transfusion reactions.
- Transfusion reactions should be considered if a change or deterioration in the patient's condition occurs.
- Hypotension, uncontrolled bleeding or generalised oozing during surgical procedures may suggest an acute haemolytic reaction due to an incompatible red cell transfusion.
- A Haemoglobinuria or oliguria may also be an early sign of an acute haemolytic transfusion reaction due to an incompatible red cell transfusion.

6.12 Completing the transfusion

- △ The time each product was completed must be recorded.
- The compatibility label or report form where in use must be retained in the patient's medical/clinical record.
- Adverse effects may manifest after the transfusion has been completed. The patient must be advised to report any adverse effects experienced after the transfusion has been completed.
- For patients undertaking transfusion at a day treatment centre, a health service may consider a period of continued observation at the completion of the transfusion appropriate, in case of delayed transfusion adverse event. Additional information such as a contact sheet or card may be given on discharge to advise them how to obtain appropriate clinical advice at any time.
- If the transfusion is completed uneventfully, the empty pack or bottle should be discarded according to the health service policy for disposal of clinical waste (glass bottles are not suitable for recycling).

If there is any suspicion of a transfusion reaction the transfusion service provider must be informed of the clinical details and the product / product pack or bottle should be returned.

6.13 Checklist for medical/clinical record documentation of transfusion

The following information must be documented:

- Indication for blood product transfusion.
- Consent for blood product transfusion.
- Blood product prescription.
- Blood transfusion compatibility label or, where used, the report form.
- Commencement and completion time of each unit.
- Patient observations.
- Outcome of the transfusion in terms of desired effect.
- Occurrence and management of any adverse reactions if applicable.

Recommendations

- R13 Health services must have a policy for all patients receiving transfusion of blood that defines and includes:
 - · positive identification of the patient
 - selection of the appropriate location and timing for the transfusion
 - validation of equipment employed in transfusion
 - administration procedures for components, compatible fluids and medications
 - optimal observation, care and monitoring of the patient

Section 7

Special Transfusion Circumstances

7.1 Out-of-hospital blood transfusions

Out-of-hospital (OOH) transfusions, such as in patients' homes or in nursing homes, require special attention for many reasons, including increased distance from emergency medical care, the need for careful selection of patients, indications and surroundings.

The decision to undertake OOH transfusion should be based on individual patient circumstances and only be considered when:

- A There are significant benefits for the patient which outweigh the risks.
- Transfusion indication, circumstances and surroundings have been carefully considered.
- The patient is willing and informed consent for transfusion specific to the OOH setting has been obtained.
- The service providing the OOH transfusion has addressed all the necessary regulatory and practical requirements.

The following points provide some general principles related to OOH transfusion practice but are not intended to be comprehensive.

- A policy for OOH transfusion must be established taking into account the recommendations made in this document for hospital transfusion, including the requirement that the patient wears an ID band and is closely observed during the transfusion. The established policy should comply with ANZSBT guidelines (including administration, transport and storage of blood products and pretransfusion specimen collection) as well as other relevant local, state, territory or national legislation, guidelines and policies.
- The responsibilities for the various aspects of OOH transfusion, including overall responsibility for the service should be defined, with clearly stated lines of communication between all stakeholders. Evaluation by the home care service provider's risk management personnel may be required.
- A multidisciplinary group or committee with appropriate transfusion expertise should be established to oversee the development, implementation and quality assurance necessary to ensure best practice.
- Occupational health and safety procedures for personnel involved in OOH transfusion must be as rigorous as those for in hospital transfusion.
- △ Education and training must be provided to all personnel involved and may include the patient's relative/carer and the courier delivering the blood. Training of the person undertaking blood product administration includes CPR and other aspects of acute care for dealing with transfusion reactions.
- A policy for appropriate patient selection must be developed and implemented, including considerations such as cardio-respiratory, haemodynamic and mental status, transfusion history, environment and distance from an acute care hospital.
- A There must be a clear plan of action in case of an emergency or transfusion reaction, with an identified registered medical practitioner responsible, a back-up support system and a 24-hour patient liaison service. An adverse reaction / emergency medication kit should be available for administration as per a medical officer's instruction.

- A Patients should be allocated a patient identification number to be used throughout the transfusion process, including sample collection, the collection and the administration of the blood product. Best practice dictates that an identification band be placed on the patient at the time of blood sample collection, if it is not already in place.
- The patient identity and product checking procedure must be performed at the patient's side, before administration of any blood product by two members of staff authorised and trained to do so (refer to 6.9.2).
- The two individuals carrying out the check must both sign the relevant documentation confirming the patient and product check has occurred.
- The person spiking/hanging the blood product must be authorised and appropriately trained by their institutions to spike/hang the product, and must be one of the two staff members who have undertaken the blood and patient identity check.
 - The pack should not be spiked until the identity check of patient and blood product is complete.
 - The pack must be spiked and commenced immediately after the check has been completed.
 - If there is a delay, the checking process must be repeated.
- Lt is the responsibility of the person spiking/hanging the blood product to clinically assess the patient prior to commencement and to ensure it is appropriate to undertake the transfusion at that time.
- Individual institutional policy may allow a relative or carer of the patient to be one of the two people checking the identity at the patient's side before administration.
- A second adult (relative or carer) must be present throughout the transfusion. The patient, and the relative or carer who remains with the patient after transfusion, should receive specific instruction and contact details in the event of an adverse reaction.

Facilities engaging in or planning to engage in OOH transfusions are referred to other resources which provide a more detailed framework for OOH transfusion practice.

7.1.1 Additional resources

AABB. Guidelines for Home Transfusion (1997)

http://www.aabb.org/Pages/Product.aspx?Product_Id=752

Benson K. Home is where the heart is: Do blood transfusions belong there too? Transfusion Medicine Reviews 2006; **20**(3): 218-229.

NZBS. Transfusion Medicine Handbook 2008

http://www.nzblood.co.nz/Clinical-information/Transfusion-

medicine/Transfusion%20medicine%20handbook

UK Blood Services. Handbook of Transfusion Medicine (2007)

http://www.transfusionguidelines.org.uk/index.aspx?Publication=HTM&Section=9

7.2 Paediatric transfusions

Obstetric and Paediatric & Neonatal modules of the national Patient Blood Management Guidelines will be produced as part of phase 3 of the review of the 2001 ASBT/NHMRC Clinical Practice Guidelines for the Use of Blood Components, which is being undertaken under the auspices of the ANZSBT and the NHMRC in conjunction with the National Blood Authority.

The transfusion of blood products to children and neonates requires special consideration. Specialised paediatric hospitals and their associated hospital transfusion services should be contacted for queries relating to paediatric transfusion. If available, a specialist paediatric transfusion practitioner should be

consulted for advice and, where possible, provide education to staff administering blood products to paediatric patients.

Children and neonates require special consideration and the following points should be addressed:

The volume of blood to be transfused

Children less than 30 kg should have the volume prescribed in mL. The volume should be
calculated on the child's weight and the desired haemoglobin to prevent transfusionassociated circulatory overload (TACO).

Special requirements

- Fresh red cells (less than five days old), K negative, CMV seronegative and/or irradiated products may be indicated.
- The Blood Service is available to advise on appropriate selection of blood for intrauterine or exchange transfusion.

Consumer information

An information leaflet on blood transfusions should be provided for the parent/guardian
to assist with education about transfusion e.g. the paediatric patient information –
Children receiving a blood transfusion – A Parents' Guide.
http://www.anzsbt.org.au/publications/documents/AParentsGuide.pdf

Positive identification of children

• Identification bands must be in place and a parent/carer/guardian (if present) should positively identify the child prior to commencing the transfusion.

Administration of products

- For neonates and infants, blood components may be administered via a paediatric blood administration set incorporating a 170-200 micron filter. Alternatively, a syringe may be used provided blood is drawn from the bag using a blood line incorporating a 170-200 micron filter.
- The clinical policy must include the importance of aseptic technique, single access to the bag and labelling of the syringe (if detached from the bag) to ensure correct patient and product identification and optimum product viability. Labelling should include the product expiry time.

Rate of infusion

- Clinical indication and fluid volumes appropriate for weight must be considered by the medical officer when determining the rate of infusion.
- Transfusion of blood components **should** be completed within four hours of leaving approved storage. In certain clinical situations such as transfusion of neonates, the hospital or health service may instead permit transfusion to be completed within four hours of commencement but no longer than four-and-a-half (4½) hours following release of the product from controlled storage to allow for a 30-minute transport time (refer to 6.10.1).
- The use of syringe drivers and volumetric infusion pumps (approved for blood products) are recommended to ensure accurate rates.

A child's cognitive ability to report or partake in care

• Infants and neonates will not be able to communicate adverse effects of transfusion and must be closely monitored.

Consideration of children's activities

• A wider variety of activities (e.g. play) should be considered and the transfusion planned for a time when the child is in a supported clinical area, allowing close observation.

Recommendations	
R14	Health service providing out-of-hospital transfusion services must have defined policy and protocols to determine staff responsibilities and best practice in all aspects of the out-of-hospital transfusion.
R15	Health services providing transfusion support to paediatric and neonatal populations must ensure policy and protocols recognise the special needs and requirements of this patient population.

Section 8

Management Of Transfusion Reactions And Other Transfusion-Related Adverse Events

Transfusion reactions or other transfusion-related adverse events can be associated with significant morbidity and, rarely, with mortality. Many of the serious adverse events following blood transfusion are unpredictable. A severe haemolytic or septic transfusion reaction can occur within a few minutes of infusing even a small volume of blood. It is essential to "recognise, react and report" suspected adverse events.

The most important events include:

- Acute and delayed haemolytic transfusion reactions.
- △ Febrile (non-haemolytic) transfusion reactions.
- Allergy and anaphylaxis (including IgA/anti-IgA reactions).
- Transfusion-related acute lung injury (TRALI).
- Transfusion-associated circulatory overload (TACO).
- Post-transfusion purpura (PTP).
- Transfusion-associated graft vs. host disease (TA-GvHD).
- Transfusion-transmitted infection (TTI) including sepsis from bacterially contaminated blood components.

If a transfusion reaction or other adverse event is suspected, other patients may be at risk either because of patient identity error (e.g. ABO-incompatible transfusion to a second patient) or because other blood components collected from the implicated donor may also be affected (e.g. in cases of bacterially contaminated blood components).

In an unconscious or anaesthetised patient, hypotension and uncontrolled bleeding may be the only signs of an acute haemolytic transfusion reaction.

Adverse events related to patient identification errors are the most common cause of preventable harm related to transfusion.

8.1 Management of possible transfusion reactions

The most common adverse transfusion outcome is a rise in the patient's temperature. This may be due to the transfusion or incidental and as a result of the patient's underlying illness. A temperature rise to \geq 38°C or \geq 1°C above baseline (if baseline \geq 37°C) should prompt the interruption of the transfusion and a clinical assessment of the patient.

The following information is provided to assist the immediate clinical management of a patient with a suspected transfusion reaction. It may not equate to the individual state, territory or national requirements for reporting of transfusion-related events to a haemovigilance program. The health service should consider and accommodate separate reporting guidelines, particularly with regard to the extent of a temperature rise, in its policies related to haemovigilance (see section 9.1.3).

8.1.1 Mild transfusion reactions

The following could be considered signs of a mild transfusion reaction:

- Isolated temperature rise <1.5°C above baseline without any signs of a serious reaction (including any of those listed below).
- Localised rash/pruritis.

If a mild transfusion reaction is suspected:

- STOP the transfusion
- Maintain IV access.
- Monitor and record the patient's temperature, pulse, respirations and blood pressure.
- Repeat all clerical and identity checks of the patient and blood pack.
- Contact medical staff immediately for further management and investigation.

If the temperature rise is <1.5°C above baseline or the patient has only localised rash or pruritis, the patient observations are stable and the patient is otherwise well, an antipyretic or antihistamines may be administered at the discretion of the physician and the transfusion then continued with caution and close observation.

If signs or symptoms persist, develop or deteriorate subsequently, **STOP** the transfusion and manage as for a severe transfusion reaction (below).

8.1.2 Moderate to severe transfusion reactions

Any of the following could be considered signs of a moderate to severe transfusion reaction:

- <u>↑</u> Temperature ≥1.5°C above baseline.
- Hypotension/shock OR hypertension.
- Tachycardia.
- Tachypnoea, wheeze, stridor.
- A Rigors or chills.
- Nausea, vomiting or pain (local, chest, back).

If a moderate or severe transfusion reaction is suspected the following steps MUST be undertaken:

- STOP the transfusion immediately and seek urgent medical advice; Medical Emergency Team (MET) support may be required depending on the specific clinical situation.
- Maintain venous access using a new administration set and 0.9% sodium chloride (normal saline), but do not discard the blood administration set and do not flush the original line.
- Repeat all clerical and identity checks of the patient and blood pack.
- Immediately report the reaction to the transfusion service provider, who will advise on return of the implicated product and administration set, and any further blood or urine samples needed from the patient.
- Monitor and record the patient's temperature, pulse, respirations and blood pressure.
- A Record the volume and colour of any urine passed (looking for evidence of haemoglobinuria).

If a blood product is returned to the transfusion service provider, the product bag and/or line should be sealed without contamination for transportation.

Further management, including subsequent transfusion, will depend on the type and severity of the reaction and results of associated investigations. Further transfusions should not be commenced

without the advice or consent of the transfusion service provider / transfusion medicine specialist / consultant haematologist in consultation with the managing clinician.

For examples of transfusion reactions and their management the following links and references may be of value. Availability in clinical areas of these references, including display of tools to assist recognition and response to transfusion reactions, is strongly recommended.

Australian Red Cross Blood Service. Adverse Reactions www.transfusion.com.au/Adverse-Reactions.aspx

BloodSafe. Flippin' Blood

http://www.health.sa.gov.au/bloodsafe/Portals/0/flippn'bloodchartSept06.pdf

NZBS. Guidelines For Management Of Adverse Transfusion Reactions

http://www.nzblood.co.nz/content/download/582/3838/file/Guidelines%20for%20Management%20of%

Queensland Blood Management Programme. Transfusion Reaction Chart http://www.health.qld.gov.au/qhcss/qbmp/documents/tr-chart.pdf

UK Blood Services. Handbook of Transfusion Medicine: Recognition and management of Acute Transfusion reactions

http://www.transfusionguidelines.org.uk/?Publication=HTM&Section=9&pageid=1145#fig10

8.2 Reporting of transfusion reactions or other transfusion-related adverse events

Some health departments mandate reporting of sentinel events related to transfusion, e.g. acute haemolytic reactions such as due to ABO-incompatibility. Similarly it may be necessary to report adverse events particularly those associated with plasma derivatives or recombinant products to the national medicines regulatory agency i.e. the Therapeutic Goods Administration (TGA) in Australia or Medsafe in New Zealand. In addition, there may be voluntary reporting of serious adverse events and near misses to a state, territory or national haemovigilance system.

Irrespective of such a requirement, health services must have a policy and process for recording and reviewing adverse events related to blood product transfusion, including near misses, which should take into account:

- If a moderate or severe reaction is suspected, the haematologist or transfusion medicine specialist must be notified for advice on appropriate clinical intervention and serological investigations.
- All adverse events related to blood product administration must be reported to the local hospital transfusion service provider as well as the Blood Service or manufacturer where appropriate.
- If a reaction is a result of a suspected ABO mismatch or bacterial contamination, the transfusion service provider must be notified IMMEDIATELY as there may be implications for other patients or products.
- Suspected cases of other TTI should be reported immediately to the transfusion service provider who will notify the product manufacturer or distributor e.g. the Blood Service, or other supplier.
- Serious near misses and adverse events related to blood transfusion, including incorrect blood product transfused, acute and delayed transfusion reactions (including anaphylaxis, TA-GvHD, TRALI, PTP) must be reported to the institution's incident reporting system and reviewed by the hospital transfusion committee or other defined governance committee.
- The reporting and analysis of near miss events is an important aspect of a quality improvement system for blood product therapy.

Recommendations

R16 Health services must have a policy for the management and reporting of adverse events and near miss events relating to blood product therapy that includes the following:

- The education, training and assessment of competency of staff to ensure recognition and appropriate response to adverse events.
- Requirements for documentation of observations and the subsequent management of an adverse event.
- Guidelines for management of transfusion reactions.
- The procedure for reporting adverse and near miss events in local incident management systems, state or national haemovigilance systems.
- The mechanism for review of adverse events and near misses.
- Requirements for reporting to the transfusion service provider and/or Blood Service or manufacturer.

Section 9

Clinical Governance

9.1 Hospital transfusion / blood management committees

All health services which perform transfusions should establish a hospital transfusion committee (HTC) to implement and oversee quality assurance of transfusion medicine activities. Alternatively, these functions may be incorporated within the role of another appropriate quality assurance or risk management committee as the local situation demands.

Smaller hospitals or institutions may utilise the resource of a regional, district or general clinical governance committee. It is strongly recommended that there is a forum for transfusion quality and safety issues to cater for these smaller facilities.

9.1.1 Membership

The composition of the HTC, its functions and activities will depend on the local factors such as size, location, and activities of an institution. The provision of safe and effective transfusion practice requires multidisciplinary collaboration.

Representation should include:

- Executive management.
- Clinical risk management / quality assurance / education.
- A Hospital transfusion service or transfusion service providers.
- Haematology/oncology/pathology.
- Clinician or nursing representatives from relevant areas, such as surgery / trauma / orthopaedics / obstetrics and gynaecology / paediatrics / anaesthetics / emergency medicine/ intensive care.
- Other relevant specialities or departmental representation, either ongoing or as required e.g. perfusionists, pharmacists and bioethicists, as determined by the institution.
- Health department.
- The Blood Service.

9.1.2 Meeting frequency and reporting

The HTC should meet at regular intervals, such as quarterly, and report within the hospital or health service quality improvement structure.

9.1.3 Terms of reference

To promote best transfusion practice HTC areas of responsibility may include:

Transfusion policy

- Dissemination and implementation of national policies and guidelines, ensuring compliance with policy directives, circulars or legislative requirements.
- Facilitation, development, implementation and review of local transfusion policies, guidelines and systems.
- Formulation of contingency plans for emergencies and blood shortages.

• Formation of contingency plans for critical bleeding events.

Education and communication

- Provision of an active forum to facilitate communication and collaboration between all staff involved in blood transfusion activities to provide solutions, feedback and education in relation to identified problems, and to ensure that transfusion practice accords with best practice.
- Communication with internal and external bodies about quality assurance matters.
- Identification of requirements and review of arrangements for staff training in transfusion policies and procedures.
- Promotion of the training of all staff involved in blood transfusion activities and the continuing education of both staff and patients.
- Development of local educational and training materials as required.
- · Blood utilisation review.
 - Establishment of criteria for auditing all aspects of blood use with positive feedbacks, reactive corrections or proactive measures to improve the blood system.
 - Collection and monitoring of blood product use, wastage and expiry statistics and development of related performance indicators.
 - Development and review of a "Maximum Surgical Blood Ordering Schedule" (MSBOS).

Haemovigilance

- Review and reporting of adverse transfusion events.
- Investigation of the use of information technology (or other technology) to improve transfusion safety.

Monitoring, review and improvement of transfusion practice

- Conducting or recommending practice audits.
- Review of the results of audits and provision of recommendations or endorsement of strategies to improve transfusion practices.
- Monitoring the appropriateness of transfusion compared to established clinical practice guidelines.
- Monitoring of all aspects of the blood transfusion process.
- Promotion of patient blood management strategies and evaluation of patient blood management programs or strategies in place.

9.2 Staff education and training in transfusion

A number of different groups of staff with various responsibilities are involved in the transfusion process. Training should be provided to all staff, including ancillary staff, involved in the transfusion process to ensure safe and appropriate transfusion practice.

Training will be defined by the responsibilities of the particular staff as described by local guidelines. Each group of staff must work within their scope of practice, taking into account state, territory or national legal requirements.

Staff training should be maintained and updated with evidence of training and competency documented. Assessment of training should be undertaken in accordance with local and national guidelines e.g. Australian Council of Healthcare Standards *Evaluation and Quality Improvement Program* (ACHS EQuIP5 Standard 1.5.5).

Staff training may be assisted by provision of, and attendance at, local education sessions, completion of locally developed self-directed learning packages or on-line resources such as the programs developed by BloodSafe e-Learning Australia (https://www.bloodsafelearning.org.au)

9.3 Sustaining clinical practice improvement

A designated staff member should be appointed by the local health service to be responsible for:

- Development and implementation of local policies and procedures.
- Facilitation and monitoring of education.
- A Facilitation and implementation of quality improvement and patient safety strategies as well as monitoring and evaluating these strategies.
- A Facilitation, monitoring and evaluating of best practice for blood product management; and overseeing and reporting on blood product wastage and expenditure where applicable.

Patient blood management "transfusion champions" should be funded and recruited from within medical, nursing and laboratory staff to assist with the development and implementation of policy and procedure, the education program and strategies.

Transfusion champions should be provided with the opportunity to develop personal expertise in this field.

9.4 Checklist for local transfusion policies and procedures

Local transfusion policies and procedures should include guidance on:

- Prescribing blood products.
- Consent and refusal for blood products.
- Collection of blood samples for pretransfusion compatibility testing, including patient identification and labelling requirements.
- Requesting blood products including critical bleeding and massive transfusion situations.
- Storage, collection and transport of blood products including:
 - Collection of blood products from the hospital transfusion service, and transport of blood products to the patient.
 - Receipt, storage and removal of blood products into and from remote blood fridges.
- Maintenance, monitoring and audit of compliance of remote blood fridges according to current national standards (e.g. AS 3864).
- Administration of blood products.
- Care and monitoring of patients receiving a transfusion.
- Documentation requirements for transfusion.
- Management and reporting of adverse events.
- Staff responsibilities, scope of practice and the training required for these procedures.
- Local responses and plan for blood shortages (see Australian National Blood Supply Contingency Plan available at http://www.nba.gov.au/nbscp/index.html).

Recommendations	
R17	All health services performing transfusion must have a committee responsible for clinical governance of the transfusion process.
R18	All health services performing transfusion must implement appropriate policy and procedures governing all aspects of local transfusion practice.
R19	A designated staff member should be appointed by the health service to be responsible for local policies for blood transfusion and for organising the training of staff involved in transfusion.
R20	Health services should maintain documentation of dedicated transfusion training and competency assessment of their staff involved in the transfusion process.

Glossary

°C Degree Celsius

AABB American Association of Blood Banks

ACHS Australian Council on Healthcare Standards

ACSQHC Australian Commission on Safety and Quality in Health Care

AIMS Australian Incident Monitoring System

Ancillary staff Porters, orderlies, patient care assistants

ANZSBT Australian and New Zealand Society of Blood Transfusion

AUSPOT Australian Specialist Practitioners of Transfusion

BCSH British Committee for Standards in Haematology; Subcommittee

of the British Society for Haematology

Blood component Used to refer to red cells, platelets, fresh frozen plasma,

cryoprecipitate, cryosupernatant, whole blood or granulocytes

Blood product Used to describe all blood components and plasma-derivatives

(The) Blood Service Australian Red Cross Blood Service and New Zealand Blood Service

(NZBS) in their respective countries

CMV Cytomegalovirus

CVAD Central venous access device such as central venous catheter

(CVC), peripherally inserted central catheter (PICC), implanted

port

CVC Central venous catheter

Cold chain A temperature-controlled supply chain; a recorded, uninterrupted

series of storage and distribution activities which maintain a

targeted temperature range

Controlled storage An appropriate facility, medical refrigeration equipment or

container validated for storage of blood products; validation should include specific policies and procedures pertaining to the packing conditions, time frame for viability of blood products,

maintenance and monitoring of the facility/container

Critical bleeding event A term used to describe a situation where it is anticipated there

will be significant blood loss leading to significant

(life-threatening) morbidity or mortality

Crossmatch Test to assess compatibility between a blood component and

intended recipient

Crossmatch expiry Crossmatched blood is valid until expiry of the pretransfusion

specimen (local policy applies)

EQuIP standards The ACHS Evaluation and Quality Improvement Program (EQuIP)

includes standards, a self-assessment process and systematic

external peer review survey

Factor VIII Specific coagulation factor used to treat Haemophilia A
Factor IX Specific coagulation factor used to treat Haemophilia B

FFP Fresh Frozen Plasma

FNHTR Febrile non-haemolytic transfusion reaction

Health service Used in this document to refer to institutions where healthcare is

provided; transfusion of blood products may occur across a range

of settings including hospitals and day treatment centres

HLA Human leucocyte antigen

HTC Hospital transfusion committee

ISO International Organization for Standardization

Medical/clinical record Documentation unique to a patient, containing transcripts of

patient care and progress, investigational data and consultations, which is retained by the managing health care professional or

health service

Medsafe New Zealand agency responsible for the regulation of medicines

and medical devices

MET Medical Emergency Team

MSBOS Maximum surgical blood order schedule

MRN Medical record number; patient identification number

NATA National Association of Testing Authorities

NBA National Blood Authority

NH&MRC National Health & Medical Research Council Australia

NHI National Health Index; a unique number (known as the NHI

number) is assigned to every healthcare user in New Zealand

NPAAC National Pathology Accreditation Advisory Council

NZBS New Zealand Blood Service

Patient identification number For example MRN, unit record number, hospital unit record

number or NHI number that is used to provide additional

identification for a patient

PICC line Peripherally-inserted central catheter

Plasma derivatives Plasma proteins fractionated from large pools of human plasma

under pharmaceutical conditions e.g. coagulation factors, albumin

and immunoglobulins

Prescription An authorisation written by a health care professional for the

administration of a blood product

Progress notes Written details of the patient status and management contained

within their unique medical/clinical record

PTP Post-transfusion purpura

RANZCOG Royal Australian and New Zealand College of Obstetrics and

Gynaecology

RCNA Royal College of Nursing Australia

Request The request constitutes the mechanism of communication or

direction to the transfusion service provider asking them to prepare and issue the blood product for administration or to

undertake testing on a specimen

RCPA Royal College of Pathologists of Australasia

Sample expiry "Group and hold" samples are valid for 3-7 days from sample

collection date and time, as indicated by the hospital transfusion service, dependent on the patient transfusion, pregnancy and red cell antibody history; longer storage times may apply to frozen plasma samples within the policy of the hospital transfusion

service provider

SHOT Serious Hazards of Transfusion UK

TACO Transfusion-associated circulatory overload

TA-GvHD Transfusion-associated graft versus host disease

TGA Therapeutic Goods Administration; Australia's regulatory

authority for therapeutic goods including blood and tissues,

medicines and medical devices

TTI Transfusion-transmitted infection

TRALI Transfusion-related acute lung injury

Transfusion service provider The hospital laboratory or other pathology service which

undertakes pretransfusion testing and supplies transfusion

services / blood products to a health service (or network of health

services)

Unit expiry The lifespan assigned to a blood product, as defined by the

supplier or manufacturer

WBIT "Wrong blood in tube"; where the contents of a pretransfusion

blood sample are not from the person named on the sample's label, usually detected when the sample's blood group does not

match the historical record for the named patient

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