

Australian and New Zealand Society of Blood Transfusion
Australian College of Nursing

3rd Edition, Revised October 2019

GUIDELINES FOR THE ADMINISTRATION OF BLOOD PRODUCTS



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Guidelines for the administration of blood products

3rd Edition

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Foreword

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

The current guidelines were developed by the ANZSBT Clinical Practice Improvement Committee (CPIC) and supersede the previous *Guidelines for the Administration of Blood Components* 2nd edition (2011). ANZSBT is pleased to recognise its continuing partnership with the Australian College of Nursing (ACN) by once again co-branding these guidelines with the College.

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Abbreviations

ACHS	Australian Council on Healthcare Standards
ACN	Australian College of Nursing
ACSQHC	Australian Commission on Safety and Quality in Health Care
ANZSBT	Australian and New Zealand Society of Blood Transfusion
BMC	Blood management or transfusion committee
BSH	British Society for Haematology
CMV	Cytomegalovirus
CVAD	Central venous access device
CVC	Central venous catheter
DOB	Date of birth
FFP	Fresh frozen plasma
FNHTR	Febrile non-haemolytic transfusion reaction
HLA	Human leucocyte antigen
IgA	Immunoglobulin A
ISO	International Organization for Standardization
IV	Intravenous
MRN	Medical record number
NBA	National Blood Authority
NHI	National Health Index
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
NSQHS	National Safety and Quality Health Service
NZBS	New Zealand Blood Service
OOH	Out-of-hospital
PICC	peripherally inserted central catheter
PTP	Post-transfusion purpura
RACF	Residential aged-care facility
SHOT	Serious Hazards of Transfusion
TACO	Transfusion-associated circulatory overload
TA-GvHD	Transfusion-associated graft versus host disease
TGA	Therapeutic Goods Administration
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
UK	United Kingdom
WBIT	Wrong blood in tube

Introduction

The aim of the *Guidelines for the administration of blood products* is to provide guidance on the appropriate storage, collection and transport of blood products, as well as the safe administration of blood products and the management of transfused patients. This document should be used as a best practice reference to inform jurisdictional and health service policy and procedural documents. To aid this process, links to relevant tools and guidelines have been incorporated into the body of the document; there is also a bibliography at the end of the document.

These guidelines must be considered in conjunction with the Australian and New Zealand Society of Blood Transfusion (ANZSBT) *Guidelines for transfusion and immunohaematology laboratory practice*, 2016 and the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for transfusion laboratory practice*, 2017 (see Section 1.1).

Scope

This document covers:

- the decision to transfuse
- consent for blood products
- prescription of blood products
- requests for blood products and pretransfusion sample collection
- storage, collection and transport of blood products
- administration of blood products
- special transfusion circumstances
- management of transfusion-related adverse events
- clinical governance.

Terminology

In these guidelines, the following directive terms are used:

Must Indicates a strongly recommended practice where compliance would be expected.

Should Indicates a recommended practice where compliance would be expected but alternative practices may be acceptable.

May Indicates a practice that is permitted within the context of the guidelines.

The term 'the Blood Service' is used throughout the document to refer to the Australian Red Cross Blood Service and the 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. Blood products are supplied under national blood product supply arrangements, but follow different pathways depending on whether they are fresh products, plasma derivatives or recombinant products. Where the term 'blood components' is specifically used, it refers to red cells, platelets, fresh frozen plasma, cryoprecipitate, cryodepleted plasma, whole blood or granulocytes. The terms '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. The term 'transfusion' covers the administration of all blood products, regardless of their route of administration.

The general principles of these guidelines apply to the administration of all blood products. However, facilities should develop local procedures and protocols using relevant product information and other jurisdictional resources (e.g. from the Blood Service, transfusion.com.au and the New Zealand *Transfusion medicine handbook*).

The Glossary provides further information on definitions.

Summary of changes

Summary of changes to the original third edition

ANZSBT thanks members for their feedback on the original third edition of these guidelines, based on which there have been some minor changes to the document. The changes have been approved by ANZSBT Council and correct some minor errors and also provide clarification where changes may have led to potential differences in interpretation.

Table 1: Summary of changes to the original third edition

Change and rationale

Section 3.1, dot point 8

[t]he number of units or dose of blood product to be given, using appropriate units of measure (e.g. number of packs, volume in millilitres, units or weight in grams); blood component volumes should be stated in millilitres *for neonatal patients and children less than 20kg*

Rationale: Correct unintentional error and clarification.

Section 3.1, dot point 12

[11] legibly written name and signature of the prescriber, and a contact telephone number or pager number

[12] *other details may be required by local health service or laboratory policies. A Medicare provider number and patient Medicare number is generally required, for Medicare funded services in Australia.*

Rationale: Clarify that Medicare details only necessary where testing is conducted under Medicare funding arrangements

Section 4.1

References to ACSQHC standards updated.

Rationale: Update for current Australian National Standards.

Section 6.2.1, dot point 4

Platelets must not be transfused through a blood administration set that has been used for red cells, because red cell debris may trap infused platelets that may not be ABO compatible. *Red cells may follow platelets through the same blood administration set, but not precede platelets.*

Rationale: Provide further clarity.

Section 6.2.3, dot point 3

Once the transfusion episode is complete, blood administration sets may be flushed with 0.9% sodium chloride to ensure that the patient receives the entire blood product. The minimum volume of 0.9% sodium chloride required to completely clear the IV line should be used, taking into account the individual circumstances of the patient where relevant (e.g. neonates, some paediatric patients or those at risk of fluid overload or on fluid restrictions). *Where a transfusion is prescribed in millilitres for children less than 20 kg the IV cannula (not the line) should be flushed to maintain IV patency. This is to ensure the patient does not receive additional fluid than that prescribed.*

Rationale:

To ensure that protocols prevent inadvertent administration of additional blood or saline flush in neonates and paediatric patients with very small blood volumes and low tolerance for additional fluid.

Change and rationale

Section 7.2.1

Children less than 20 kg should have the volume prescribed in millilitres. The volume should be calculated based on the child's weight and the desired haemoglobin *increment*, to prevent transfusion-associated circulatory overload.

Rationale: To improve guidance and align terminology with NBA Patient Blood Management Guidelines.

Section 7.3, reference added

ional Blood Authority (NBA) (2016). Patient Blood Management Guidelines: Module 6: - Neonatal and Paediatrics. NBA, Canberra Australia. https://www.blood.gov.au/system/files/14523_NBA%20Module%206%20Neonat_Paediatrics_internals_5_FA_updated_15Feb2017.pdf

Section 8.1, paragraph 2; clarification 8.1.1 'mild adverse transfusion events'

A common adverse transfusion outcome is an **unexpected** rise in the patient's temperature. This rise may be due to the transfusion or may be incidental (i.e. as a result of the patient's underlying illness). **A temperature rise of 1 °C or more above baseline and more than 38°C should prompt the interruption of the transfusion and a clinical assessment of the patient. Transfusions should also be interrupted and responded to, as per jurisdictional observation and response charts for the recognition of clinical deterioration, and in New Zealand as per the Early Warning Score.**

8.1.1 Mild adverse transfusion events

- an isolated temperature **rise of 1 °C to less than 1.5 °C**, above baseline **and more than 38 °C** without any signs of a serious event (including any of those listed below in Section 8.1.2). *A lower temperature rise occurring early in the transfusion (eg. a 1 °C rise within the first 2 hours, to less than 38 °C) may also be a sign of an adverse transfusion reaction. Stopping the transfusion seeking medical assessment is recommended.*
- localised rash or pruritus.

If a mild adverse transfusion event is suspected:

- **STOP the transfusion**
- maintain IV access
- monitor and record the patient's temperature, pulse, respirations, *oxygen saturation* and blood pressure
- repeat all documentation and identity checks of the patient and blood pack
- contact medical staff immediately for further management and investigation.

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

If signs or symptoms persist or redevelop, or the patient's condition subsequently deteriorates, the transfusion should be **stopped** and managed as for a moderate to severe adverse transfusion event (see Section 8.1.2).

Rationale: The wording has been changed to align with international guidelines on minor reactions, in particular, febrile non-haemolytic transfusion reactions, while still encouraging clinicians to consider the significance of changes, particularly rapid changes during the early stages of a transfusion.

Glossary, revised definition 'double independent checking'

Clinicians individually and without requiring direct involvement of each other, check the prescription, patient and blood product identification, and blood product characteristics (including expiry, compatibility and special requirements (if any)).

This process must ensure that each clinician is individually satisfied that, and responsible for, the correct product is transfused in the correct way to the correct patient.

Change and rationale

[continued] The clinicians must agree before the transfusion is commenced. In a teaching environment the teacher may indicate what needs to be checked and where to find it, but the learner must still independently view each item and confirm the match to the patient.

Rationale: The previous definition was obtained from high risk pharmaceutical administration. Members expressed concerns that this was not appropriate for transfusion, where independent checking of calculations away from the patient was not required. It has been modified to clarify the fundamental principle of two professionals independently carrying out and taking responsibility for the procedure, while allowing institutions to have different strategies to achieve this.

Summary of changes from the second edition

Significant changes from the second edition are highlighted below. However, it is recommended that readers review the document in its entirety to ensure that their policies and procedures are valid and consistent with what is recommended in these guidelines.

This third edition attempts to capture the current transfusion-related resources and tools now in established use throughout Australia and New Zealand. Information from existing guidelines and standards – for example, related to pretransfusion laboratory practice, patient identification and refrigeration – has purposely not been reproduced within this document to avoid inconsistency and the need to synchronise content as each independent document is updated. Instead, these guidelines provide links and references for the necessary information where applicable.

Table 2: Summary of major changes from the second (2011) edition of the guidelines

Section	Change details	2 nd edition	3 rd edition
General	The term ‘informed consent’ has been changed to ‘valid, informed consent’ throughout the guidelines.		
	The term ‘intellectual impairment’ has been changed to ‘cognitive impairment’ throughout the guidelines.		
	In-text references have been removed from the text and added to the appropriate additional resources section.		
	The sections on additional resources have been updated throughout the guidelines.		
	Where appropriate, the language has been changed to align with that of the National Safety and Quality Health Service (NSQHS) Standards throughout the guidelines.		
Section 1	The term ‘individual needs’ has been modified to ‘of that person’s individual needs’, for clarity.	R1	R1
	The term ‘chosen alternative’ has been changed to ‘other blood management strategies’.	R2	R2
Section 2	Documentation of refusal or treatment-limiting orders has been added.	2.3	2.5
	The term ‘Jehovah’s Witnesses’ has been changed to ‘people refusing blood transfusion therapy’. This change was made because focusing only on people of Jehovah’s Witness faith was considered too restrictive to inform contemporary clinical practice, where people decline blood products for many reasons. Also, Sections 2.5.1 and 2.5.2 have been removed, because the content does not inform the clinical process of administration of blood products. This information is available elsewhere, and a range of resources has been included.	2.5	2.4

Summary of changes

Section	Change details	2 nd edition	3 rd edition
Section 2 <i>continued</i>	<p><i>[continued]</i> The guidelines now include strategies to enable staff to support these decisions, advocate for those declining blood products, and clearly communicate acceptable and unacceptable blood products.</p> <p>It is the responsibility of jurisdictions or facilities to outline requirements for managing refusal.</p> <p>It is the responsibility of individuals to identify their wishes with health-care providers (especially as these may change over time), as per local requirements.</p>		
	This recommendation has been expanded to give more information about inability to give consent; it has also been edited for clarity and grammar.	R3	R3
Section 3	Guidance regarding phone orders has been added.	X	3.1
	The wording of these recommendations has been edited for clarity and grammar.	R5 and R6	R5 and R6
Section 4	The wording of these recommendations has been edited for clarity and grammar.	R7 and R8	R7 and R8
	The term 'must' has been changed to 'should' because the clinical indication is documented in the clinical history and is not mandated with consequences.	R9	R9
Section 5	The following wording has been added to this section: 'All other blood components and products must also be stored according to their specific requirements and, as with red cells, must never be stored in ward or domestic refrigerators.'	5.1	5.1
	The following wording has been added to this section: 'There is an increased risk of wrong transfusion when multiple units for more than one patient are collected.'	X	5.2
	The heading of this section has been modified to make clear that it is specific to collection checking procedures.	X	5.3
	In this section, the preamble has been removed and the following added: 'Transport of blood products must comply with the ANZSBT <i>Guidelines for transfusion and immunohaematology laboratory practice</i> , 2016.'	5.5	5.5
	The wording of this recommendation has been revised for clarity.	R11	R11
Section 6	The following text has been removed: 'Red cells may follow platelets through the same blood administration set, but not precede platelets.'	6.2.1	X
	Guidance on 'multi-lumen central venous access device (CVAD)' has been included.	X	6.2.1
	Additional guidance on priming has been included.	X	6.2.2
	The text of this subsection has been revised to strengthen the statement that there is no evidence of benefit of microaggregate filters.	X	6.3.2
	A subsection on additional resources for other filters has been created, and the ANZSBT statement on preoperative autologous donation has been added.	6.3.4	6.3.4

Summary of changes

Section	Change details	2 nd edition	3 rd edition
Section 6 <i>continued</i>	The following wording has been added: ‘the patient is available to proceed with transfusion; for example, the patient is not scheduled for a procedure.’	X	6.8
	The following wording has been added: ‘The transfusion service provider must be notified immediately if patient details change. Consecutive temporary identifying patient numbers should not be used.’	X	6.9.1.2
	The heading of this section has been revised to indicate that it is specific to ‘Pretransfusion checking procedures’.	X	6.9.2
	The wording regarding the two staff member check process has been revised to include ‘double independent checking’.	6.9.2.1	6.9.2.1
	The heading of this section has been revised to include ‘matching patients to their care’.	6.9.2.2	6.9.2.2
	Additional wording (given here in bold) has been added: The blood group and the donation or batch code or number on the compatibility label...	6.9.2.3	6.9.2.3
	The following wording has been added: ‘Clinical deterioration should be managed as per facility or jurisdictional policies. In New Zealand, the standardised recording chart is the Early Warning Score. There is a separate chart for adults and paediatrics.’	X	6.11
	The following wording, which was ambiguous, has been removed: ‘The patient MUST be closely observed for the first 15 minutes after commencement of each unit, and SHOULD be closely with frequent visual observation throughout the transfusion, to detect any adverse effects.’ It has been replaced by wording that clarifies the guidance.	6.11	6.11
	The guidance regarding patients not in an open area has been strengthened to ‘must’.	X	6.11
	The guidance regarding 15 minutes vital signs has been changed from ‘should’ to ‘must’, and now reads, ‘Measurement of vital signs must be undertaken and recorded 15 minutes after the start of transfusion and compared with baseline.’	6.11	6.11
	The following wording has been added: ‘Signs and symptoms of acute reactions may present differently in paediatric patients and can include irritability, agitation and inconsolability by the parent or main caregiver. These signs and symptoms may be present in the absence of, or before, changes in vital signs.’	6.11.1	6.11.1
	The following wording has been added: ‘If the product (or product pack or bottle) has already been discarded into clinical waste, do not retrieve pack from waste.’	X	6.12
	The following points have been added to the policy for transfusion: <ul style="list-style-type: none"> • documentation requirements for the transfusion process • reporting of adverse events and outcomes of the transfusion.’ 	R13	R13
Section 7	Further guidance has been included regarding out-of-hospital (OOH) transfusion, and the text has been revised for clarity.	7.1	7.1
	Guidance for retrieval organisations has been added.	X	7.1.3

Summary of changes

Section	Change details	2 nd edition	3 rd edition
Section 7 <i>continued</i>	The guidance has been revised to reflect the <i>Patient blood management guidelines: Module 6 Neonatal and Paediatrics</i> , and numbering has been added to the headings.	7.2	7.2
	The following wording has been added to <i>A child's cognitive ability to report or partake in care</i> : 'Signs and symptoms of acute reactions may present differently in paediatric patients, and can include irritability, agitation and inconsolability by the parent or main caregiver. These signs and symptoms may be present in the absence of or before changes in vital signs (see Section 6.11.1).'	7.2	7.2.7
	Wording has been added for clarity: 'residential aged-care facilities or supported accommodation...'	R14	R14
Section 8	The heading of this section has been changed to 'Management of transfusion-related adverse events'. The term 'events' is used where relevant to include transfusion incidents and reactions.	8	8
	This section has been revised to include a list of the symptoms and signs of acute transfusion reactions.	X	8
	The following wording has been added: 'Any deterioration in a patient's condition during the transfusion of a blood product must be considered an adverse transfusion event unless assessed otherwise.'	X	8
	This section has been revised to better reflect clinical scenarios of temperature rise, and to include reference to the need to follow facility clinical deterioration escalation procedures and the New Zealand Early Warning Score.	8.1	8.1
Section 9	Some phrases in this subsection have been revised for clarity.	8.1.2	8.1.2
	This recommendation has been revised to be consistent with the changes to the text of this section.	R16	R16
	The heading of this subsection has been changed to 'Blood management or transfusion committees'.	9.1	9.1
	The representation in the blood management committee (BMC) has been modified to include: <ul style="list-style-type: none"> • nurse or professional with transfusion responsibilities • consumer involvement, where appropriate.'	9.1.1	9.1.1
	The BMC terms of reference have been expanded and headings have been added, for clarity.	9.1.3	9.1.3
	In this section on education and training, 'should' statements have been changed to 'must' statements.	9.2	9.2
	This recommendation has been revised for clarity and now reads, 'A designated staff member should be appointed by the health service to support the development of local policies for blood transfusion and education of staff involved in transfusion.'	R19	R19
Glossary	The Glossary has been updated and redundant items have been removed.	Glossary	Glossary
	The definition of 'wrong blood in tube' has been adjusted to be consistent with definitions in the international literature.	Glossary	Glossary

Summary of changes

Section	Change details	2nd edition	3rd edition
Glossary <i>continued</i>	The definition of 'incorrect blood component transfused' has been added, from the National Blood Authority National Haemovigilance Data Dictionary.	X	Glossary
Bibliography	The title of this section has been changed to 'Bibliography', the list of references has been updated and redundant items have been removed.	References	Bibliography

Summary of recommendations

Table 3: Summary of recommendations made in the guidelines

Section 1: Decision to transfuse

R1 The decision to administer blood products, and the consideration of other blood management strategies, must be based on a thorough clinical assessment of the patient and of that person's individual needs.

R2 The indication for transfusion and other blood management strategies must be documented in the patient's health-care 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 valid, informed consent for blood products
 - the period of time for which the consent remains valid
 - refusal of blood products
 - inability to give consent, including in an emergency situation.
-

Section 3: Prescription of blood products

R4 The prescription must give a clear, legible instruction.

R5 The prescription must be available to check in the presence of the patient when the transfusion is administered, and must form part of the pretransfusion verification checks.

R6 The prescription must be retained within a patient's health-care record following completion of a transfusion.

Section 4: Requests for blood products and pretransfusion sample collection

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

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 staff 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

- R13 Health services must have a policy for all patients receiving transfusion of blood and blood products 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
 - documentation requirements for the transfusion process
 - reporting of adverse events and outcomes of the transfusion.
-

Section 7: Special transfusion circumstances

- R14 Health services, residential aged-care facilities or supported accommodation providers undertaking 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 that policy and protocols recognise the special needs and requirements of this patient population.
-

Section 8: Management of transfusion-related adverse events

- R16 Health services must have a policy for the management and reporting of adverse events and near miss events relating to blood transfusion that includes:
- 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 adverse transfusion events
 - the procedure for reporting adverse and near miss events in local incident management systems, and state, territory or national haemovigilance systems
 - the mechanism for review of adverse events and near misses
 - requirements for reporting to the transfusion service provider, or to the 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.
-
- R19 A designated staff member should be appointed by the health service to support the development of local policies for blood transfusion and education 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 of that person's individual needs. The indication for transfusion, or other blood management strategies, must be documented in the patient's health-care record.

Australia's National Blood Authority (NBA) has produced a series of guidelines about patient blood management (see Section 1.1 below). These documents provide guidance about clinical indications, assessment and reassessment for specific patient populations and scenarios:

- *Module 1 – Critical bleeding massive transfusion*
- *Module 2 – Perioperative*
- *Module 3 – Medical*
- *Module 4 – Critical care*
- *Module 5 – Obstetrics and Maternity*
- *Module 6 – Neonatal and Paediatrics*

This document is not intended to provide extensive detail on appropriate use of blood products; however, current resources that may inform the decision to transfuse are provided below.

1.1 Additional resources on the decision to transfuse

Australian and New Zealand Society of Blood Transfusion (ANZSBT). *Guidelines for transfusion and immunohaematology laboratory practice*. 1st Edition. ANZSBT November 2016.

https://www.anzsb.org.au/data/documents/guidelines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20_.pdf

Australian Commission on Safety and Quality in Health Care (ACSQHC). *Standard 7 Blood and blood products*. National Safety and Quality Health Service (NSQHS) Standards. ACSQHC October 2012.

https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard7_Oct_2012_WEB.pdf

Australian Haemophilia Centre Directors' Organisation (AHCDO). *Guidelines for the management of haemophilia in Australia*. AHCDO 2016. <https://www.blood.gov.au/haemophilia-guidelines>

Australian Red Cross Blood Service. *Blood component information – an extension of blood component labels*. March 2015. <http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/18>

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

Haemophilia Foundation of New Zealand Inc. (HFNZ). Guidelines on treatment of haemophilia. Available at <http://www.haemophilia.org.nz/bleeding-disorders/haemophilia/guidelines/>

International Accreditation New Zealand (IANZ). *Specific criteria for accreditation: medical testing AS LAB C7*. 2nd Edition. IANZ 2014.

<https://go.promapp.com/ianz/view/Documents/Minimode/Permalink/E1ZsIUQ11s40wFzLOmAKi>

Jurisdictional Blood Committee, for and on behalf of the Australian Health Ministers' Conference. *Criteria for the clinical use of intravenous immunoglobulin in Australia*. 2nd Edition. Commonwealth of Australia July 2012.

https://www.blood.gov.au/system/files/documents/NBA_IVIgCriteria_SecondEdition_Internals-WEB_updated_ref.pdf

National Blood Authority (NBA). *Patient blood management guidelines: Module 1 Critical bleeding, massive transfusion*. NBA 2010. <https://www.blood.gov.au/pbm-module-1>

National Blood Authority (NBA). *Patient blood management guidelines: Module 2 Perioperative*. NBA 2012. <https://www.blood.gov.au/pbm-module-2>

- National Blood Authority (NBA). *Patient blood management guidelines: Module 3 Medical*. NBA 2012. <https://www.blood.gov.au/pbm-module-3>
- National Blood Authority (NBA). *Patient blood management guidelines: Module 4 Critical care*. NBA 2010. <https://www.blood.gov.au/pbm-module-4>
- National Blood Authority (NBA). *Patient blood management guidelines: Module 5 Obstetrics and Maternity*. NBA 2015. <https://www.blood.gov.au/pbm-module-5>
- National Blood Authority (NBA). *Patient blood management guidelines: Module 6 Neonatal and Paediatrics*. NBA 2016. <https://www.blood.gov.au/pbm-module-6>
- National Health and Medical Research Council (NHMRC) and National Blood Authority (NBA). *Guidelines on the prophylactic use of Rh D immunoglobulin (anti D) in obstetrics*. Commonwealth of Australia 2003. <https://www.blood.gov.au/system/files/documents/glines-anti-d.pdf>
- National Pathology Accreditation Advisory Council (NPAAC). *Requirements for transfusion laboratory practice*. 3rd Edition. Australian Government Department of Health 2017. <http://www.health.gov.au/internet/main/publishing.nsf/Content/npaac-pub-transfusion>
- New Zealand Blood Service (NZBS). *Transfusion medicine handbook: a guide to the clinical use of blood components, blood products and blood transfusion procedures in New Zealand*. 3rd Edition. NZBS 2016. <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/transfusion-medicine-handbook/>
- Norfolk, D (ed.). *Handbook of transfusion medicine*. 5th Edition. UK Blood Services 2013. <http://www.transfusionsguidelines.org.uk/transfusion-handbook>
- Tran, HA, Chunilal, SD, Harper, PL, Tran, H, Wood, EM & Gallus, AS on behalf of the Australasian Society of Thrombosis and Haemostasis. An update of consensus guidelines for warfarin reversal. *Medical Journal of Australia* 2013; 198 (4): 198–199. <https://www.mja.com.au/journal/2013/198/4/update-consensus-guidelines-warfarin-reversal>
- World Health Organization (WHO) Blood Transfusion Safety. *The clinical use of blood handbook*. WHO 2002. Available at http://www.who.int/bloodsafety/clinical_use/en/

Recommendations

- | | |
|----|--|
| R1 | The decision to administer blood products, and the consideration of other blood management strategies, must be based on a thorough clinical assessment of the patient and of that person's individual needs. |
| R2 | The indication for transfusion and other blood management strategies must be documented in the patient's health-care record. |
-

Section 2

Consent for blood products

All elements of the process for obtaining consent, which must be valid and informed, must reflect prevailing local, state, territory and national requirements. The process must include:

- variations in requirements by blood product type; for example, blood components versus plasma-derived products
- variations in documentation; for example, generic or dedicated transfusion consent form versus documentation in the patient's health-care record
- the period of time that consent is valid; for example, a single prescription or an episode of care
- the patient's capacity to give consent
- the age of the consenting person.

2.1 Obtaining valid, informed consent

Valid, informed consent for transfusion means that a documented dialogue has occurred between the patient and a clinician that includes:

- the reason for the proposed blood product transfusion
- the proposed blood product for transfusion
- the risks and benefits of the blood product, and 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 health service approved interpreter where the patient has limited proficiency in English.

The communication methods used need to be tailored to the diversity of the consumers and the needs of local communities. Any written information provided should be appropriate for the Australian and New Zealand context, and for the patient's language and cognitive ability. The written materials should be in plain English, or translated into other languages relevant to the local community, and should be culturally appropriate. It may also be helpful to provide information in other forms (e.g. infographics or electronic). Information specific for parents and children should be available where relevant.

2.1.1 Additional resources on obtaining valid, informed consent

Australian Commission on Safety and Quality in Health Care (ACSQHC). *Safety and quality improvement guide; Standard 2: Partnering with consumers*. ACSQHC October 2012. http://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard2_Oct_2012_WEB.pdf

Australian Commission on Safety and Quality in Health Care (ACSQHC). *National statement on health literacy: taking action to improve safety and quality*. ACSQHC August 2014. <http://www.safetyandquality.gov.au/wp-content/uploads/2014/08/Health-Literacy-National-Statement.pdf>

Australian Red Cross Blood Service. Information for consumers on transfusion. Available at www.mytransfusion.com.au

BloodSafe. Quick reference guides to prescribing of blood and blood components. BloodSafe, SA Health and the Australian Red Cross Blood Service. Available at <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/blood+management/transfusion+practice>

Care of Children Act 2004 (New Zealand). <http://www.legislation.govt.nz/act/public/2004/0090/latest/DLM317233.html>

Clinical Excellence Commission. Blood Watch program patient information on blood transfusion. Available at <http://www.cec.health.nsw.gov.au/patient-safety-programs/assurance-governance/blood-watch/resource-list>

CSL Behring. Consumer information sheets for plasma-derived therapies. (CSL Behring is the main provider of fractionated products.) Available at <http://www.cslbehring.com.au/products/product-finder.htm>

Department of Health and Human Services, Victoria, Blood Matters Program. *Blood transfusion: have all your questions been answered?* Victorian Government October 2016.

<https://www2.health.vic.gov.au/about/publications/factsheets/blood-transfusion-questions-english>

Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 (New Zealand). <http://www.legislation.govt.nz/regulation/public/1996/0078/latest/DLM209085.html>

Health and Disability Commissioner. Code of health and disability services consumers' rights; Right 7. Available at [http://www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-\(full\)](http://www.hdc.org.nz/the-act--code/the-code-of-rights/the-code-(full))

Health and Disability Commissioner Act 1994 (New Zealand).

<http://www.legislation.govt.nz/act/public/1994/0088/latest/096be8ed816834f2.pdf>

Medical Council of New Zealand (MCNZ). Information, choice of treatment and informed consent. MCNZ March 2011. <https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Information-choice-of-treatment-and-informed-consent.pdf>

New Zealand Bill of Rights Act 1990 (New Zealand).

<http://www.legislation.govt.nz/act/public/1990/0109/latest/096be8ed80b62589.pdf>

New Zealand Blood Service (NZBS). Information for recipients – consent forms. Available at

<http://www.nzblood.co.nz/Clinical-information/Transfusion-medicine/Information-for-recipients/Consent-forms>

New Zealand Blood Service (NZBS). Information for recipients. Available at <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/information-for-recipients/>

Protection of Personal and Property Rights Act 1988 (New Zealand).

<http://legislation.govt.nz/act/public/1988/0004/latest/DLM126528.html>

2.2 Documentation of consent

Consent must be documented by the clinician, and recorded as per jurisdictional or facility requirements; for example:

- on a generic or transfusion-specific consent form
- in the health-care record.

2.3 Inability to give consent (including in an emergency situation)

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 cognitive impairment, inability to communicate consent or loss of consciousness). Inability to give consent may need to be considered as part of an 'advance care directive' or where there is a substitute decision maker.

2.4 People refusing blood transfusion therapy

People may decline blood products for a variety of reasons; for example, as part of end-of-life management plans or as faith-based decisions. Many people document their choices in some capacity; for example, an 'advance care directive'. Jurisdictional requirements for managing such directives should be followed.

Where possible, managing the refusal of transfusion therapy should include a detailed conversation with the patient to:

- identify the reason for refusal
- discuss the blood components, products and procedures that are available for use in that jurisdiction or facility, and identify which of those are acceptable and unacceptable to the patient
- clarify the patient's expectations and answer questions.

2.5 Documentation of refusal or treatment-limiting orders

Refusal of consent for transfusion or treatment-limiting orders must be documented in the patient's health-care record in either the progress notes or in a document specific for this purpose, consistent with jurisdictional or facility requirements.

Where a patient refuses consent for the transfusion of specific blood products, both the acceptable and unacceptable products for transfusion should be clearly documented.

2.6 Additional resources on consent for blood products

ACT Health, Chronic Care Program. Advance care planning information. Available at <http://health.act.gov.au/our-services/chronic-disease-management/chronic-disease-services/advance-care-planning>

Associates for Jehovah's Witness Reform on Blood (AJWRB). Information advocating for reforms to the Watchtower blood policy. Available at www.ajwrb.org

Department of Health and Human Services, Tasmania. Advance care planning for healthy dying information. Available at http://www.dhhs.tas.gov.au/palliativecare/advance_care_planning_for_healthy_dying

Department of Health and Human Services, Victoria. Advance care planning information. Available at <https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/end-of-life-care/advance-care-planning>

Department of Justice, Western Australia. Advance health directives information. Available at http://www.publicadvocate.wa.gov.au/A/advance_health_directives.aspx

Government of South Australia. Advance care directives information. Available at <http://www.advancecaredirectives.sa.gov.au/>

Jehovah's Witnesses. Official website. Available at <https://www.jw.org/en/>

Northern Territory Government. Advance personal plan information. Available at <https://nt.gov.au/law/rights/advance-personal-plan>

NSW Health. Advance care planning resources. Available at <http://www.health.nsw.gov.au/patients/acp/Pages/more-info.aspx>

Queensland Government. Advance health directive information. Available at <https://www.qld.gov.au/law/legal-mediation-and-justice-of-the-peace/power-of-attorney-and-making-decisions-for-others/advance-health-directive/>

Recommendation

- R3 Health services must have a transfusion consent policy for both adults and children for:
- acquisition and documentation of valid, informed consent for blood products
 - the period of time for which the consent remains valid
 - refusal of blood products
 - inability to give consent, including in an emergency situation.
-

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 health-care record when the transfusion is complete.

In New Zealand, blood products that are prescribed are classified as medicines. In Australia, most blood products are currently exempt from scheduling classification as a medication.

The prescriber is responsible for ensuring that:

- the transfusion is clinically appropriate
- the expected benefits outweigh the potential risks
- valid, informed patient consent has been obtained and documented
- clinical staff caring for the patient have been informed that the blood product has been prescribed
- patient risk factors have been identified and assessed (e.g. risk of transfusion-associated circulatory overload [taco]), and special requirements have been documented
- the patient's known allergies, history of adverse drug reactions and previous transfusion reactions have been considered.

3.1 Requirements for blood product prescription

All prescriptions for blood products, including eHealth requirements, must comply with local, and state or territory prescribing regulations. Telephone orders for blood prescription may be appropriate in some special circumstances; therefore:

- local policies and procedures should outline conditions where telephone prescription is appropriate
- local policies should include the processes that need to be undertaken to ensure that telephone orders comply with all aspects of these guidelines.

The prescription must be legible and contain:

- patient identification details: family name and 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; for example, irradiated or cytomegalovirus (CMV) seronegative

Any special blood product requirements must be communicated to the transfusion service provider as soon as they become known, so that a record can be made in the laboratory information system.

The special requirements must also be documented on the prescription each time the product is prescribed.

- the route of administration
- the number of units or dose of blood product to be given, using appropriate units of measure (e.g. number of packs, volume in millilitres, units or weight in grams); blood component volumes should be stated in millilitres for neonatal patients and children less than 20 kg.
- the duration over which the blood product is to be administered

- special instructions; for example, use of a blood warmer, or any medication required before or after the transfusion
- legibly written name and signature of the prescriber, and a contact telephone number or pager number
- other details may be required by local health service or laboratory policies. A Medicare provider number and patient Medicare number is generally required for Medicare funded services in Australia.

The prescription must be available to check at the patient’s side when the transfusion is administered, and must form part of the pretransfusion verification checks.

Standardised terminology for blood components is not yet agreed nationally. Nevertheless, clinicians prescribing blood components 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.

Giving the brand name may be in contradiction to jurisdictional requirements for generic name prescribing. However, this strategy mitigates the risks associated with identifying products that are not interchangeable (e.g. Biostate® is not the same as Recombinate®).

3.2 Additional resources on prescription of blood products

Alam, A, Lin, Y, Lima, A, Hansen, M & Callum JL. The prevention of transfusion-associated circulatory overload. *Transfusion Medicine Reviews* 2013; 27(2): 105–112. [http://www.tmreviews.com/article/S0887-7963\(13\)00005-9/fulltext](http://www.tmreviews.com/article/S0887-7963(13)00005-9/fulltext) (see page 108).

Australian Commission on Safety and Quality in Health Care (ACSQHC). National Safety and Quality Health Service Standards (2nd Edition). ACSQHC 2017. <https://www.safetyandquality.gov.au/wp-content/uploads/2017/12/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf>

Australian Haemophilia Centre Directors’ Organisation (AHCDO). *Guidelines for the management of haemophilia in Australia*. AHCDO 2016. <https://www.blood.gov.au/haemophilia-guidelines>

Health Quality and Safety Commission New Zealand (HQSC). Medication safety. Available at <https://www.hqsc.govt.nz/our-programmes/medication-safety/>

Health Quality and Safety Commission New Zealand (HQSC). *Medication charting standard. Version 3*. HQSC September 2012. https://www.hqsc.govt.nz/assets/Medication-Safety/Med-Rec-PR/Medication_Chart_Standard_v3.pdf

Serious Hazards of Transfusion (SHOT). Transfusion checklist for every transfusion. SHOT 2012. <http://www.shotuk.org/wp-content/uploads/2010/03/SHOT-Transfusion-Process-Checklist-May-2012.pdf>

Serious Hazards of Transfusion (SHOT). Annual SHOT report 2016. SHOT 2016. https://www.shotuk.org/wp-content/uploads/SHOT-Report-2016_web_11th-July.pdf (see page 165).

Recommendations

- | | |
|----|--|
| R4 | The prescription must give a clear, legible instruction. |
| R5 | The prescription must be available to check in the presence of the patient when the transfusion is administered, and must form part of the pretransfusion verification checks. |
| R6 | The prescription must be retained within a patient’s health-care record following completion of a transfusion. |
-

Section 4

Requests for blood products and pretransfusion sample collection

The request constitutes the mechanism of communication with transfusion service providers. It directs providers to perform pretransfusion blood testing or product preparation (or both), and issue blood products for administration.

Failure to correctly identify the patient at the time of sample collection continues to be a significant cause of patient morbidity and mortality. Similarly, haemovigilance programs have identified errors related to prescribing of the wrong product or transfusion of the wrong patient as a significant source of error. Thus, patients must be positively identified and labelling of samples must be done at the patient's side. Otherwise, a 'wrong blood in tube' (WBIT) event could occur that may compromise safety in two ways:

- by acting as a precursor to transfusion of the incorrect, and possibly incompatible, blood product
- by leading to inappropriate therapy due to incorrectly allocated results.

This document does not provide extensive detail on requests, request forms or sample collection. Instead, it provides current resources available for this purpose (see Section 4.1 below). The blood product request should include the clinical indication for the transfusion and any special blood product requirements for the patient.

4.1 Additional resources on requests for blood products and pretransfusion sample collection

Australian and New Zealand Society of Blood Transfusion (ANZSBT). *Guidelines for transfusion and immunohaematology laboratory practice*. 1st Edition. ANZSBT November 2016.

[https://www.anzsb.org.au/data/documents/guidlines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20 .pdf](https://www.anzsb.org.au/data/documents/guidlines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20.pdf)

Australian Commission on Safety and Quality in Health Care (ACSQHC). *National Safety and Quality Health Service Standards; 6. Communicating for Safety Standard* ACSQHC Sydney 2017.

<https://www.safetyandquality.gov.au/wp-content/uploads/2017/12/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf>

Department of Health and Human Services, Victoria, Blood Matters Program. ABCD safe sample taking education templates. Available at <https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/blood-matters/tools-nsqhs-standard-7/governance-and-systems>

National Pathology Accreditation Advisory Council (NPAAC). *Requirements for transfusion laboratory practice*. 3rd Edition. Australian Government Department of Health 2017.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/npaac-pub-transfusion>

New Zealand Blood Service (NZBS). *Transfusion medicine handbook: a guide to the clinical use of blood components, blood products and blood transfusion procedures in New Zealand*. 3rd Edition. NZBS 2016.

<http://www.nzblood.co.nz/clinical-information/transfusion-medicine/transfusion-medicine-handbook/>

Victorian Managed Insurance Authority (VMIA). *Reducing harm in blood transfusion – investigating the human factors behind 'wrong blood in tube' (WBIT) events in the emergency department*. Report prepared by S Jeffcott. VMIA 2010. <http://www2.health.vic.gov.au/about/publications/researchandreports/Reducing-Harm-in-Blood-Transfusion>

Recommendations

- R7 Pretransfusion sample collection must include positive patient identification processes and labelling of specimens in the presence of the patient.
-
- R8 The blood product request must include positive patient identification processes and communicate clear details to the transfusion service provider as to the product, urgency and dose required.
-
- R9 The blood product request should 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

The viability of blood products must be preserved, to maximise the efficacy of transfusion while minimising any risk to the patient from functional deterioration or contamination of the product. Viability is preserved by maintaining an appropriate cold chain at all times (including during transfer between hospitals and other facilities), and this preservation is ensured by monitoring and recording the movement of the blood product from receipt to administration.

Appropriate checking procedures at each point of product transit also help to decrease the risk of incorrect blood component transfused (IBCT).

This document does not 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). However, additional resources are provided in Section 5.6.

5.1 Storage of blood products

The current Australian and New Zealand standards relating to the storage of blood products (AS3864.2 2012 *Medical refrigeration equipment – for the storage of blood and blood products* and NZBS: *Refrigeration guidelines requirements for the storage of blood, blood products and tissue for DHB blood banks*) specify that red cells must only be stored in temperature-controlled, dedicated blood refrigerators, and not in ward or domestic refrigerators. All other blood components and products must also be stored according to their specific requirements and, as with red cells, must never be stored in ward or domestic refrigerators.

Temperature-controlled storage refrigerators must have an uninterruptable power supply. Also, they 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 alarm activation or failure, in order to maintain blood product viability and continued support for patient transfusion requirements.

Where a temperature-controlled storage refrigerator is located at a remote site (i.e. one not situated within the laboratory of the transfusion service provider), the 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 temperature-controlled storage refrigerator must be documented in a paper-based or electronic register designated for this purpose. Documentation must include the:

- product type, donation or batch number
- patient name and medical record number (MRN, used in Australia, also known as a patient identification number) or National Health Index (NHI, used in New Zealand) number if available, otherwise the patient's family name and given name and DOB
- staff member's identification
- 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 temperature-controlled storage refrigerator

Before blood products are collected, both the patient and the staff must be adequately prepared to start the transfusion process without delay. Requirements for administration are detailed in Section 6, with Section 6.8 giving details of a checklist to go through before a blood product is collected.

Where a patient is haemodynamically stable, only one unit of red cells should be removed at a time from a temperature-controlled storage refrigerator, both to avoid wastage and reduce risk. There is an increased risk of wrong transfusion when multiple units for more than one patient are collected.

5.3 Collection checking procedures

Staff collecting blood products from the transfusion service provider, or from a remotely located temperature-controlled storage refrigerator, must provide appropriate documentation for each patient requiring transfusion. This documentation can take the form of a blood collection slip, prescription chart or patient's medical record, and it must show the patient's identification details and specific details of the blood product ordered for that patient. The documentation must also comply with existing national standards for patient identification as listed in the additional resources (see Section 5.6).

The staff member removing the blood product from storage (See Recommendation 11) is responsible for ensuring that the information recorded on the blood product labelling exactly matches the documentation presented (further information on this is given in Section 6.9).

The following information must be verified as being identical:

- the patient identification (family name and given name, and DOB, MRN or NHI number, as per local jurisdictional requirements) 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.

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

On arrival of the blood product 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. In such situations, 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 an adverse transfusion reaction due to pre-existing antibodies.

Where a health service or transfusion service provider determines that an inventory of emergency group O red cells is needed, policies must clearly define:

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

The inventory of emergency group O red cells 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 use of emergency group O red cells must be documented so that 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. Providing this information assists traceability and allows replenishment of emergency group O red cells; it also starts a dialogue on obtaining a specimen from the patient for rapid grouping and antibody screening, and subsequent move to group-specific or crossmatched red cells.

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

5.5 Transport of blood products

Once issued, blood products must be transported immediately to the requesting clinical area or to a temperature-controlled remote blood refrigerators where indicated. The ANZSBT *Guidelines for transfusion and immunohaematology laboratory practice*, 2016, listed in the additional resources in Section 5.6, provide information about transport of blood products. Transport of blood products must comply with the ANZSBT *Guidelines for transfusion and immunohaematology laboratory practice*, 2016.

5.1.1 '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 must be placed back into a temperature-controlled blood refrigerator and the transfusion service provider informed accordingly. The time of return must be documented in the register.

Less than 30 minutes

Red cell units that have been out of temperature-controlled storage for **less than 30 minutes** and not transfused can, at the discretion of the transfusion service provider, be accepted back into the blood bank inventory.

More than 30 minutes

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

- transfusion of the unit must be completed within 4 hours (as per Section 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, with the time of return documented in the register and the transfusion service provider informed.

5.6 Additional resources on storage, collection and transport of blood

AABB. *Guidelines for pneumatic tube delivery systems: validation and use to transport blood components* [digital publication]. Developed for the Scientific Section Coordinating Committee by M Mohammed, R Richard & L Uhl. AABB 2005. <https://marketplace.aabb.org/ebusiness/Marketplace/Guidelines-for-Pneumatic-Tube-Delivery-Systems-Validation-and-Use-to-Transport-Blood-Components/ProductDetail/1747>

Australian and New Zealand Society of Blood Transfusion (ANZSBT). *Guidelines for transfusion and immunohaematology laboratory practice*. 1st Edition. ANZSBT November 2016. https://www.anzsb.org.au/data/documents/guidelines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20_.pdf

Australian Commission on Safety and Quality in Health Care (ACSQHC). *National Safety and Quality Health Service Standards*. ACSQHC 2012. <https://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf>

Australian Red Cross Blood Service. *Blood component information – an extension of blood component labels*. March 2015. <http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/18>

Australian Red Cross Blood Service. *Blood service shippers – receipt and use by external institutions*. 2013, modified June 2016. <http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/137>

BloodSafe eLearning Australia. Transporting blood course. Available at <https://bloodsafelearning.org.au/course/transporting-blood/>

National Blood Authority (NBA). BloodMove Project case study. Available at <https://www.blood.gov.au/bloodmove-project-case-study>

National Blood Authority (NBA). *National blood and blood product wastage reduction strategy 2013–2017: working smarter to minimise blood and blood product wastage*. <https://www.blood.gov.au/system/files/documents/nba-wastage-strategy.pdf>

National Blood Authority (NBA). *National haemovigilance data dictionary: a guide for formatting haemovigilance data for the Australian National Haemovigilance Data Set*. Version 3. NBA January 2010. https://www.blood.gov.au/system/files/documents/national-haemovigilance-data-dictionary-2010_0.pdf

National Blood Authority (NBA). Stop the Waste! Available at <https://www.blood.gov.au/stopthewaste>

National Pathology Accreditation Advisory Council (NPAAC). *Requirements for transfusion laboratory practice; Section 14. Storage, transport and inventory management of blood components and blood products*. 3rd Edition. Australian Government Department of Health 2017. <http://www.health.gov.au/internet/main/publishing.nsf/Content/npaac-pub-transfusion>

New Zealand Blood Service (NZBS). *Refrigeration guidelines: requirements for the storage of blood, blood products and tissue for DHB blood banks*. 7th Edition. NZBS October 2017. <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/refrigeration-guidelines/>

New Zealand Blood Service (NZBS). *Transfusion medicine handbook: a guide to the clinical use of blood components, blood products and blood transfusion procedures in New Zealand*. 3rd Edition. NZBS 2016. <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/transfusion-medicine-handbook/>

Pharmaceutical and HealthCare Sciences Society (PHSS). *Guidance document for cold storage monitoring and mapping for blood products*. PHSS 2013. <https://phss.site-ym.com/store/ViewProduct.aspx?id=1996017>

Robinson, S, Harris, A, Atkinson, S, Atterbury, C, Bolton-Maggs, P, Elliott, C, Hawkins, T, Hazra, E, Howell, C, New, H, Shackleton, T, Shreeve, K & Taylor, C. The administration of blood components: a British Society for Haematology guideline. *Transfusion Medicine* 2017. <http://onlinelibrary.wiley.com/doi/10.1111/tme.12481/abstract>

Standards Australia. AS3864.2–2012 *Medical refrigeration equipment – for the storage of blood and blood products*. Standards Australia 2012. <https://infostore.saiglobal.com/store/details.aspx?ProductID=1600490>

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 staff education, training and competency requirements. |
| R12 | Health services must have a policy and protocol for requesting and obtaining blood in a critical bleeding scenario. |
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Section 6

Administration of blood products

6.1 Venous access

The size of an intravenous (IV) access cannula must be large enough to maintain an adequate flow rate for the transfusion. A gauge of 18–20G or larger is recommended for nonemergency 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. A gauge of 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 or 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 can be used but may restrict the flow rate and impact on infusion times.

Central venous access devices (CVADs) include peripherally inserted central catheters (PICCs), implanted ports and central venous catheters (CVCs). Most CVADs 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. The set must incorporate a standard filter that 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.
- Platelets must be transfused through a new blood administration set unless administered in the setting of massive or rapid transfusion, in which case platelets and plasma may need to be transfused through the same administration set.
- Platelets must not be transfused through a blood administration set that has been used for red cells, because red cell debris may trap infused platelets that may not be ABO compatible. Red cells may follow platelets through the same blood administration set, but not precede platelets.
- Blood and other solutions can be infused through the separate lumens of multi-lumen CVCs because rapid dilution occurs in the bloodstream. Where possible, one lumen should be reserved for the administration of blood components.
- Albumin and IV 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.
- For other plasma-derived blood products, individual product information should be consulted.

6.2.2 Priming and connecting blood administration sets

- When priming and connecting blood administration sets:
 - the blood product should be mixed thoroughly by gentle inversion before use
 - it is not necessary to prime the blood administration set with anything other than the blood component, although the blood administration set may be primed with 0.9% sodium chloride
 - the manufacturer's recommendations must be followed when priming the blood administration set

- the blood administration sets should not be 'piggy-backed' into other lines (see Section 6.6)
- it is acceptable to attach the set to extension tubing on an IV cannula.
- When administering blood products through a multi-lumen venous access device, other lumens can be used concurrently for medications and infusion of fluids. Section 6.6 provides further information on 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 between red cell packs is not evidence-based and may be unnecessary; however, 0.9% sodium chloride may be required to maintain IV access if the next red cell unit is not readily available.
- Compatible blood products can be administered sequentially, and sequential administration is the usual practice in critical bleeding. However, platelets must not be transfused through a blood administration set that has been used for red cells (see Section 6.2.1).
- Once the transfusion episode is complete, blood administration sets may be flushed with 0.9% sodium chloride to ensure that the patient receives the entire blood product. The minimum volume of 0.9% sodium chloride required to completely clear the IV line should be used, taking into account the individual circumstances of the patient where relevant (e.g. neonates, some paediatric patients or those at risk of fluid overload or on fluid restrictions). Where a transfusion is prescribed in millilitres for children less than 20 kg the IV cannula (not the line) should be flushed to maintain IV patency. This is to ensure the patient does not receive additional fluid than what was prescribed.

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 reduces 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 (see Section 6.2.1). This reduces the risk of incompatible fluids or drugs causing haemolysis of residual red cells in the administration set or drip chamber.

6.2.5 Additional resources on equipment

New Zealand Blood Service (NZBS). eResource. Available at <http://xtk.me/fs>

Norfolk, D (ed.). *Handbook of transfusion medicine*. 5th Edition. UK Blood Services 2013.
<http://www.transfusionsguidelines.org.uk/transfusion-handbook>

6.3 Microaggregate filters

6.3.1 Leucocyte depletion filters

All red cells and platelets issued by the Australian Blood Service, and all red cells, platelets and plasma issued in New Zealand, are leucocyte depleted; therefore, additional bedside leucocyte depletion filters are not required. In the rare cases when blood components have been collected within a local health service in Australia (e.g. autologous units or directed donation), bedside leucocyte depletion filters may be indicated. In such cases, the requirement for filters must be verified with the provider or local health service policy. This practice does not occur in New Zealand, where all autologous units or directed donation are supplied leucodepleted. 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

There is no evidence from controlled trials that microaggregate filters offer clinical benefit; hence, their use is not generally recommended. In view of universal leucodepletion by the Blood Services in Australia and New Zealand, there is no additional benefit of using a microaggregate filter, because the blood-giving set contains a debris filter. Microaggregate filters can slow the rate of administration.

6.3.3 Other filters (cell salvage)

Local or manufacturer policies and product information may apply where other filters are used in settings such as intraoperative or postoperative cell salvage.

In addition, the guidelines listed in Section 6.3.4 may be of assistance in creating local health service policy.

6.3.4 Additional resources on cell salvage

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](http://www.aagbi.org/sites/default/files/cell%20salvage_2009_amended.pdf)

Australian and New Zealand Society of Blood Transfusion (ANZSBT). Preoperative autologous donation statement. ANZSBT April 2015. <https://www.anzsbt.org.au/data/documents/ANZSBTPADstatementApr2015.pdf>

National Blood Authority (NBA). Guidance for the provision of intraoperative cell salvage. Available at <http://www.blood.gov.au/ics>

National Institute for Health and Clinical Excellence (NICE). Intraoperative blood cell salvage in obstetrics. <http://www.nice.org.uk/guidance/IPG144>

National Institute for Health and Clinical Excellence (NICE). Intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy. <https://www.nice.org.uk/guidance/ipg258>

UK Cell Salvage Action Group. Webpage. Available at <http://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group>

6.4 Infusion devices

Local health service policy should indicate whether volumetric infusion and external pressure or rapid infusion devices can be used, and 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 must specify the maximum infusion rate and pressure setting at which safety was demonstrated.

6.4.1 Volumetric infusion pumps

Volumetric infusion pumps are 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; for example, via PICC or small gauge cannula.

Volumetric infusion pumps may be used to deliver products via peripheral lines or 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 use of such pumps according to health service policy.

- The checking procedure before spiking and hanging the blood must include a check of the device and device settings, as well as the blood product and the patient's identity checks.
- Both pump settings and volume delivered must be monitored hourly throughout the infusion to ensure that the 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; for example, 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 facilitate 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 noncritical 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 described above. External pressure devices should:

- exert pressure evenly over the entire bag
- have a gauge to measure the pressure
- not exceed 300 mm Hg of pressure
- be monitored at all times when in use.

Note: in some devices filter pore size may vary to achieve higher infusion rates. See section 6.4 for guidance regarding validation for use with blood products.

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 Section 7.2).

If a syringe driver is used for administration of fresh components, the configuration must ensure that the 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 (i.e. a single time) 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, and in which situations they are appropriate. The device must be validated by the manufacturer for the administration of blood products, and must be used exactly as specified by the manufacturer.

6.5.1 Indications for blood warmers

A blood warmer may be indicated for:

- large volume rapid transfusions (i.e. > 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 fetomaternal specialist
- patients with clinically significant cold agglutinins
- trauma situations in which core-rewarming measures are indicated

- the patient rewarming phase during cardiopulmonary bypass surgical procedures.

6.5.2 General recommendations

- 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; for example, by the health service biomedical provider.
- When a commercial blood warmer is used to warm red cells, the operating temperature of the warmer must be recorded on the patient's infusion record.
- Red cells must not be warmed above the set point temperature of the approved device.
- Blood administration sets used with the warmer must be primed before use, as for other blood administration sets.
- Due to the risk of contamination from infected water baths, these types of device should be replaced with dry heat blood warming equipment.
- Improvised warming (e.g. putting the pack in hot water, in a microwave oven or on a radiator) must **never** be used. Such warming methods may damage red cells and cause harm to the patient.

6.5.3 Additional resources on blood warmers

AABB. *Primer of blood administration* (available to individual and institutional AABB members). AABB revised September 2012. Available at <http://www.aabb.org/development/education/materials/Pages/default.aspx>

Australian and New Zealand Society of Blood Transfusion (ANZSBT). *Guidelines for transfusion and immunohaematology laboratory practice*. 1st Edition. ANZSBT November 2016. https://www.anzsb.org.au/data/documents/guidelines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20_.pdf

British Society for Haematology (BSH). Guideline on the administration of blood components. BSH December 2009 (and Addendum August 2012). Available at <http://www.b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/>

National Health Service Blood and Transplant (NHSBT) Patient Blood Management Practitioner Team. *A drop of knowledge: guidance for new and developing transfusion practitioners*. NHSBT September 2016. http://hospital.blood.co.uk/media/28600/blc682-v10-1-a-drop-of-knowledge-sep16-2_.pdf

New Zealand Blood Service (NZBS). *Transfusion medicine handbook: a guide to the clinical use of blood components, blood products and blood transfusion procedures in New Zealand*. 3rd Edition. NZBS 2016. <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/transfusion-medicine-handbook/>

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, because it allows for rapid dilution in the bloodstream. 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, because during 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. In relation to other fluids:

- 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.

For additional resources see Section 6.6.4.

6.6.2 Incompatible fluids

Certain IV fluids are incompatible with blood components; for example:

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

There is low-level in vitro evidence to support the safety of co-infusion of dextrose-containing fluids and red cells in a low flow and volume setting such as neonatal transfusion. However, based on current available evidence it is not possible to recommend co-infusion of dextrose-containing fluids and red cells in the neonatal population.

For additional resources see Section 6.6.4.

6.6.3 Medications

Medication must **not** be added to the blood bag or blood administration set or IV line before or during transfusion, because the medication may interact with the anticoagulant, additive solutions or the blood component contained in the bag. Also, a break in the integrity of the infusion line may increase the risk of bacterial contamination of the component. Finally, if an adverse 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 (e.g. amphotericin).

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

1. **STOP** the transfusion.
2. Flush the line, via the injection port, using 0.9% sodium chloride (normal saline) to clear blood from the IV port and tubing.
3. Administer the medication.
4. 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 4 hours.

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

Co-administration of morphine, pethidine 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. 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 on concurrent fluids and medications

Birch, C, Hogan, C & Mahoney, G. Co-administration of drugs and blood products. *Anaesthesia and Intensive Care* 2001; 29(2): 137–140. <https://www.ncbi.nlm.nih.gov/pubmed/11314832>

Gelofusine® product information. Available at

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-02477-3&d=2017031516114622483>

Keir, A, Callum, J & Jankov, RP. Is it safe to co-infuse dextrose-containing fluids with red blood cells? *Journal of Pediatrics and Child Health* 2013; 49(8): 687–691. <http://onlinelibrary.wiley.com/doi/10.1111/jpc.12372/full>

Murdock, J, Watson, D, Dorée, CJ, Blest, A, Roberts, MM & Brunskill, SJ. Drugs and blood transfusions: dogma- or evidence-based practice? *Transfusion Medicine* 2009; 19: 6–15. <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3148.2008.00896.x/abstract>

Stark, MJ, Story, C & Andersen, C. Effect of co-infusion of dextrose-containing solutions on red blood cell haemolysis during packed red cell transfusion. *Archives of Disease in Childhood, Fetal and Neonatal Edition* 2012; 97(1): F62–64. <http://fn.bmj.com/content/97/1/F62>

Yousef, HM, Padmore, RF, Neurath, DD & Rock, GA. The effect of patient-controlled analgesia on coadministered red blood cells. *Transfusion* 2006; 46: 372–376. <http://onlinelibrary.wiley.com/doi/10.1111/j.1537-2995.2006.00731.x/abstract>

6.7 Location and timing of the transfusion

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

The transfusion (after completion of the pretransfusion checks) must begin as soon as the blood component is:

- delivered to the clinical area or
- removed from the designated transport box or controlled storage (e.g. at a satellite centre).

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

Before requesting issue of a blood product or collecting the blood product, clinical staff must check that:

- the prescription has been satisfactorily completed (see Section 3.1)
- valid, informed consent has been obtained and the indication for transfusion has been documented in the patient's health-care record
- the patient has been assessed, including baseline vital signs, to determine whether it is appropriate to undertake the transfusion at the planned time
- IV access is appropriate and patent, and all necessary equipment is available and in working order (e.g. infusion pumps or blood warmers)
- any premedication prescribed for the patient has been administered at an appropriate time to ensure effectiveness, before commencing the transfusion
- 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
- the patient is available to proceed with transfusion; for example, the patient is not scheduled for a procedure.

6.9 The preadministration 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.

Standards for practice regarding patient identification and patient identification bands are mandated by the Australian Commission on Safety and Quality in Health Care (ACSQHC) *National Safety and Quality Health Service (NSQHS) Standards* and the NZBS *Transfusion medicine handbook* that are current at time of production of these guidelines, as referenced below. *Flippin' blood* is a valuable resource to support clinical practice.

Information regarding patient identification on compatibility labels and reports can be obtained from the ANZSBT *Guidelines for transfusion and immunohaematology laboratory practice*, 2016.

6.9.1 Identification bands

All patients receiving a blood product – whether inpatient, outpatient or day patient – **must** be positively identified and should have an identification (ID) band attached to their body that complies with Australian and New Zealand standards or guidelines (see Section 6.9.3). The following minimum core patient identifiers are mandatory:

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

Individual hospitals or health services should determine how they meet the specifications for identification bands. Issues that will need to be determined locally at the hospital or 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 patient identifiers specified in Section 6.9.1 should also apply to neonates.

Local operational policy may stipulate that neonates wear two identification bands at all times; that is, with the same details on two different limbs.

6.9.1.2 Unconfirmed identity and name changes

Sometimes a patient’s identity cannot be reliably confirmed; for example, because of temporary or long-term cognitive impairment, inability to communicate or loss of consciousness. In such cases, the patient must be registered according to the documented hospital procedure as, for example, ‘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.

Key issues are as follows:

- The transfusion service provider must be notified immediately if patient details change.
- Consecutive temporary identifying patient numbers should not be used.
- Local operational policy must provide procedures to ensure that such patients can be correctly identified throughout their admission, particularly in relation to the reconciliation of samples or investigations, including those related to pretransfusion testing.
- In the event that core patient identification details (i.e. family name and given names, or DOB) are legitimately changed or updated (e.g. unknown patient, baby name change or 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.

6.9.2 Pretransfusion checking procedure

- The patient’s identity **must** always be confirmed before transfusion (see Section 6.9.2.2).

- The patient's family name and given name, DOB and MRN or NHI number must be checked and found to be identical on all of the following:
 - the patient's identification band
 - the compatibility label attached to the blood product
 - the blood product prescription.

In some circumstances, the MRN or NHI number may not be available on a compatibility label or report as a third patient identifier; for example, when pretransfusion testing is requested as an outpatient before admission, or when the MRN or NHI number is not provided to a private pathology transfusion service by a health service. Where provided or recorded, the MRN or 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

Two members of staff must undertake the identity check of the patient and blood product **at the patient's side** immediately before administration. Each of these two staff is responsible for the accuracy of the checking procedure. Although the two staff commonly do the checking together, this approach leaves room for error, including the administration of incorrect products to patients. Thus, each person must complete all the checks independently (a process referred to as 'double independent checking').

- The staff performing the identity check must be authorised by the relevant professional regulatory body and appropriately trained by their health service, and must comply with any jurisdictional requirements.
- The two individuals carrying out the check must both sign the relevant documentation confirming that the patient and product check has occurred, and is correct and compatible.
- The person spiking or hanging the blood product must be authorised and appropriately trained by their institutions to spike or hang the product, and must be one of the two staff members who have independently 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 transfusion started immediately after the check has been completed. If there is a delay, the checking process must be repeated.
- It is the responsibility of the person spiking or hanging the blood product to ensure that it is appropriate to undertake the transfusion at that time. This may include assessing the patient's clinical status and confirming with the prescriber.

6.9.2.2 Confirmation of patient identity and matching patients to their care

The identification band checking procedure must include the following steps:

- Check that the identification band is securely attached to the patient.
- Ask the patient (if conscious and competent) to state and spell their family name and given name in full, and their DOB; ensure that the stated family name and given names and DOB are identical to those on the identification band; also, confirm that the names are spelled correctly and match the patient details on the blood product prescription.
- 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 that the stated family name and given 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 family name and given name, DOB and MRN or 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, the product and the laboratory compatibility label
- the blood product is checked for compliance with any special requirements on the prescription (e.g. irradiated or CMV seronegative)

- the blood group and the donation or batch code or number on the compatibility label are identical to that information on the product from the Blood Service
- 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 is the most suitable available)
- the blood component or product has not passed its crossmatch expiry or unit or 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 discolouration 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.

6.9.3 Additional resources on the preadministration identity check of patient and blood product

Australian and New Zealand Society of Blood Transfusion (ANZSBT). *Guidelines for transfusion and immunohaematology laboratory practice*. 1st Edition. ANZSBT November 2016.

https://www.anzsb.org.au/data/documents/guidelines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20_.pdf

Australian Commission on Safety and Quality in Health Care (ACSQHC). Patient identification. Available at <https://www.safetyandquality.gov.au/our-work/patient-identification/>

Australian Commission on Safety and Quality in Health Care (ACSQHC). National specifications for patient identification bands. Available at <https://www.safetyandquality.gov.au/our-work/patient-identification/a-national-standard-for-patient-identification-bands-in-australia/>

BloodSafe. *Flippin' blood: a BloodSafe flip chart to help make transfusion straightforward*. 2nd Edition. BloodSafe, SA Health and the Australian Red Cross Blood Service June 2012.

<http://resources.transfusion.com.au/cdm/singleitem/collection/p16691coll1/id/20/rec/1>

New Zealand Blood Service (NZBS). Clinical policies and procedures. Available at

<http://www.nzblood.co.nz/clinical-information/transfusion-medicine/clinical-compendium/clinical-policies-and-procedures/>

New Zealand Blood Service (NZBS). eResource. Available at <http://xtk.me/fs>

New Zealand Blood Service (NZBS). *Transfusion medicine handbook: a guide to the clinical use of blood components, blood products and blood transfusion procedures in New Zealand*. 3rd Edition. NZBS 2016.

<http://www.nzblood.co.nz/clinical-information/transfusion-medicine/transfusion-medicine-handbook/>

World Health Organization (WHO) Collaborating Centre for Patient Safety Solutions. Patient identification.

Patient Safety Solutions 2007; 1(2). <http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution2.pdf>

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, nonbleeding adult patients typical administration durations are:

Table 4: Infusion rates for blood products

Product	Infusion rate
Red cells	60–180 minutes per unit
Platelets	15–30 minutes (Australia) or 30–60 minutes (New Zealand) per standard adult equivalent dose equivalent dose
Fresh frozen plasma	30 minutes per unit (i.e. 10–20 mL/kg/hr)
Cryoprecipitate	30–60 minutes per standard adult dose (i.e. 10–20 mL/kg/hr)
Granulocytes	Infusion rates should follow local protocols
Plasma-derived products	Infused in a timeframe in accordance with product-specific instructions.

Note: 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 hypovolaemic shock require blood components to be transfused rapidly. During major haemorrhage, very rapid transfusion may be required (as fast as the patient and their IV access can tolerate). The use of a blood warmer is recommended in critical bleeding or massive transfusion situations.

Information on paediatric and neonatal transfusion practices is given in Section 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, provided 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 or protocols.

6.10.1 Maximum duration for transfusion

The transfusion should normally be completed within 4 hours of the product leaving approved temperature-controlled storage (or sooner if specified on the pack or transfusion report) and **no longer than 4.5 (four and a half) hours** following release of the product from temperature-controlled storage.

6.10.2 Additional resources on infusion rates and precautions

Australian Red Cross Blood Service. *Blood component information – an extension of blood component labels*. March 2015. <http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/18>

New Zealand Blood Service (NZBS). Clinical policies and procedures. Available at <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/clinical-compendium/clinical-policies-and-procedures/>

New Zealand Blood Service (NZBS). eResource. Available at <http://xtk.me/fs>

6.11 Observations and monitoring

The following points relate specifically to transfusion of blood components. Although the general principles apply to the infusion or administration of plasma-derived products, specific guidance should be sought from relevant product information and local procedures or protocols. Clinical deterioration should be managed as per facility or jurisdictional policies. In New Zealand, the standardised recording chart is the Early Warning Score. There is a separate chart for adults and paediatrics.

- All observations must be recorded in the patient's health-care record and must comply with any

jurisdictional requirements.

- **Observations associated with transfusion should be clearly identified with the documentation.**
- Patients receiving transfusions must be monitored for signs of potential complications of the transfusion, and any suspected problems must be dealt with promptly.
- Before the transfusion is started, 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 where enough trained staff are available to monitor the patient, the patient can be readily observed and emergency support is available.
- The start time of the transfusion must be documented.
- Serious and life-threatening reactions – for example, anaphylaxis, transfusion-related acute lung injury (TRALI), haemolysis and sepsis – can occur unpredictably and progress rapidly; this situation emphasises the need for close observation throughout the transfusion.
- Where the patient is not in an open area, frequent visual observation of the patient for the duration of the transfusion **must** occur. As a minimum, the vital signs of temperature, pulse, respiration rate and blood pressure **must** be measured and recorded:
 - before the start (i.e. within 60 minutes before commencement) of each individual blood component pack being administered
 - 15 minutes after starting the administration of each blood component pack
 - when administration of each blood component pack is completed.
- Measurement of vital signs **must** be undertaken and recorded 15 minutes after the start of transfusion 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 as 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. Frequent 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 or jurisdictional requirements. The frequency and recording of vital signs must be adjusted according to the individual patient's clinical condition. More frequent monitoring may be required if there are underlying comorbidities and intercurrent factors; for example, if the patient has congestive heart failure, bleeding, increased intracranial pressure or renal dysfunction, or is unable to respond or shows signs or symptoms of a reaction.
- Assessment of skin condition, before and during transfusion (i.e. for the presence or absence of rash), can assist recognition of a transfusion-related allergic reaction.

6.11.1 Children, and unconscious or anaesthetised patients

- 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 to use the call bell because of mental or physical limitations.
- Signs and symptoms of acute reactions may present differently in paediatric patients and can include irritability, agitation and inconsolability by the parent or main caregiver. These signs and symptoms may be present in the absence of, or before, changes in vital signs.
- Unconscious or anaesthetised patients should be monitored more frequently and with increased vigilance for signs of adverse transfusion reactions.
- Adverse transfusion reactions should be considered where there is a change or deterioration in the patient's condition.
- Hypotension, uncontrolled bleeding or generalised oozing during surgical procedures may suggest an

acute haemolytic reaction due to an incompatible red cell transfusion.

- 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 health-care 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 it appropriate to have a period of continued observation at the completion of the transfusion, to monitor for a transfusion-related adverse event. Additional information such as a contact sheet or card may be given on discharge, to advise the patient on 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 or blood products. Glass bottles are not suitable for recycling.
- If there is any suspicion of an adverse transfusion reaction, the transfusion service provider must be informed of the clinical details, and the product (or product pack or bottle) should be returned. **If the product (or product pack or bottle) has already been discarded into clinical waste, do not retrieve it from waste.**

6.13 Checklist for health-care 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 (including the donation code)
- start 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.

Recommendation

R13 Health services must have a policy for all patients receiving transfusion of blood and blood products 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
 - documentation requirements for the transfusion process
 - reporting of adverse events and outcomes of the transfusion.
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Section 7

Special transfusion circumstances

7.1 Out-of-hospital blood transfusions

7.1.1 Community

Out-of-hospital (OOH) transfusion – such as in a patient’s home, a residential aged-care facility (RACF) or supported accommodation – requires special attention, because of the reduced access to emergency medical care, the particular needs of the patient and the transfusion setting. Therefore, the decision to undertake OOH transfusion should be based on individual patient circumstances and should only be considered where:

- 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 valid, 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.

Health service, RACF and supported accommodation providers undertaking OOH transfusion must establish a policy for OOH transfusion. That policy should comply with ANZSBT guidelines (including those related to administration, transport and storage of blood products) as well as other relevant local, state, territory or national legislation, guidelines and policies. The policy should:

- include criteria for patient selection, including considerations such as cardiorespiratory, haemodynamic and mental status, transfusion history, environment and distance from an acute care hospital
- include the responsibilities for the various aspects of OOH transfusion, with clearly stated lines of communication between all stakeholders
- be overseen by a multidisciplinary group or committee with appropriate transfusion expertise to ensure best practice.

Evaluation by the OOH service provider’s risk management personnel may be required. Also, work health and safety procedures for personnel involved in OOH transfusion must be as rigorous as those for in-hospital transfusion.

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

- Education and training must be provided to all personnel involved, which may include the patient’s relative or carer and the courier delivering the blood. Training of the person undertaking blood product administration includes cardiopulmonary resuscitation (CPR) and other aspects of acute care for managing transfusion reactions.
- OOH transfusion providers must have an action plan to manage an emergency or transfusion reaction. This could include, for example, an identified registered medical officer responsible and provision for 24-hour patient liaison service. An adverse reaction or emergency medication kit should be available for administration as per a medical officer’s instruction or standing orders.
- 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.
- Patients should be allocated a patient identification number to be used throughout the transfusion process, including sample collection, and the collection and administration of the blood product.

- 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 (see Section 6.9.2).
- 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.
- Facilities engaging in or planning to engage in OOH transfusions should consult other resources that provide a more detailed framework for OOH transfusion practice.

7.1.2 Additional resources on OOH blood transfusions

Australian Commission on Safety and Quality in Health Care (ACSQHC). Standard 5 in Guide to the National Safety and Quality Health Service Standards for community health services. ACSQHC February 2016.

<https://www.safetyandquality.gov.au/wp-content/uploads/2016/03/Guide-to-the-NSQHS-Standards-for-community-health-services-February-2016.pdf>

Australian Commission on Safety and Quality in Health Care (ACSQHC). *Safety and quality improvement guide; Standard 5: Patient identification and procedure matching*. ACSQHC October 2012.

<https://www.safetyandquality.gov.au/publications/safety-and-quality-improvement-guide-standard-5-patient-identification-and-procedure-matching-october-2012/>

Benson, K. Home is where the heart is: do blood transfusions belong there too? *Transfusion Medicine Reviews* 2006; 20(3): 218–229. <http://www.sciencedirect.com/science/article/pii/S0887796306000149>

Friday, JL. General principles of home blood transfusion. UpToDate. Available at

<https://www.uptodate.com/contents/general-principles-of-home-blood-transfusion>

Friday, JL. The path to safer home transfusion. UpToDate. Available at <https://www.uptodate.com/contents/the-path-to-safer-home-transfusion-standard-operating-procedures>

Green, J & Pirie, L. *Framework for the provision of blood transfusion out of the acute hospital setting*. 3rd Edition. NHS Blood and Transplant November 2012 (amended October 2013).

http://hospital.blood.co.uk/media/27199/home_tx_framework_post-shot-2013.pdf

New Zealand Blood Service (NZBS). *Transfusion medicine handbook: a guide to the clinical use of blood components, blood products and blood transfusion procedures in New Zealand*. 3rd Edition. NZBS 2016.

<http://www.nzblood.co.nz/clinical-information/transfusion-medicine/transfusion-medicine-handbook/>

Nova Scotia Provincial Blood Coordinating Program (NSPBCP). Guidelines for home transfusion. Version 2.0. NSPBCP May 2014. <https://www.novascotia.ca/DHW/nspbcp/docs/Home-Transfusion-Guideline.pdf>

7.1.3 Retrieval

OOH transfusion also occurs during retrieval of patients to acute hospital care. Retrieval organisations must have policies and procedures to support safe and timely blood product transfusion; the policies and procedures must be consistent with these guidelines.

7.2 Paediatric transfusions

Transfusion should be consistent with the *Patient blood management guidelines: Module 6 Neonatal and Paediatrics*.

The transfusion of blood products to children and neonates requires special consideration because of their small body mass and blood volume, and because of fetal, neonate and paediatric haematopoietic development.

Specialised paediatric hospitals and their associated hospital transfusion services should be contacted for queries relating to paediatric transfusion. Where available, a specialist paediatric transfusion practitioner should be consulted for advice; also, where possible, the specialist should provide education to staff administering blood products to paediatric patients.

Children and neonates require special consideration; therefore, health-care providers should address the points raised in Sections 7.2.1–7.2.8.

7.2.1 The volume of blood to be transfused

Children less than 20 kg should have the volume prescribed in millilitres. The volume should be calculated based on the child's weight and the desired haemoglobin increment, to prevent transfusion-associated circulatory overload (TACO).

7.2.2 Special requirements

Fresh red cells (<5 days old), K (Kell) negative, and CMV seronegative or irradiated components (or both) may be indicated in some instances. See the *Patient blood management guidelines: Module 6 Neonatal and Paediatrics*.

Selection of blood for intrauterine and exchange transfusion should be discussed with the transfusion laboratory.

7.2.3 Consumer information

An information leaflet on blood transfusions should be provided for the parent or guardian to assist with education about transfusion; for example, the paediatric patient information – *Children receiving a blood transfusion, a parents' guide*.

7.2.4 Positive identification of children

Identification bands must be in place and a parent, carer or guardian (if present) should positively identify the child before the transfusion is started.

7.2.5 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 that blood is drawn from the bag using a bloodline 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. For flushing of blood administration sets, see Section 6.2.3.

7.2.6 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 4 hours of the components 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 4 hours of commencement but no longer than 4.5 (four and a half) hours following release of the product from temperature-controlled storage, to allow for a 30-minute transport time (see Section 6.10.1).

The use of syringe drivers and volumetric infusion pumps (approved for blood products) are recommended to ensure accurate rates.

7.2.7 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 therefore must be closely monitored.

Signs and symptoms of acute reactions may present differently in paediatric patients, and can include irritability, agitation and inconsolability by the parent or main caregiver. These signs and symptoms may be present in the absence of or before changes in vital signs (see Section 6.11.1).

7.2.8 Consideration of children's activities

The transfusion should be planned for a time when the child can be given support in a clinical area with close observation and emergency equipment. Age-appropriate activities can be provided during the transfusion period.

7.3 Additional resources on paediatric transfusions

Australian and New Zealand Society of Blood Transfusion (ANZSBT), BloodSafe, Australian Red Cross Blood Service & New Zealand Blood Service (NZBS). *Children receiving a blood transfusion, a parents' guide*. ANZSBT. <https://www.anzsb.org.au/data/documents/AParentsGuide.pdf>

National Blood Authority (NBA) (2016). Patient Blood Management Guidelines: Module 6: - Neonatal and Paediatrics. NBA, Canberra Australia. https://www.blood.gov.au/system/files/14523_NBA%20Module%206%20Neonat_Paediatrics_internals_5_FA_updated_15Feb2017.pdf

Recommendations

- | | |
|-------|---|
| R14 | Health services, residential aged-care facilities or supported accommodation providers undertaking 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. |
| <hr/> | |
| R15 | Health services providing transfusion support to paediatric and neonatal populations must ensure that policy and protocols recognise the special needs and requirements of this patient population. |
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Section 8

Management of transfusion-related adverse events

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; however, prior history can be valuable. 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, respond and report'** suspected adverse events.

The most important transfusion-related adverse reactions include:

- febrile (nonhaemolytic) transfusion reactions
- allergy and anaphylaxis (including immunoglobulin A (IgA)/anti-IgA reactions)
- transfusion-associated circulatory overload (TACO)
- acute and delayed haemolytic transfusion reactions
- transfusion-related acute lung injury (TRALI)
- transfusion-associated graft versus host disease (TA-GvHD)
- post-transfusion purpura (PTP)
- transfusion-transmitted infection (TTI); for example, sepsis from bacterially contaminated blood components.

Acute transfusion reactions can present with a range of symptoms and signs of varying severity. These may include:

- fever and related inflammatory symptoms or signs, such as chills, rigors, myalgia, nausea or vomiting
- cutaneous symptoms and signs including urticaria (hives), other skin rashes and pruritus
- angioedema (localised oedema of the subcutaneous or submucosal tissues), which may be preceded by tingling
- respiratory symptoms and signs including dyspnoea, stridor, wheeze and hypoxia
- hypotension
- pain
- severe anxiety or 'feeling of impending doom'
- bleeding diathesis with acute onset.

If an adverse transfusion-related event is suspected, other patients may be at risk, because of one of the following:

- patient identity error (e.g. ABO-incompatible transfusion to a different patient)
- 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.

Any deterioration in a patient's condition during the transfusion of a blood product must be considered an adverse transfusion event unless assessed otherwise.

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

8.1 Management of possible adverse transfusion-related events

The following information is provided to assist the immediate clinical management of a patient with a suspected adverse transfusion event. 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). For documentation requirements, see Section 6.13.

A common adverse transfusion outcome is an **unexpected** rise in the patient's temperature. This rise may be due to the transfusion or may be incidental (i.e. as a result of the patient's underlying illness). **A temperature rise of 1 °C or more above baseline and more than 38 °C should prompt the interruption of the transfusion and a clinical assessment of the patient. Transfusions should also be interrupted and responded to, as per jurisdictional observation and response charts for the recognition of clinical deterioration, and in New Zealand as per the Early Warning Score.**

8.1.1 Mild adverse transfusion events

The following could be considered signs of a mild adverse transfusion event:

- an isolated temperature **rise of 1 °C to less than 1.5 °C**, above baseline **and more than 38 °C** without any signs of a serious event (including any of those listed below in Section 8.1.2). A lower temperature rise occurring early in the transfusion (eg. a 1°C rise within the first 2 hours, to less than 38 °C) may also be a sign of an adverse transfusion reaction. Stopping the transfusion seeking medical assessment is recommended.
- localised rash or pruritus.

If a mild adverse transfusion event is suspected:

- **STOP the transfusion**
- maintain IV access
- monitor and record the patient's temperature, pulse, respirations, *oxygen saturation* and blood pressure
- repeat all documentation and identity checks of the patient and blood pack
- contact medical staff immediately for further management and investigation.

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

If signs or symptoms persist or redevelop, or the patient's condition subsequently deteriorates, the transfusion should be **stopped** and managed as for a moderate to severe adverse transfusion event (see Section 8.1.2).

8.1.2 Moderate to severe adverse transfusion events

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

- temperature of 1.5 °C or more above baseline
- hypotension, shock or hypertension
- tachycardia
- tachypnoea, wheeze or stridor
- rigors or chills
- nausea or vomiting
- pain (localised, chest, flank or discomfort at infusion site).

If a moderate or severe adverse transfusion event is suspected, the following steps **must** be undertaken:

- **STOP the transfusion immediately and seek urgent medical advice**; follow the health-care facility's clinical deterioration escalation procedures

- 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 documentation and identity checks of the patient and blood pack
- immediately report the event 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
- 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 line should be handled and sealed to prevent any contamination to the bag and line space before transportation.

Further management, including subsequent transfusion, will depend on the type and severity of the event and the results of associated investigations. Further transfusions should not be started without the advice or consent of the transfusion service provider, transfusion medicine specialist or consultant haematologist, in consultation with the managing clinician.

The additional resources given in Section 8.1.3 provide examples of adverse transfusion events and their management. It is strongly advised that these references be made available in clinical areas, together with tools to assist recognition and response to adverse transfusion events.

For individual fractionated, plasma-derived and recombinant products, see relevant product and consumer information.

8.1.3 Additional resources on management of possible adverse transfusion events

Australian Commission on Safety and Quality in Health Care (ACSQHC). Recognising and responding to clinical deterioration. Available at <https://www.safetyandquality.gov.au/our-work/recognising-and-responding-to-clinical-deterioration/>

Australian Commission on Safety and Quality in Health Care (ACSQHC). *Standard 1 Governance for safety and quality in health service organisations; Criterion: Incident and complaints management*. National Safety and Quality Health Service (NSQHS) Standards. ACSQHC 2012. https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard1_Oct_2012_WEB1.pdf

Australian Commission on Safety and Quality in Health Care (ACSQHC). *Standard 7 Blood and blood products*. National Safety and Quality Health Service (NSQHS) Standards. ACSQHC October 2012. https://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard7_Oct_2012_WEB.pdf

Australian Red Cross Blood Service. Adverse events app. Available at <https://transfusion.com.au/apps>

Australian Red Cross Blood Service. Adverse reactions. Available at https://www.transfusion.com.au/adverse_events_overview

Australian Red Cross Blood Service. *Blood component information – an extension of blood component labels*. March 2015. <http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/18>

BloodSafe. *Flippin' blood: a BloodSafe flip chart to help make transfusion straightforward*. 2nd Edition. BloodSafe, SA Health and the Australian Red Cross Blood Service June 2012. <http://resources.transfusion.com.au/cdm/singleitem/collection/p16691coll1/id/20/rec/1>

Bolton-Maggs, PHB & Cohen, H. Serious Hazards of Transfusion (SHOT) haemovigilance and progress is improving transfusion safety. *British Journal of Haematology* 2013; 163(3): 303–314. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935404/>

National Blood Authority (NBA). Australian haemovigilance minimum data set. Version 1. NBA August 2015. <https://www.blood.gov.au/system/files/aust-haemovigilance-min-data-set.pdf>

New Zealand Blood Service (NZBS). eResource. Available at <http://xtk.me/fs>

New Zealand Blood Service (NZBS). Guidelines for management of adverse transfusion reactions. Available at <http://www.nzblood.co.nz/clinical-information/transfusion-medicine/adverse-reaction-reporting-and-management/>

Queensland Blood Management Programme. *A safer future for Emily: Queensland incidents in transfusion (Qiit) June 2007–2009 report; Appendix B Transfusion reaction chart*. Queensland Health 2012.

https://www.health.qld.gov.au/_data/assets/pdf_file/0025/432349/cass-qiit-report-09.pdf

Serious Hazards of Transfusion (SHOT). Lessons for clinical transfusion staff: update 2013 incorporating guidance from SHOT Annual Reports 2011 and 2012. SHOT 2013. https://www.shotuk.org/wp-content/uploads/66444-PR_72511-SHOT-Clinical-Lessons_28-01-p1-LR-PS.pdf

Serious Hazards of Transfusion (SHOT). Annual SHOT report 2016. SHOT 2016. https://www.shotuk.org/wp-content/uploads/SHOT-Report-2016_web_11th-July.pdf

Tinegate, H, Birchall, J, Gray, A, Haggas, R, Massey, E, Norfolk, D et al. Guideline on the investigation and management of acute transfusion reactions. Prepared by the British Society for Haematology Blood Transfusion Task Force. *British Journal of Haematology* 2012; 159: 143–153.

<http://onlinelibrary.wiley.com/doi/10.1111/bjh.12017/abstract>

8.2 Reporting of adverse transfusion-related events

Some health departments mandate reporting of sentinel events related to transfusion; for example, acute haemolytic reactions such as those 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; that is, to the Therapeutic Goods Administration (TGA) in Australia or Medsafe in New Zealand. In addition, there may be 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. The policy and process should take the following into account:

- where a moderate or severe event 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 and, where appropriate, the Blood Service or manufacturer
- if an event is a result of a suspected ABO mismatch or bacterial contamination, the transfusion service provider must be notified **immediately** because 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 manufacturer) of serious adverse events and near misses related to blood transfusion. These include incorrect blood product transfused, and acute and delayed adverse transfusion reactions (including anaphylaxis, TA-GvHD, TRALI and PTP); all such events 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 transfusion.

8.2.1 Additional resources on reporting of adverse transfusion-related events

National Blood Authority (NBA). Strategic framework for the national haemovigilance program. NBA September 2014. <https://www.blood.gov.au/document/strategic-framework-national-haemovigilance-program-pdf>

Recommendation

- R16 Health services must have a policy for the management and reporting of adverse events and near miss events relating to blood transfusion that includes:
- 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 adverse transfusion events
 - the procedure for reporting adverse and near miss events in local incident management systems, and state, territory or national haemovigilance systems
 - the mechanism for review of adverse events and near misses
 - requirements for reporting to the transfusion service provider, or to the Blood Service or manufacturer.
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Section 9

Clinical governance

9.1 Blood management or transfusion committees

All health services that perform transfusions should establish a hospital blood management or transfusion committee (BMC) 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 use the resource of a regional, district or general clinical governance committee. It is strongly advised 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 BMC, its functions and activities will depend on local factors such as the size, location and activities of an institution. The provision of safe and effective transfusion practice requires multidisciplinary collaboration.

Representation should include:

- executive management, sponsor
- clinical risk management, quality assurance, education
- hospital transfusion service, transfusion service providers, pathology
- haematology, oncology
- medical, nursing, midwifery representatives from relevant areas, such as surgery, trauma, orthopaedics, obstetrics and gynaecology, paediatrics, anaesthetics, emergency medicine, intensive care
- transfusion nurse or trainer where available, or a designated nurse or professional with transfusion responsibilities
- other relevant specialities or departmental representation, either ongoing or as required; for example, perfusionists, pharmacists and bioethicists, as determined by the institution
- health department (optional)
- the Blood Service (optional)
- co-opted members, as required
- consumer involvement, where appropriate.

9.1.2 Meeting frequency and reporting

The BMC should meet at regular intervals (e.g. quarterly), and report within the hospital or health service quality and safety framework.

9.1.3 Terms of reference

To promote best practice in transfusion, BMC areas of responsibility may include transfusion policy; education and communication; review of blood use; haemovigilance; and monitoring, review and improvement of transfusion practice. Possible responsibilities under these areas are given below.

Transfusion policy

- Facilitation, development, implementation and review of local transfusion policies, and patient blood management guidelines and systems.
- Dissemination and implementation of national policies and guidelines, ensuring compliance with policy directives, circulars or legislative requirements.
- 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 patient blood management and blood transfusion activities, and continuing education for both staff and patients.
- Development of local educational and training materials, as required.

Review of blood use

- 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 (and 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 with established clinical practice guidelines.
- Monitoring of all aspects of the blood transfusion process.
- Promotion of patient blood management strategies, and evaluation of all patient blood management programs or strategies that are in place.

9.1.4 Additional resources on blood management or transfusion committees

Australian Red Cross Blood Service. Patient blood management committee handbook. May 2014.
<http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/702>

9.2 Staff education and training in transfusion

Several different groups of staff with various responsibilities are involved in the transfusion process. Training must be provided to all staff, including ancillary staff, involved in the transfusion process to ensure safe and appropriate transfusion practice. The training required will depend on 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 must be maintained and updated, with evidence of training and competency documented. Assessment of training should be undertaken in accordance with local and national guidelines such as ACSQHC National Safety and Quality Health Service Standard 7.

In Australia, BloodSafe eLearning Australia courses are the preferred education resource for transfusion practice and patient blood management, and are supported by all Australian governments, the Australian Red Cross Blood Service and ANZSBT. Similarly, in New Zealand, the BloodSafe eLearning Australia courses are recommended as a resource for transfusion medicine; these courses are incorporated in the NZBS resource folder. In addition, the NZBS eLearn module is available via the healthLearn (South Island Alliance) and Ko Awatea learning platforms. Staff training may be further assisted by provision of, and attendance at, local education sessions, and use of education resources from the Australian Red Cross Blood Service.

9.2.1 Additional resources on staff education and training in transfusion

Australian Red Cross Blood Service. Transfusion online learning. Available at <https://learn.transfusion.com.au/>

BloodSafe eLearning Australia. Transfusion practice and patient blood management education online. Available at <https://www.bloodsafelearning.org.au>

New Zealand Blood Service (NZBS). eResource. Available at <http://xtk.me/fs>

The Blood Matters Program and the University of Melbourne deliver a Specialist Certificate in Blood Management Foundations that builds to a Graduate Certificate in Transfusion Practice, which is endorsed by the International Society of Blood Transfusion Academic Standing Committee.

<https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/blood-matters/graduate-certificate-transfusion>

9.3 Sustaining clinical practice improvement

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

- development and implementation of local policies and procedures
- facilitation and monitoring of education
- facilitation and implementation of quality improvement and patient safety strategies, and monitoring and evaluation of these strategies
- facilitation, monitoring and evaluation of best practice for blood product management, and oversight of 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. These transfusion champions can assist with the development and implementation of policy and procedure, the education program and strategies, and they 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 must 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 refrigerators
- maintenance, monitoring and audit of compliance of remote blood refrigerators according to current national standards (e.g. AS3864)
- 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 (in Australia, see the National Blood Supply Contingency Plan; in New Zealand, it is the New Zealand Blood Service, in consultation with the local blood bank, that manages the movement of blood inventory in response to clinical urgency).

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 support the development of local policies for blood transfusion and education 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

Ancillary staff	Porters, orderlies and patient care assistants
Blood component	Red cells, platelets, fresh frozen plasma, cryoprecipitate, cryodepleted plasma, whole blood or granulocytes
Blood product	Used to describe all blood components and plasma derivatives
Blood Service	In Australia, the Australian Red Cross Blood Service and in New Zealand, the New Zealand Blood Service (NZBS)
Central venous access device (CVAD)	Devices such as a central venous catheter, peripherally inserted central catheter or implanted port
Cold chain	A temperature-controlled supply chain; a recorded, uninterrupted series of storage and distribution activities that 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, timeframe for viability of blood products, maintenance and monitoring of the facility or container
Critical bleeding event	Used to describe a situation where it is anticipated there will be major blood loss leading to significant (life-threatening) morbidity or mortality
Crossmatch	Test to assess compatibility between a blood component and the intended recipient
Crossmatch expiry	Crossmatched blood is valid until expiry of the pretransfusion specimen (local policy applies)
Double independent checking	<p>Clinicians individually and without requiring direct involvement of each other, check the prescription, patient and blood product identification, and blood product characteristics (including expiry, compatibility and special requirements (if any)).</p> <p>This process must ensure that each clinician is individually satisfied that, and responsible for, the correct product is transfused in the correct way to the correct patient. The clinicians must agree before the transfusion is commenced.</p> <p>In a teaching environment the teacher may indicate what needs to be checked and where to find it, but the learner must still independently view each item and confirm the match to the patient.</p>
Health service	Used in this document to refer to institutions where health care is provided; transfusion of blood products may occur across a range of settings including hospitals and day treatment centres
Health-care 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
Incorrect blood component transfused	A patient receives a blood component destined for someone else, or receives a component not to specification
Medical record number (MRN)	A number used to identify a patient (also referred to as a 'patient identification number')

Glossary

Medsafe	New Zealand agency responsible for the regulation of medicines and medical devices
National Health Index (NHI)	A unique number (known as the NHI number) assigned to every health-care user in New Zealand
National Safety and Quality Health Service Standards	An Australian national accreditation scheme for health service organisations
Patient	A person receiving health care; synonyms for 'patient' include consumer and client
Patient identification number	A number – for example, MRN, unit record number, hospital unit record number or NHI number – that is used to provide additional identification for a patient
Plasma derivatives	Plasma proteins fractionated from large pools of human plasma under pharmaceutical conditions; for example, 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's status and management contained within the patient's unique health-care record
Request	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
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
Therapeutic Goods Administration	Australia's regulatory authority for therapeutic goods including blood and tissues, medicines and medical devices
Transfusion	The administration of all blood and blood products, regardless of their route of administration
Transfusion service provider	The hospital laboratory or other pathology service which undertakes pretransfusion testing and supplies transfusion services and 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
Wrong blood in tube (WBIT) errors	Errors that occur where patient identification information (label and request form) belong to one patient but the blood in the tube belongs to another patient (see Dzik et al. 2003 and Jeffcott 2013)

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