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1. BACKGROUND

1.1. About this document

Blood management comprises the principles of Patient Blood Management (PBM), and the identification and management of risks related to transfusion practice and the supply of blood and blood products. Safe transfusion practice depends on the administration of quality blood products of the right type, for the right indication, in the right quantity or dose, via the right route, at the right time to the right patient.

This Policy consolidates:

- regulatory requirements for blood and blood products in Australia (see 1.3)
- Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products
- recognised clinical practice standards and guidelines, such as those published by the Australian Commission on Safety and Quality in Health Care (Australian Commission on Safety and Quality in Health Care), National Blood Authority and Australian Red Cross Lifeblood.

This Policy applies to NSW Health facilities that that offer services related to blood management and, is to be used to develop local detailed procedures and protocols.

This Policy provides clinicians, pathology providers, support personnel and health service managers with direction to ensure safety and quality in blood management related activities.

1.2. Key definitions

Blood Products	Includes fresh blood components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate and cryodepleted plasma) and plasma-derived (fractionated) blood products such as albumin, coagulation factors, immunoglobulins and recombinant products.
Cold Chain	The systematic process for safe storage and transportation of blood products so that they are always kept at the correct temperature from blood collection from a donor to administration of blood to a patient.
Haemovigilance	A set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up [1].
Health Care Record	Includes a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription

	records and medication charts for an episode of care. Health care records can be electronic, or paper based. Some patient transfusion related records may be held in departments such as Pathology.
Patient Blood Management	Medical and surgical strategies that aim to conserve and optimise the patient's own blood. It is an evidence-based practice that aims to improve clinical outcomes by reducing unnecessary exposure to transfusion of blood products. Patient Blood Management is underpinned by three pillars aiming to optimise blood volume and red cell mass; minimise blood loss and optimise the patient's tolerance of anaemia[2].
Fate	The ability to trace a blood product from the donor through to the final recipient/s or destruction, via accurate documented and/or electronically stored Lifeblood, laboratory and patient records.
Transfusion History	A list of transfusions a patient has had before presentation, including details of any adverse reactions to the transfusion and any special transfusion requirements. The completeness of the history will depend on the availability of information. It is expected that information will be obtained by reviewing any available referral information and interviewing the patient (and/or their carer).
Transfusion related activity	Transfusion related activity includes but is not limited to: • Prescribing and ordering • Obtaining patient blood samples • Obtaining patient consent for transfusion • Pre transfusion laboratory testing and product issue • Documentation • Storage • Handling of products • Transport • Administration • Monitoring and patient assessment.
Wrong blood in tube (WBIT)	An error that occurs where identification information (specimen labelling and request form) belongs to one patient but the blood in the tube belongs to another patient[3].

1.3. Regulation of blood and blood products

Blood, blood components and plasma derivatives are regulated under the Therapeutics Goods Act 1989[4].

The Human Tissues Act 1983 (NSW) [5] sets out the legislative requirements for the collection of blood from donors and the regulation of businesses supplying blood and blood products.

Under the National Blood Authority Act 2003[6], the National Blood Authority manages and coordinates arrangements for the supply of blood and blood products and services on behalf of the Australian Government and, state and territory governments.

Jurisdictional issues relating to the national blood supply, including planning, production, supply and budgeting are managed through the Jurisdictional Blood Committee (JBC). The Deputy Secretary, Population & Public Health represents NSW on the JBC[7].

2. GOVERNANCE

In NSW, the supply of blood, transfusion practice and patient blood management are governed by multiple stakeholders within NSW Health and national agencies.

The NSW Blood Management Governance Committee is the multiagency group that monitors and manages risks associated with blood and blood products in NSW.

The NSW Blood Management Clinical Advisory Committee is a multidisciplinary group which provides expert clinical advice and strategic direction for the clinical use of blood and blood products and patient blood management in NSW Health.

All public health facilities that undertake transfusion related activities must comply with NSW Health Policy Directive Australian Health Service Safety and Quality Accreditation Scheme in NSW Health facilities (PD2023_011)[8].

2.1. The Blood Management Committee

All public health facilities in NSW must have a formally constituted, multidisciplinary Blood Management Committee in place, or have access to a local health district or specialty health network blood management committee.

The Blood Management Committee is responsible for governing the blood management systems, and ensuring the appropriate, safe, efficient use of blood products in the health facility, local health district or specialty health network. The Committee will be responsible for the governance of safe storage, prescribing, supply, and administration of blood and blood products.

The Committee must include representation from: the health service executive; the pathology provider; medical; nursing and/or midwifery disciplines, with appropriate blood management expertise. The Australian New Zealand Society of Blood Transfusion (ANZSBT) Guidelines For The Administration of Blood Products provides further guidance on the membership, role and operation of Blood Management Committees.

Under facility procedures, the Committee will report to the Chief Executive of the public health organisation via a senior executive officer, such as the Director of Clinical Governance. The Committee must also report to the organisation's clinical quality committee (however named).

The Chief Executive must ensure each Blood Management Committee is established with appropriate terms of reference that include integrated governance systems to promote patient safety and quality blood management practices. The terms of reference are to clearly articulate organisational and individual accountabilities and, outline how that the committee's effectiveness is monitored.

The Committee will, among other duties, oversee the development and monitoring of blood management local policies and procedures, monitor wastage of blood and blood products, and escalate risks associated with transfusion related activities to the relevant clinical quality committee.

The Committee is to oversee local haemovigilance activities and if required, respond to the activation of the National Blood Supply Contingency Plan (See 2.6).

2.2. NSW Health Pathology

NSW Health Pathology is responsible for the provision of transfusion laboratory services for NSW Health. The NSW Health Policy Directive Accreditation of Pathology Laboratories in NSW Health (PD PD2017_011) or any subsequent versions, requires transfusion laboratory services to maintain accreditation under the National Pathology Accreditation Scheme.

The requirements of this policy apply to NSW Health Pathology and any other transfusion laboratory service providers used by NSW Health services.

The National Pathology Accreditation Advisory Council (NPAAC) Requirements for Transfusion Laboratory Practice (4th Ed) 2019, and any subsequent versions, apply to transfusion laboratories.

2.3. Australian Red Cross Lifeblood (Lifeblood)

Lifeblood is responsible for the collection, manufacture, and distribution of blood products to NSW.

Lifeblood provides 24-hour clinical advice and consultation on fresh components, plasma-derived products and recombinant products and on urgent clinical matters including significant transfusion reactions (see 3.6.2 for contact details and further advice about notification and management of transfusion reaction and incidents).

2.4. Education

Health workers involved in transfusion related activities must complete the relevant BloodSafe eLearning®. Clinical Transfusion Practice Course or module. See the Health Education and Training Mandatory Training Matrix and Targeting Guide for details.

Postgraduate Years 1 and 2 medical officers only, are to complete Clinical Transfusion Practice.

Health workers involved in non-clinical handling of blood products, such as hospital porters and orderlies, are to complete the separate Transporting Blood module only.

Health workers employed only to perform phlebotomy or venepuncture are to complete the separate Collecting Blood Specimens module only.

BloodSafe eLearning® courses are mandated for completion once only; Local Health Districts and Special Health Networks may determine any ongoing BloodSafe eLearning® course or other learning requirements to meet local needs.

2.5. Haemovigilance

Health services must have systems and processes in place to support the appropriate identification, management, notification, follow up, and documentation of all transfusion related incidents. These systems and processes are to ensure that incident reviews are sufficiently robust, to ensure compliance with the National Safety and Quality Health Service Blood Management Standard and facilitate compliance with the National Haemovigilance Program. Guidance for this process can be located on the CEC Blood Watch web page.

The NSW Clinical Excellence Commission, via the Blood Watch Program is responsible for collating and reporting haemovigilance activities in NSW for the National Haemovigilance Program.

2.6. National Blood Supply Contingency Plan

The National Blood Supply Contingency Plan (NBSCP) is overseen by the National Blood Authority to enable a rapid national response to supply threats[9]. In NSW, activation of the NBSCP will be communicated by the Chief Health Officer to NSW Health facilities.

3. CLINICAL BLOOD MANAGEMENT

3.1. Patient Blood Management (PBM)

The National Safety and Quality Health Service Blood Management Standard requires PBM strategies to be in place for patients facing a medical or surgical intervention who are at high risk of significant blood loss. Health services must have systems in place to support clinicians in their obligations to provide safe, efficient and appropriate use of blood products when clinically indicated.

The prescription and use of blood products are to comply with the current and any subsequent versions of:

- National Patient Blood Management Guidelines
- Lifeblood Component information
- Relevant Australian New Zealand Society of Blood Transfusion (ANZSBT) Guidelines:

Decisions on whether to prescribe blood products, and the dose or number of units to prescribe should consider: the presence or absence of proven benefit; risks associated with the use of blood products; and other treatment options, including appropriate management of reversible causes of deficiencies[10].

3.2. Emergency provision of Group O red blood cells

Health services must have systems in place that align with the National Statement for the Emergency Use Of Group O Red Blood Cells.

3.3. Consent

Health services providing blood and blood products must have procedures and processes in place to ensure clinicians are able to obtain and document informed consent for their use.

These procedures and processes must comply with the requirements for consent as outlined in the NSW Health Consent to Medical and Healthcare Treatment Manual (Consent Manual) including:

- the use of the relevant consent forms as described in the above Manual
- who can obtain consent
- the right to decline any proposed treatment

- patients who are unable to provide consent (including minors)
- emergency treatment.

When facilitating informed consent for the administration of blood products, the clinician is to address the reason for the blood products and discuss the risks and benefits of those blood products. The clinician is to discuss the availability of treatment options other than blood products as relevant to the patient's clinical condition.

Specific information related to consent for Rh (D) Immunoglobulin is outlined in NSW health Guideline Maternity - Rh (D) Immunoglobulin (Anti D) (GL2015_011).

Where patients decline blood products, clinicians must document this in the healthcare record. This documentation is to outline the blood products and associated procedures that are acceptable and unacceptable to the patient.

Information for patients on the use of blood products is available to support the consent process at:

- CEC Blood Watch Information for consumers page, including information in multiple languages, and information for children and parents
- Australian Red Cross Lifeblood Receiving a Transfusion: Informed Consent.

3.3.1. Long term consent for transfusion

Where treatment involves the administration of blood products over a period of time for the same clinical indication, it is not necessary to obtain consent for every transfusion episode [11]. Consent is to be obtained and documented as outlined in NSW Health Consent Manual. Further information is outlined in Section 4.10 of the NSW Health Consent Manual [11], including when a new consent form should be completed.

Requirements for long term consent should be described in health service procedural documents. For patients with long term transfusion requirements, reviewing and obtaining consent at regular intervals of at least 1 year (but no greater than 2 years) is considered best practice.

3.4. Patient identification

Health services are to have systems in place to ensure correct patient identification and procedure verification for transfusion-related activities. All procedures are to comply with NSW Policy Directive Patient Identification Bands (PD2021_033) and principles for patient identification and procedure matching as outlined in the NSW Health Policy Directive Clinical Procedure Safety or any subsequent versions.

Correct patient identification procedures from the collection of specimens, delivery to the clinical environment, to the transfusion of blood products, are vital to ensure that all patients receive the correct blood product, for the appropriate indication. Failure to correctly identify the patient at any stage can lead to serious adverse outcomes.

3.4.1. Pre-Transfusion testing and specimen labelling

Pre-transfusion specimen collection and specimen labelling requirements and related procedures must comply with:

- ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice or any subsequent versions
- NSW Health Pathology Policy Minimum Patient Identification requirements for Pre-Transfusion Testing NSWHP_PD_009 (or other accredited pathology provider policy and procedures,
- Principles for patient identification, and pre and post procedure matching for level 1 procedures, as outlined in the NSW Health Policy Directive Clinical Procedure Safety (PD2017_032) or any subsequent versions.

3.4.2. Collection and delivery to the clinical area

Health services must ensure patient identification procedures related to the collection of blood products comply with the requirements of ANZSBT Guidelines for the administration of blood products.

Health workers collecting blood products from the pathology laboratory must provide pathology staff with written documentation identifying the patient and the products to be collected[12].

Where blood products are collected from a remote blood fridge, health workers must take written documentation with them identifying the patient and the blood product to be collected[12].

The patient identifiers and blood product information on documentation used to collect blood products must match the blood product labelling.

3.4.3. Pre-transfusion checking procedure

Operational procedures must include a requirement for the administering and checking clinicians to undertake patient identity and blood product checks at the patient's side before administering the transfusion. Each health worker is responsible for the accuracy of these checks. The ANZSBT Guidelines for the administration of blood products provide detailed information about this check. Resources are available from BloodSafe eLearning Australia® to support health services.

3.5. Safe administration of blood products

Health services are to have systems and processes in place to support clinicians to safely administer blood products when clinically indicated[12]. See section 2.4 for the minimum education requirements.

The ANZSBT Guidelines for the Administration of Blood Products and, Lifeblood Component Information provide detailed guidance to support the safe administration of blood products. NSW Health facility procedures are to comply with these guidelines and any subsequent versions.

Policy Directive Intravascular Access Devices (IVAD) – Infection Prevention and Control (PD2019_040) provides guidance about selection of devices for peripheral cannulation.

3.5.1. Massive Haemorrhage Protocols (MHP)

Health services are to have systems and processes in place to ensure reliable implementation of agreed MHPs. This includes reliable communication strategies between clinical areas and the pathology laboratory, and prioritisation of staff and resources to ensure timely delivery of urgent blood products to the clinical area.

3.6. Transfusion-related incidents

A transfusion-related incident is an unplanned transfusion-related event that results in, or has the potential for: injury, damage or loss, including near misses such as WBIT [3,13].

Transfusion incidents may cause severe, potentially fatal complications including ABO Haemolytic Transfusion reaction (HTR), and Transfusion Associated Circulatory Overload (TACO).

Some transfusion incidents are classified as a transfusion reaction.

3.6.1. Transfusion reactions

Transfusion reactions are when patients experience an undesirable response associated with the use of blood products. Reactions can occur during the transfusion (acute transfusion reactions) or days to weeks later (delayed transfusion reactions) and may be immunologic or non-immunologic[14].

Health services must have systems in place to recognise and clinically respond to patients with a suspected transfusion reaction that align with state and local clinical emergency response systems.

These systems are to define when: a transfusion should be paused, recommenced or ceased; level of clinical emergency response required; and when escalation to further appropriate clinical consultation (e.g. Haematology and Lifeblood) is required or recommended. Information about when to notify the pathology provider and required transfusion reaction investigations is to be included in facility procedures. Resources for clinical management of transfusion reactions include:

- ANZSBT Guidelines for the Administration of blood products or any subsequent versions
- Lifeblood: Management of suspected reactions.

3.6.2. Recognition, management and notification of transfusion incidents

All health services providing transfusion therapy are to have systems in place for the recognition, management and notification of transfusion related incidents, including transfusion reactions. All NSW Health services must enter all incidents into the incident

management system[13] Recognition, management and notification must comply with NSW Health Policy Directive Incident Management (PD2020_047) or any subsequent versions.

Reviewing managers are to liaise with transfusion clinicians and teams where specialist advice is required. All transfusion related incidents to are to be tabled at the facility Blood Management Committee. Transfusion specific advice to support health workers managing transfusion related notifications in ims+ can be found on the CEC Blood Watch resources webpage.

A Haemolytic Transfusion Reaction (HTR) as a result of ABO (Blood Group) incompatibility, and causing serious harm or death, is an Australian Sentinel Event. This is a reportable incident requiring a Reportable Incident Brief (RIB).

Some types of transfusion reactions are to be reported to Lifeblood, as part of active haemovigilance strategies.

The following adverse events **must** be reported to the Lifeblood via the 24 hour customer service line: 1300 478 348:

- All suspected Transfusion Transmitted Infections (bacterial, viral, parasitic or other)
- All suspected Transfusion Related Acute Lung Injury reactions

See Appendix 1: Transfusion Reaction Reporting Flow Chart

Consider seeking advice from Lifeblood for the following transfusion reactions where expert advice and/or alternative component or product support may be required. These include:

- post transfusion purpura (PTP)
- transfusion associated graft-vs-host disease (TA-GVHD)
- severe allergic reactions
- immediate and delayed haemolytic and serological transfusion reactions
- reactions to plasma-derived recombinant products.
- reactions associated with the use of plasma derived blood products should also be reported to Lifeblood, and to the Australian Adverse Drug Reaction Reporting System.

3.7. Documentation and medical records

Health services must have in place processes for all models of documentation and management of health care records in compliance with NSW Health Policy Health Care Records – Documentation and Management (PD2012_069) or any subsequent versions.

3.7.1. Patient health care record

Documentation of transfusion related activity should be available to all clinical health workers and include:

- transfusion history (including previous complications) if available
- indication for the use of blood product
- consent

- prescription (all modes)
- blood product compatibility information or product batch number as applicable
- administration commencement and completion times
- patient observations and monitoring as applicable to the type of blood product
- outcome of the transfusion
- occurrence and management of any incidents or reactions.
- summary details on the discharge summary.

3.7.2. Laboratory

Transfusion laboratories must comply with the documentation requirements for blood products, immunohaematology specimens, and patient information as described in the ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice or any subsequent versions.

The fate of fresh blood products, either transfused, transferred or discarded, must be documented in the BloodNet Fate module. If discarded, the reason must be entered, as per the definitions provided.

3.8. Wastage

Health services are to have systems in place to minimise avoidable wastage of blood products. This is an expectation under the Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products.

While some level of discards is unavoidable and appropriate, the avoidable discarding of fresh blood products is considered wastage[15].

Further information to reduce wastage can be found on the National Blood Authority website Stop the Waste.

4. TRANSPORTATION AND STORAGE

Health services providing transfusion therapy must have procedures in place to ensure the safe storage and where relevant, transport of blood and blood products. The transport and storage of blood products must comply with the:

- National Pathology Accreditation Advisory Council (NPAAC) Requirements for Transfusion Laboratory Practice or any subsequent versions.
- Australia and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for Transfusion and Immunohaematology Laboratory Practice or any subsequent versions.

4.1. Transportation

Transport of blood products within and between facilities, including packing configurations and the use of validated shipping containers, is to comply with:

- Relevant NSW Health Pathology policy directives and procedures (or other accredited pathology provider policy and procedures).
- Lifeblood Shippers – Receipt and Use by External Institutions.

The processes for handling fresh blood products within hospitals are to consider environmental sustainability requirements. Facilities should undertake a risk assessment of the available options to transport single units or small quantities of blood products from laboratories to clinical areas that are consistent with best practice guidelines[16]. This risk assessment should specifically consider the frequency of incidents:

- Occurring in transit between the laboratory and the clinical area
- Of wastage or inappropriate storage related to transport options

4.2. Storage

Storage of blood products must comply with the Australian Standard AS 3864 – Medical Refrigeration Equipment – for the storage of blood and blood products; and relevant NSW Health Pathology policy or procedures outlining storage requirements of blood products (or other accredited pathology provider policy and procedures).

This includes:

- storage in dedicated fridges and/or freezers that are remote from a transfusion laboratory (satellite)
- storage in facilities without dedicated blood storage equipment, including the use of validated shipping containers for short term storage
- storage of blood products accompanying transferred patients
- storage of products for use by emergency retrieval teams.

Blood products delivered to a clinical environment, e.g. ward, operating theatre must be stored in accordance with this Policy Directive, or administered to the patient within the appropriate time frame as described in the ANZSBT Guidelines for Administration of Blood Products or any subsequent versions.

Guidance about the handling blood products in clinical isolation patient care areas can be found in Chapter 5 of the COVID-19 Infection Prevention and Control Manual.

A blood product must not be transfused, except at the discretion of the laboratory director, where it is:

- Stored at temperatures outside specified limits.
- Stored in non-conforming equipment.
- There is doubt regarding storage equipment.

5. REFERENCES

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16. Office of the Chief Health Officer (2022). Memo: Plastic bag ban and transporting blood products.

6. RELATED RESOURCES

- Clinical Excellence Commission – Blood Watch https://www.cec.health.nsw.gov.au/keep-patients-safe/blood-watch
- Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products https://www.blood.gov.au/system/files/documents/nba-stewardship-stewardship-statement.pdf
- National Blood Management Improvement Strategy 2018-2024 https://blood.gov.au/blood-product-management-improvement
- National Statement for the Emergency Use of Group O Red Blood Cells https://blood.gov.au/sites/default/files/National%20Statement%20for%20the%20Emergency%20Use%20of%20Group%20O%20Red%20Blood%20Cells_1.pdf
- BloodSafe eLearning Australia® https://bloodsafelearning.org.au
- NSW Health Pathology Positive Patient Identification for Collection of Pathology Specimens NSWHP_PR_092 file:///C:/Users/52802430/Downloads/NSWHP_PR_092%20-%20Positive%20Patient%20Identification%20for%20Collection%20of%20Pathology%20Specimens%20V2.0.pdf

7. APPENDIX

7.1. Transfusion Reaction Reporting Flow Chart

To be read in conjunction with section 3.6.2. Recognition, management and notification of transfusion incidents