



NATIONAL BLOOD AUTHORITY
AUSTRALIA

MANAGING BLOOD AND BLOOD PRODUCT INVENTORY

Guidelines for Australian Health Providers

> FEBRUARY 2014

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- > **Module 5 - Albumin (under development)**
- > **Module 6 - Intravenous and Subcutaneous Immunoglobulin (under development)**
- > **Module 7 - Hyperimmune Immunoglobulins (under development)**
- > **Module 8 - Clotting Factors (under development)**



7 February 2014

Ms J Cameron
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Dear Jo

NATA recognises that the National Blood Authority's Managing Blood and Blood Product Inventory guidelines is an important initiative which may help in ensuring a reduction in unnecessary wastage of blood and blood products.

NATA supports the National Blood Authority's initiative in producing these guidelines.

It is also recognised that the implementation of a blood and blood product transfer agreement between users could assist laboratories to enhance the availability of blood and blood products.

Yours sincerely

Andrew Griffin *(FIBMS, MSc, CSc)*
DEPUTY SECTOR MANAGER – LIFE SCIENCES

Managing Blood and Blood Product Inventory



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Introduction



The *National Blood Authority Act 2003* states that the National Blood Authority (NBA) is "to carry out national blood arrangements to ensure that there is a sufficient supply of blood products and services in all the States and covered Territories; and to carry out national blood arrangements relating to safety measures, quality measures, contingency measures and risk mitigation measures for the supply of blood products and services".

The *National Blood Agreement* requires that all parties identify opportunities to develop and implement strategies for the Australian blood sector, to:

- promote optimal safety and quality in the supply, management and use of products, including through uniform national standards; and
- make best use of available resources to give financial and performance accountability, by all entities involved in the Australian blood sector.

Australian Health Ministers have issued the "Statement on National Stewardship Expectations for the Supply of Blood and Blood Products" which states that health providers should have processes, programs and facilities in place that minimise wastage of blood and blood products and that national planning, management and governance are supported by:

- health providers having an ordering and receipt verification process in place which provides adequate financial accountability as required by governments; and

- inventory data is provided on a regular and timely basis to assist in supply and demand planning requirements especially in times of national shortages.¹

The National Safety and Quality Health Service (NSQHS) Standard 7, Blood and Blood Products, requires health service organisations to have 'systems to receive, store, transport and monitor wastage of blood and blood products safely and efficiently'.²

Many of the risks associated with receipt, storage, collection and transport of blood and blood products can be reduced. Systems and processes can be designed to address these risks. Systems for cold chain integrity, sample collection, cross-matching, product collection, and inventory management including storage, handling and transport should be monitored to identify and address weak spots.

These guidelines provide better practice processes that can be used by health providers to ensure these risks are mitigated and improvement opportunities are identified and implemented.

WHAT BLOOD AND BLOOD PRODUCTS ARE COVERED?

These guidelines are intended to cover the following products:

Fresh blood components and products

- Red blood cells
- Platelets
- Clinical fresh frozen plasma
- Cryoprecipitate
- Cryodepleted plasma
- Whole blood and other products such as autologous serum eye drops

Plasma & recombinant products

- Albumin
- Immunoglobulins, including immunoglobulin replacement therapy (e.g. IVIg)
- Hyperimmune globulins
- Clotting factors





Inventory Management Basics

> WHAT IS INVENTORY MANAGEMENT?

Good inventory management encompasses all the activities associated with ordering, storing, handling and issuing of blood and blood products to optimise efficiency.

Managing blood and blood product inventory is made up of two key factors:

1. **Product availability.** Planning of inventory levels held, timing of deliveries and order volume; and
2. **Product integrity.** Physical and process control of product in your facility, to ensure efficient and effective handling to maintain availability and minimise wastage.

Inventory management procedures, records and systems may vary significantly from one health provider to the next depending on the size and nature of the services provided. There is no single set of activities that will suit all health providers so you should examine which activities might work

to improve inventory management for you. An effective inventory manager understands how to make use of the data available in order to determine how each part of the supply chain affects their facility and how it could be improved on.

WHY IS INVENTORY MANAGEMENT IMPORTANT?

Good inventory management is vital for health providers holding blood and blood products to ensure appropriate utilisation of a precious resource. Not holding enough inventory can potentially put patients at risk or disrupt routine services. However, having too much inventory can deplete products held by the supplier to insufficient levels, increase the age of product at transfusion and increase wastage through increased expiry. By managing inventory efficiently, health providers will be aware of their usage patterns and can order blood and blood products accordingly.

- The National Stewardship Statement of Expectations¹ states that health providers play an important part in minimising wastage. The statement also requires that health providers have an ordering and receipting verification process (such as BloodNet) in order to provide adequate financial accountability as required by governments. These processes are also required by healthcare organisations under NSQHS *Standard 7 – Blood and Blood Products*².

SUPPLY CHAIN AND LOGISTICS

The term 'supply chain and logistics' describes the activities for supply and management of blood and blood products. Health providers can be involved in influencing many parts of the supply chain. This can be achieved through planning, implementing and controlling activities concerning:

- orders, deliveries and storage of products;
- stock movement and handling; and
- issue of blood and blood products to end users, including clinicians and patients.

Inventory management improvement activities can involve addressing the size, location, and number of deliveries, whether health providers supply to other health providers (hub and spoke type arrangements), as well as on-site storage arrangements and conditions for different products. It also involves addressing relationship issues among suppliers, distributors and end users (e.g. clinicians). This requires creating strong channels of communication with suppliers, distributors and end users so that important information gets through.

10 Tips to Help Manage Your Blood Product Inventory

> Blood products are a valuable perishable resource, sometimes scarce despite efforts to ensure a sustainable supply. Being able to use blood and blood products before they expire is desirable to maintain cost efficiency. Therefore, it makes sense to maintain an inventory of product that is at a level sufficient to meet requirements. Balancing this level with having sufficient product to meet clinical demand is often a challenge for health providers.

Blood and blood product inventory management is a trade-off between shortage and wastage. Practice has shown that there is a strong relationship between blood and blood product inventory levels and wastage³. Reducing the level of inventory usually results in less wastage, so understanding how to appropriately and efficiently manage your inventory is important.

These guidelines aim to provide health providers with 10 simple tips for better practices in inventory management that can be applied to all blood and blood products. Some health providers will find that it is not possible to adopt all

of these practices however you should use these guidelines to assess whether there is any room for improvement in your facility in any of the areas mentioned. More specific information around particular products, including advice on how to set inventory levels, is given in the modules relating to those products.



1 UNDERSTAND YOUR INVENTORY

Expert inventory managers understand and regularly monitor their inventory. This means they know and review patterns of inventory holdings, where inventory is held, trigger levels, delivery patterns, wastage rates, and usage rates. Understanding the patterns of all of these items will help plan requirements for improving the inventory management practices involved.

MONITORING INVENTORY PATTERNS

You should examine your current inventory practices to determine their efficiency. This involves looking at what your current inventory holdings are, as well as your usage and discard patterns, in conjunction with delivery and transport schedules. Ordering and delivery patterns should be examined to determine the best schedule to suit workflow requirements while maintaining cost effectiveness. The patterns may be reliant on the capacity to store products, the level of staffing, and the shelf life of product and demand patterns. For example, your facility may have

a large haemophilia clinic once per week and this may determine when the bulk of the clotting factor products are ordered and delivered.

You may need to determine what you think is a safe level of stock for each type of product, i.e. inventory levels should be sufficient to ensure blood components are available to maintain expected daily patient needs, but not so high that results in high rates of discard due to expiry. You should also have an understanding of how these inventory levels will work in periods of short supply. Monitoring the number of blood products ordered, transfused, transferred and discarded can provide information regarding your inventory management, and can provide a basis for planning ahead. You can use a variety of resources available to perform this monitoring such as:

- reports available in BloodNet at www.blood.gov.au
- reports available from suppliers
- reports you generate yourself from your Laboratory Information System and associated databases.



INVENTORY LOCATIONS

Managing blood and blood product inventory is made up of two key factors:

1. Product Availability: Planning of inventory levels held, timing of deliveries and order volume; and
2. Product Integrity: Physical and process control of product in your facility, to ensure efficient and effective handling to maintain availability and minimise wastage.

Inventory management procedures, records and systems may vary significantly from one health provider to the next depending on the size and nature of the services provided. There is no single set of activities that will suit all health providers so you should examine which activities might work to improve inventory management for them. An effective inventory manager understands how to make use of the data available in order to determine how each part of the supply chain affects them and how it could be improved on.

BloodNet Reports

Some BloodNet reports that might help monitor your inventory include:

- Issues (INV002)
- Inventory (INV001, 006, 007 & 008)
- Discard (Fate 001, 002 & 007)
- Transfers (Fate 003 & 004)
- Fresh Blood Orders & Issues (FUL010e)

CHECKLIST FOR INVENTORY MANAGEMENT BEST PRACTICE

ACTIVITY	✓
Do you have a set time for placing orders?	<input type="checkbox"/>
Do you do an inventory count before placing orders?	<input type="checkbox"/>
Do you return unused reserved product to inventory before counting?	<input type="checkbox"/>
Do you receipt product into BloodNet / LIS within one hour of receipt?	<input type="checkbox"/>
Do you maintain and monitor blood product refrigerators according to guidelines?	<input type="checkbox"/>
Do you have Standard Operating Procedures that cover inventory management?	<input type="checkbox"/>
Do you have a training protocol that covers inventory management?	<input type="checkbox"/>
Do you have policies that cover movement of product between facilities?	<input type="checkbox"/>
Do you have policies that cover movement of product to ward areas?	<input type="checkbox"/>
Do you monitor and report on your discard rates to a governing body?	<input type="checkbox"/>
Do you monitor and report on your usage rates to a governing body?	<input type="checkbox"/>
Do you monitor and report on your transfer rates to a governing body?	<input type="checkbox"/>
Do you maintain up to date and accurate records?	<input type="checkbox"/>
Do you regularly review your inventory requirements?	<input type="checkbox"/>
Are your procedures simple enough for everyone involved to understand?	<input type="checkbox"/>
Do you regularly communicate with others outside your area who are involved in supply, handling and use of blood and blood products?	<input type="checkbox"/>
Are you able to inform others about better practice processes?	<input type="checkbox"/>
Do you use Electronic Crossmatching where possible?	<input type="checkbox"/>
Do you utilise a Group and Screen or Maximum Blood Ordering Schedule where possible?	<input type="checkbox"/>
Do you have short reservation periods where possible?	<input type="checkbox"/>
Do you sort your inventory to allow oldest product to be used first?	<input type="checkbox"/>
Do you have contingency plans?	<input type="checkbox"/>
Are your contingency plans linked to your state or territory health emergency plan?	<input type="checkbox"/>
Do you have a patient blood management program?	<input type="checkbox"/>

2 PROVIDE EXPERT TRAINING

Research has shown that having staff that are well trained can have an overall positive effect on inventory management and reducing wastage⁴. You should ensure that all staff involved in the handling of blood and blood products participate in a well-designed training program. Staff should learn the importance of inventory management and be instructed on how their decisions impact the supply chain.

Tools

The National Blood Authority is developing some tools to assist in designing your training and will make them available on www.blood.gov.au

Performing procedures in a consistent manner is important, along with having training protocols and procedures that ensure that only experienced personnel provide direction to new starters. Standard Operating Procedures (SOPs) should be easy to follow and clearly outline required tasks and processes, to minimise inconsistencies amongst staff.

Staff should be aware of the impact of inadequate storage and handling, as well as the implications of wasting blood. You can avoid putting patients at risk by assuring product integrity. Wasted product not only has financial implications, but can also mean less product is available where required, potentially resulting in an adverse clinical outcome.

Training should be provided, not only for laboratory staff, but for all staff in the organisation that order or use blood and blood products. The organisation's Medical Officer induction program should include a session on blood use, including prescribing, ordering and use of blood and blood products. This has been shown to bring about a significant reduction in the stock required to be held on site³.



3 SET APPROPRIATE INVENTORY LEVELS

Each health provider is responsible for setting their own inventory levels and ensuring these are appropriate. There is a strong relationship between inventory levels and wastage. Hospitals and laboratories that hold more blood and blood products relative to their average daily use often have high wastage rates. The key to good inventory management is balancing sufficient inventory to meet clinical need while keeping wastage rates at a minimum.

Specific advice and guidance on how to set inventory levels for each different product, ie red cells, platelets, plasma and manufactured and recombinant products will be found in the specific modules relating to those products. The following are important factors that may influence decisions on inventory levels:

- **Type of health provider.** Hospitals and blood banks that have an emergency or obstetrics department can sometimes need a large volume of product available in a short time. If your hospital has this type of service you may like to set a higher minimum or trigger level of product, as restocking during an emergency may not always be possible.
- **Daily usage rates.** You can examine your average daily use by using the Fresh Blood Orders and Issues report found in the Inventory Report section in BloodNet. You should also examine your Days Cover relative to your usage (see below).
- **Supply patterns (product received from suppliers or other health providers).** You should consider all product entering your inventory. Product may be received either from the supplier or transferred from another health provider. The pattern of this may be consistent or may vary, and this can have an effect on your ordering patterns
- **Distance from supplier (leadtime).** You may need to consider how far away your hospital or blood bank is from the Australian Red Cross Blood Service (Blood Service) or other supplier depot as this will have an effect on how quickly you will be able to re-stock once you reach your minimum level. If you are a long way from the Blood Service or other supplier depot you may like to set a higher minimum level. Refer to the BloodNet user manual for definitions of different order types and priorities. User manuals and tip sheets can be found at www.blood.gov.au/bloodnet

Variability

It can be helpful to look at the degree of variability by blood type or product. If the variability is high, then you may consider holding more inventory. If the variability is relatively low, then you will not need to hold as much.

- **Frequency of deliveries.** Hospitals or laboratories that get few deliveries may need to set higher target levels than those that are restocked more frequently.
- **Transfer patterns.** Hospitals and laboratories that transfer product back and forth need to carefully examine the effects this has on inventory. For example, product may be able to be transferred to another health provider to enable it to be used before expiry, but should be transferred with sufficient expiry to ensure it is used. Arrangements should be in place with these laboratories to ensure this process is appropriate.
- **Your discards as a percentage of issues (DAPI).** If your discard rates are high, you may need to consider whether holding less stock is appropriate.

Balancing Costs

Each health provider should consider whether the level of inventory holdings will balance costs in relation to the level of discards and the number of deliveries

DAY'S COVER

Day's Cover is the number of days of available stock that is held in inventory for a particular product. It can be calculated by dividing the number of available product units in inventory by the number of product units used (on average) per day over a given time period. It is generally recommended that you look at a time period that will be representative of current practice to determine this. For example, if your hospital has added a new surgical unit you may want to look at the time period since the unit was set up to determine the usage.

$$\text{Day's Cover} = a \div b$$

Where

a = Number of available units in stock

b = Average daily use = number of units used over a one year period \div 365 (or you may like to use a different denominator if your facility doesn't use blood and blood products every day of the week)⁴

This can be done for each type of product individually. For example:

11,000 units of red cells ordered over a 12 month period = $11000 \div 365 = 30$ units per day

Number of available units in stock = 180

Days cover = $180 \div 30 = 6$

This can be described as a health provider holding a stock of 180 units having about 6 day's cover.

The ideal inventory level in terms of day's cover may differ for each product type and type of health provider. However a good inventory manager will base the levels on experience and will allow for small changes over time to adapt to any practice changes at your facility.

If you use BloodNet you can calculate your day's cover for each fresh blood product using the Fresh Blood Orders and Issues Reports found in the Inventory Report section. You may like to set a minimum trigger level to alert you when product is getting low, and have well documented actions to take in these circumstances.

Issuable Stock Index (ISI)

Day's cover can also be referred to as the Issuable Stock Index or ISI, a term used internationally.

DISCARDS AS A PERCENTAGE OF ISSUES (DAPI)

Discard as a Percentage of Issues (DAPI) is a good way to make your discard data comparable with other health providers. You should use the FATE007 Fresh Component Health Provider Discards Report in BloodNet to compare your facility to those of a similar size nationally in the group category and against those in your state. This will allow you to benchmark your discards against others which is now occurring on a jurisdictional and national level.

A certain level of discards of blood and blood products, particularly fresh products with short expiry dates is both inevitable and appropriate to ensure that products are available where and when they are clinically necessary. However, there is a proportion of discards of blood and blood products that is neither inevitable nor appropriate and is this is termed wastage. Total discards are reported in BloodNet.

DAPI is calculated by taking the amount of blood and blood product units discarded in a given time period and dividing this by the total amount of blood and blood product units received by your facility in the same time period and multiplying this figure by 100 to give a percentage value.

$$\text{DAPI} = \frac{x}{y} \times 100\%$$

Where

x = Number of units discarded

For example:

50 Albumin units wasted over 12 months and 5,000 Albumin units issued to your facility over 12 months

$$\text{DAPI} = 50 \div 5000 \times 100\% = 1\%$$

Wastage as a Percentage of Issues (WAPI)

If you are comparing your results with international data, DAPI is frequently referred to as 'Wastage as a Percentage of Issues' (WAPI) internationally.

y = Number of units issued to you

If you use BloodNet you can examine your discard patterns using BloodNet reports. Not all health providers will be able to limit discards to the same level. You should examine your own practice for each product and assess whether there is any room for improvement. Recording the reason for discard of a product is important for monitoring purposes. Monitoring trends of wastage will help identify those areas for improvement.

More information on discards, and strategies for reducing wastage can be found at www.blood.gov.au/wastage.

4 KEEP PROCEDURES SIMPLE

Making procedures too complicated can discourage people from performing them properly⁴. Hospital and laboratory staff are usually very busy, therefore simple procedures and/or checklists work best for maintaining effective inventory management.

One example of where a simple procedure might help is the laboratory stock count procedures. Sometimes performing a physical count of stock may give a more accurate picture of inventory levels if electronic records are organised in a complicated manner. Setting trigger ordering levels can prevent staff from placing unnecessary orders and therefore having excess inventory.

Simple planning may also help with inventory management. If possible, ask clinicians to provide you with details of product requirements in advance. Provide them with a simple procedure for informing the lab of requirements. You may like to order your product requirements in line with these requests plus only a small amount for unforeseen usage.

Platelet Requests

Asking clinicians to plan ahead can be particularly helpful in planning platelet inventory where the shelf life is short.





5 BUILD COLLABORATIVE RELATIONSHIPS

Having good relationships with all people involved in the supply, handling and use of blood and blood products can help with managing inventory. You should encourage clinicians to understand the inventory and ordering process to minimise the number of unnecessary orders that could lead to product unavailability. Explain to clinicians who are requesting blood and blood products the requirements and time frames needed when ordering product.

Collaborate

Good relationships with those outside your facility such as other health providers and suppliers can also help when transferring or ordering product. If you order for, or from, another health provider you should ensure they understand inventory management best practice.

Clinicians often turn to laboratory staff for advice when ordering blood and blood products. You should help raise awareness around patient blood management (refer to tip 10 below) and appropriate use by referring clinicians to local policies as well as national guidelines found at www.blood.gov.au/patientbloodmanagement.

6 USE OLDEST PRODUCT FIRST

Where appropriate, when products are received they should be sorted to allow them to be used on an oldest-product-first-out basis. This is particularly important for those products with a short shelf life such as platelets or thawed FFP, or when receiving products that may have been transferred to you from another health provider.

If you believe product may be stored for an extended period of time with a lower likelihood of being used, for example reserve emergency stock in a remote location within your facility, it may be better to choose fresher product but rotate it more regularly back into general inventory, to enable it to be used before expiry. Product should have adequate shelf life left before expiry when moved from reserved or remote locations back to general inventory. You should have documented arrangements for ensuring this occurs on a regular basis.

Options to consider if product is getting close to expiry might include transferring to another hospital or laboratory, rotating segregated inventories where possible and highlighting to others that product is soon to expire. One example may be to make up a sign for the fridge that clearly identifies stock with short expiry, enabling it to be the first selected for issue.

Special Circumstances

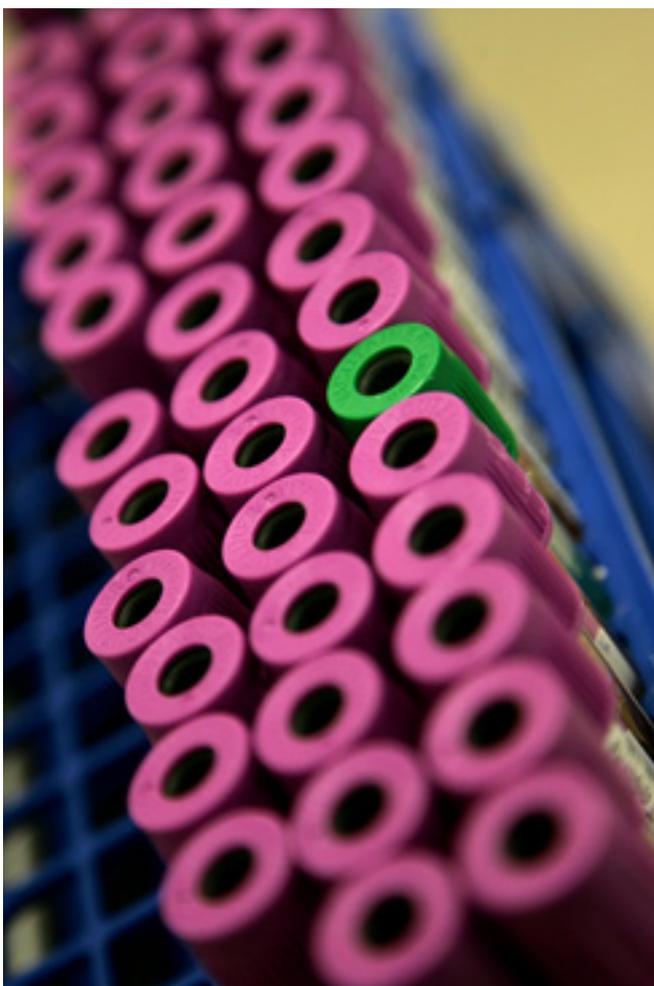
There are some special clinical circumstances where it may not be appropriate to use the oldest blood first (e.g Neonatal exchange transfusions). Hospitals should have a policy that describes the limited clinical situations where use of the oldest blood first may not be appropriate.

ATTENTION:

**Product at the front of this shelf is soon to expire.
Please use first!**

7 OPTIMISE CROSSMATCHING PROCEDURES

You should avoid reserving product, by crossmatch or otherwise, for a specific patient where the likelihood of use is uncertain. Each time blood and blood products are reserved for a patient, this product is effectively removed from 'available' inventory. This can create an artificial shortage and can cause unnecessary replacement orders.



Electronic Crossmatching

Where possible your laboratory should consider Electronic Crossmatching procedures. These procedures work well with Group and Screen policies, helping to maximise product in available inventory.

Laboratories should encourage using "Group and Screen" or "Maximum Blood Order Schedule (MBOS)" policies for red cell orders in patients without clinically significant red cell antibodies. Ideally a MBOS should be developed specifically for your hospital to give clinicians an idea of what the appropriate ordering patterns for blood and blood products are. One example of a "Maximum Surgical Blood Order Schedule (MSBOS)" can be found in Frank et al (2013)⁵.

Where blood and blood products have been reserved for specific patients, consider short reservation periods to enable product to be moved back to general inventory if not used.

8 MAINTAIN ALL EQUIPMENT APPROPRIATELY

All equipment used for the storage, transportation and handling of blood and blood products, such as transport containers, refrigerators, freezers and plasma thawers should be maintained and monitored in accordance with relevant standards and guidelines.

These are:

- AS3864.2 2012 – Medical Refrigeration Equipment - For the storage of blood and blood products⁶
- NPAAC Requirements for Transfusion Laboratory Practice⁷
- ANZSBT guidelines for Pretransfusion Laboratory Practice⁵

You should have a back-up plan for refrigerator failure, and be able to provide documented procedures to other hospital staff as to the correct storage and handling procedures for blood and blood products in these circumstances. Any remote refrigerators such as those at remote sites, emergency areas and other associated off-site facilities should also be maintained appropriately. Discarding product due to equipment failure can be avoided by following proper maintenance schedules and being prepared for unforeseen failures.

Remote Refrigerators

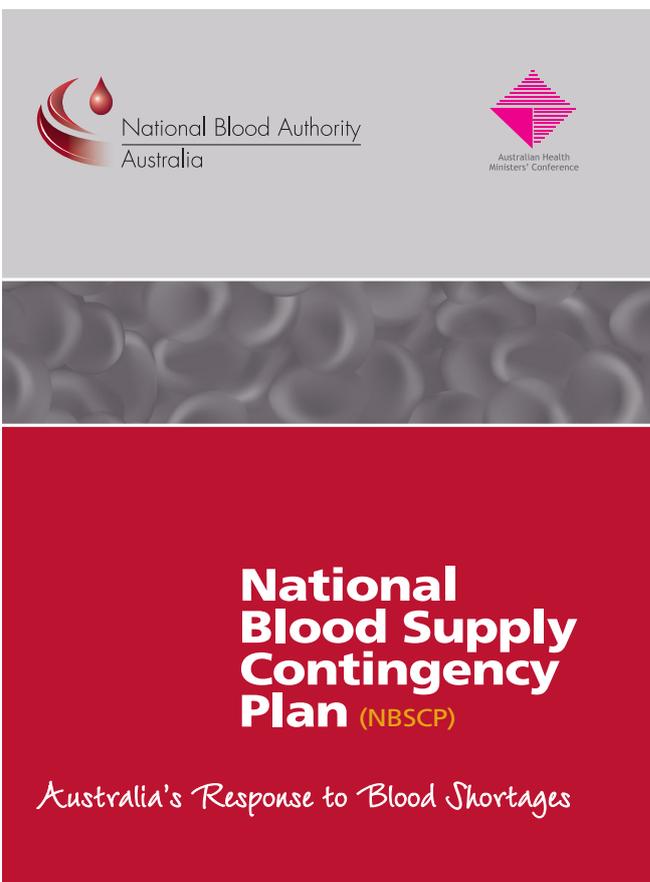
AS 3864.2 2012⁶ states "The organisation which owns the medical refrigeration equipment used to store blood and blood products is responsible for ensuring that it is properly managed in accordance with the Standard and other regulatory requirements".

9 HAVE A PLAN TO CONSERVE INVENTORY IN TIMES OF SHORTAGE

Where inventory levels are running low, (either within your organisation or more widespread) you should have a plan for what to do to conserve product. You should develop local policies concerning the management of contingency events. These policies can cover shortages ranging from a small short-term shortage of a particular product to much more widespread shortages.

Communication

You should communicate shortages in supply to clinicians ordering the product. You may be able to ask them to consider the patient's immediate requirements and whether the product could be ordered at a later date, when product becomes more available.



In times of more widespread shortage, your state or territory health department will have a contingency plan that you can adapt to fit your setting, and this should involve identifying key personnel to be responsible for communicating any shortages to those affected.

You should also be familiar with the National Blood Supply Contingency Plan⁸ found at www.blood.gov.au.

10 HAVE A PATIENT BLOOD MANAGEMENT PROGRAM

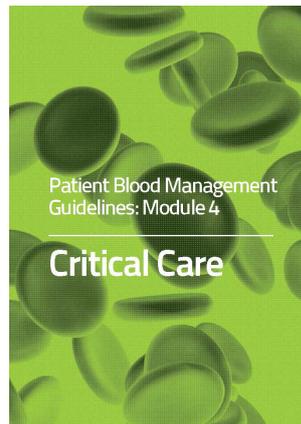
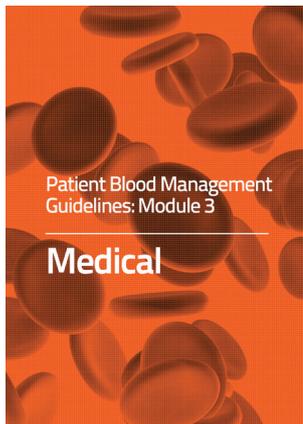
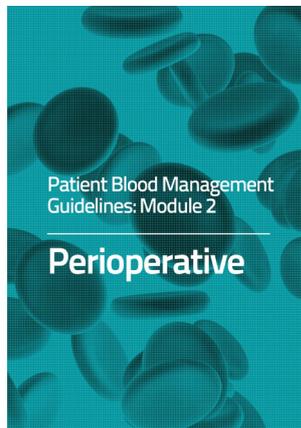
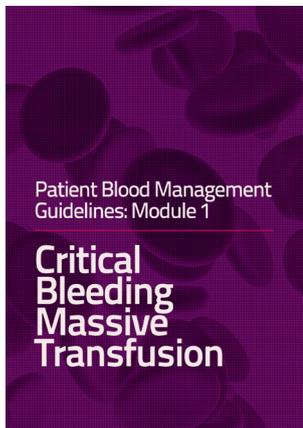
One of the best ways to conserve blood and blood products is to avoid its use. Before the decision to transfuse is made, all of the alternatives, risks and benefits should be considered as there may be another, more appropriate product or treatment that can be used.

You should have an organisation-wide patient blood management program. This program should aim to manage and preserve the patient's own blood to reduce or avoid the need for a blood transfusion. The program is a way to link clinical areas across a health provider such as medical officers, transfusion nurses and laboratory staff to ensure the most appropriate use of blood and blood products.

Finding the Guidelines

The NHMRC endorsed Patient Blood Management Guidelines⁹ can be found on the NBA website www.blood.gov.au

The iPad app is also available from the Apple App Store.



Implementation

Now that you have been provided with these 10 steps to improving inventory management practice, how do you start to make any changes to improve current practice?

- Read the modules on specific product types to get some further help with things you can do to improve inventory management and learn how to calculate recommended stock levels.
- Talk to other health providers that you know may be performing well, and have reduced their wastage rates, as they may be able to share some other better practice ideas with you.
- Establish champion networks to promote good inventory management practice.

Tools to help implement better practice inventory management are being developed by the National Blood Authority and will be found at www.blood.gov.au when available.

Contact the NBA for advice on support@blood.gov.au or call 13 000 BLOOD (13 000 25663).



NATIONAL BLOOD AUTHORITY
AUSTRALIA

MODULE 1: MANAGING BLOOD AND BLOOD PRODUCT TRANSFERS

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Scope

This document provides guidance to health providers on better practice in transfers of blood and blood products around Australia.

Additionally it offers tools that health providers can use to comply with relevant standards and accreditation.

Introduction

Under the National Blood Agreement all Governments are committed to providing an adequate, safe, secure and affordable supply of blood products, services and promoting high quality management of blood products.

This module for Blood and Blood Product Transfers aims to assist health providers in meeting the requirement of the Statement on National Stewardship Expectations for the Supply of Blood and Blood Products.¹ This module will assist health providers to develop a guideline or Memorandum of Understanding (MOU) to facilitate blood and blood product transfer arrangements between providers.

The intention is for this guideline to:

- Help identify transfer options for blood and blood products between health providers, including between public and private.
- Outline how to ensure that acceptable temperature ranges for blood and blood products are maintained during transportation.
- Outline how health providers can ensure blood has been stored and transported correctly before accepting a transfer.
- Provide a uniform process for transferring blood and blood products.
- Foster a culture throughout the blood sector that strives to transfuse all units before expiry, noting that some discards are appropriate but not inevitable.

The term health provider in this document refers to an organisation providing health services to the Australian community and approved by the NBA to receive blood and/or blood products through the NBA supply contracts.

This guideline covers blood and blood products as outlined in the National Safety and Quality Health Service (NSQHS) Standard 7, Blood and Blood Products Standard², including:

Fresh blood components	Plasma-derivatives and recombinant products
<ul style="list-style-type: none">▪ red blood cells▪ platelets▪ clinical fresh frozen plasma▪ cryoprecipitate▪ cryodepleted plasma	<ul style="list-style-type: none">▪ albumin▪ immunoglobulins, including immunoglobulin replacement therapy (e.g. IVIg) and hyperimmune globulins▪ clotting factors.

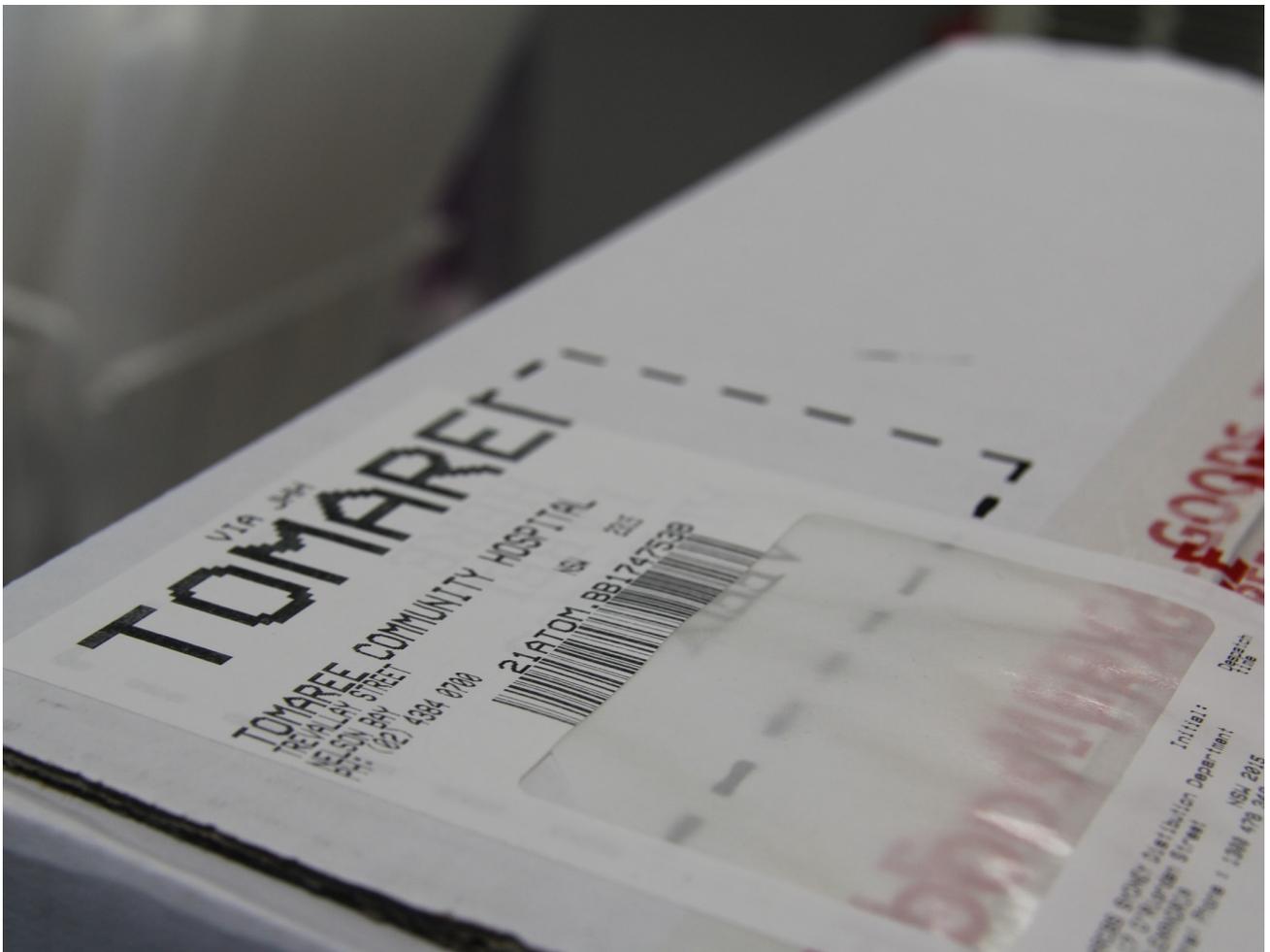
Preparation

WHY SET UP A TRANSFER NETWORK?

All health providers are required to identify and develop processes that maximise the appropriate use and minimise the wastage of blood and blood products in line with the statement on *National Stewardship Expectations for the Supply of Blood and Blood Products*¹ issued by the Australian Health Ministers.

Implementing a blood and blood product transfer agreement can assist laboratories to:

- enhance the availability of blood and blood product
- manage a limited resource
- reduce unnecessary wastage by transferring blood and blood product to a health provider where it is more likely to be used appropriately.



WHAT DO YOU NEED TO CONSIDER?

IDENTIFY POSSIBLE PARTICIPATING TRANSFER HEALTH PROVIDERS

Consider the following factors:

- Other health providers with whom you could set up a transfer arrangement. This could include the following:
 - health providers you currently have informal arrangements with;
 - health providers located in your local area that you can approach to set up a transfer arrangement;
 - health providers within your organisation located in other suburbs or health networks.
- A larger laboratory or health provider that you could transfer your product to, to enhance the possibility of its use before expiry.
 - Larger health providers service a varied patient group and are more likely to utilise a range of products before expiry.
- If you are a large laboratory or health provider consider receiving transfers from smaller facilities to enhance the possibility product is used before expiry.
 - As a large laboratory or health provider you are more likely to utilise a product before expiry. You could consider reducing your usual order depending on the amount of product you are aware will be transferred in.
 - You will need to continually consider the impact on your inventory levels and whether or not you can use the transferred product.
- If you are a smaller laboratory consider reviewing your current inventory if frequent transfers are required.
- If you have an established hub and spoke arrangement consider including other health providers outside these arrangements or your organisation.
 - For example, a public local health network hub and spoke could include smaller private health providers in the local area.
 - Alternatively, you could consider becoming a hub if you are a large laboratory with a high blood and blood product turnover. This will allow you to manage your own inventory and that of smaller regional facilities with a low turnover. In turn, smaller sites can operate with a lower inventory and still maximise blood use before expiry.
- The proximity of the other health providers to your site.

- Proximity will factor into transport or courier costs and have an effect on validated shipper configuration requirements. Data loggers are currently recommended for all shipments beyond the Blood Service validated transport times when using their shippers.¹⁰
- Great distance does not mean a transfer arrangement is not possible. A number of local health networks have transfer or hub and spoke arrangements between a large metropolitan laboratory and smaller regional and remote sites. Examples include Hunter Area Pathology Service in NSW, BloodMove South Australia and Pathology Queensland. For more information see the NBA website at www.blood.gov.au/case-studies.
- Transfer arrangement between public and private health providers.
 - Transfer arrangements can work with health providers from different organisations, local health networks, pathology organisations and across the public and private health sectors. BloodMove in South Australia is an example where there is a formal arrangement to transfer blood and blood product between public and private health providers.
 - Public health providers who work with a devolved blood budget may wish to discuss the impact of a transfer agreement with the relevant manager of blood budgets within their jurisdiction.
 - Suitable options could include exchange of supply with short for long expiry and using existing courier networks. Any issues that may arise with these (or any other proposed options) should be considered, agreed and documented by all parties.
 - Transfers between National Association of Testing Authorities (NATA) accredited health providers with blood fridges that are compliant with *AS3864 Medical refrigeration equipment – For the storage of blood and blood products*⁶ are relatively easy to set up and should provide assurance that blood and blood products are maintained within manufacturer's temperature specifications.

ACCREDITATION

Participating health providers are responsible for maintaining the necessary accreditation, standards and legislation (for example as outlined by NATA or Standard 7). This should provide assurance to receiving health providers that any transferred blood and blood products they receive have been stored appropriately. Include a point in your MOU outlining responsibilities of all parties if accreditation requirements are not met.

REVIEW INVENTORY MANAGEMENT PRACTICE AT PARTICIPATING PROVIDERS

It is recommended that health providers review the current inventory management practice with each product at each laboratory or site participating in the MOU. 10 Tips to Help Manage Your Blood Product Inventory located within *Managing Blood and Blood Product Inventory* can provide practical advice to appropriately manage blood and blood product inventory.

REVIEW TRANSPORT OPTIONS AND PRACTICES AT PARTICIPATING HEALTH PROVIDERS

Review existing blood courier system

Determine if there is an existing courier service you could utilise. If so, investigate the cost to use this service. If not, investigate courier or taxi options and discuss with management to determine the division of costs.

When taking transport into consideration a cost benefit analysis can be undertaken to understand the workload and financial cost of transferring blood and blood products in and out versus the financial cost and loss of a valuable resource. If the cost of transport outweighs the cost of the blood product/s then it may not be feasible to develop regular transfer arrangements in exceptional circumstances.



All signatories on the MOU may invest in a transport option to reduce costs. Examples of transport options include:

- using an existing health provider courier service;
- engaging hire cars, buses or taxis;
- investigating a courier service that specialises in cold product transfer. This may be especially useful for longer distances and flights.

You may consider entering into a Service Level Agreement with your chosen courier company.

Review existing shipping configuration for the transfer of blood and blood products

In accordance with the National Pathology Accreditation Advisory Council blood and blood products must be transported in validated shipping containers.⁷ It is important to review what shipping configurations and containers, if any, are currently in use with each health provider participating in the MOU. More information on packing and transport shippers can be found under Packing Requirements, section below.

See *Appendix 1: Transfer arrangement checklist* for a summary of items to consider when setting up formal transfer arrangements.

See *Appendix 2: Example Validation Process* for an outline of a possible shipper configuration and validation process.



Implementation

REQUIREMENTS FOR PACKING AND TRANSPORT

Health providers should agree to a validated method for packing and transporting blood and blood products and document in an MOU.

HANDLING OF BLOOD AND BLOOD PRODUCT

Care must be taken when handling blood and blood products. In particular the following steps should be completed:

- minimal physical handling of all blood and blood products must be practiced to ensure those products are kept within their recommended temperature ranges;
- ensure that when you are handling any red blood cell product that it is not exposed to temperatures outside refrigeration specifications for longer than 30 minutes;
- ensure that when you are handling any frozen blood products outside storage conditions that it is kept on dry ice or frozen ballast within a container to prevent temperature changes;
- the blood and blood product bag and/or packaging integrity must be inspected before sending to another health provider;
- management of out of specification consignments to be included in the MOU.

PACKING REQUIREMENTS

Blood and blood products must be packed for transport in accordance with the validated specifications agreed to between participating health providers.^{7,11} If packing materials such as dry ice are used it is recommended that relevant policies and procedures are developed and appropriate training is provided for staff.¹²

When choosing validated packing methods, you may like to consider implementing existing validated shipper configurations. For example an existing validated blood and blood product packing configuration and transport times is detailed in Australian Red Cross Blood Service *Receipt and Use of Blood Service Shippers by External Institutions to Transport Blood and Blood Products*¹⁰ and *Transportation of blood components and fractionated products*¹³. The Blood Service recommend the use of data loggers outside their *validated transport times*¹⁴ with specific packing configurations.

You may wish to validate your own shipper configurations or the shippers and packing configurations used by the Blood Service for extended time frames. Principles and guidelines on validation can be found in the National Association of Testing Authorities *Guidelines for the validation and verification of quantitative and qualitative test methods*.¹⁵ An example of one method of shipper validation is located at [Appendix 2](#). Validation data must be documented, reproducible and available to NATA on request.

Consideration of the ambient temperature is important when transporting blood and blood products.¹⁶ There are vast temperature differences across Australia that can affect transport shipper validation times and ensuring blood and blood products remain within manufacturer's temperature specifications.

It is important to consider all temperature conditions and length of time that may be experienced by the blood or blood product you are packing and transporting. Think about where your blood or blood product is being transferred to and all the environments the shipper may experience. The validation process must be repeated for all possible temperatures the blood and blood product may be exposed to during its transport. Some examples of items to consider when transferring blood and blood product include:

- If the product is going by plane:
 - the cargo hold might not be heated resulting in very low temperatures
 - the items might be held in air conditioned storage before or after the flight
 - the items might be left on the tarmac for some time in extreme hot or cold temperatures.



- If the product is travelling by road:
 - it may travel long distances on a truck that could experience extremes of hot or cold temperatures
 - it might be left on a loading dock for an extended period of time before arriving at the storage site.

Consider conducting initial and ongoing seasonal courier temperature audits and ad hoc quality assurance audits as required. If you are transporting blood or blood product outside of a validated timeframe or condition you must ensure manufacturers' temperature specifications are met.¹¹ Where a validated shipper has a minimum number of packs specified, ballast must be used to ensure minimum numbers are maintained.

TRANSPORT REQUIREMENTS

Blood and blood products must be transported at the temperature range specified in Table 1.

*Table 1: Transport temperature manufacturer's requirements**

Product	Transport temperature range	Comments
Red blood cells [#]	2-10°C	All blood refrigerators, including theatre and other holding refrigerators, must comply with current AS3864
Fresh frozen plasma, cryoprecipitate, cryodepleted plasma [#]	At or below -25°C	Plasma freezers must comply with current AS3864
Platelets [#]	20-24°C	Discontinuation of agitation of platelets during transportation should not exceed 24 hours
Manufactured Products		See relevant manufacturer's Product Information Leaflet.

[#]Adapted from the Australian Red Cross Blood Service (2012). *Blood Component Information, circular of information*¹⁷

It is recommended that a temperature data logger, or other temperature monitoring device, is utilised in the transport of all blood and blood products. Various temperature monitoring devices are available on the market.

TRANSFER PROCEDURE OUTLINE

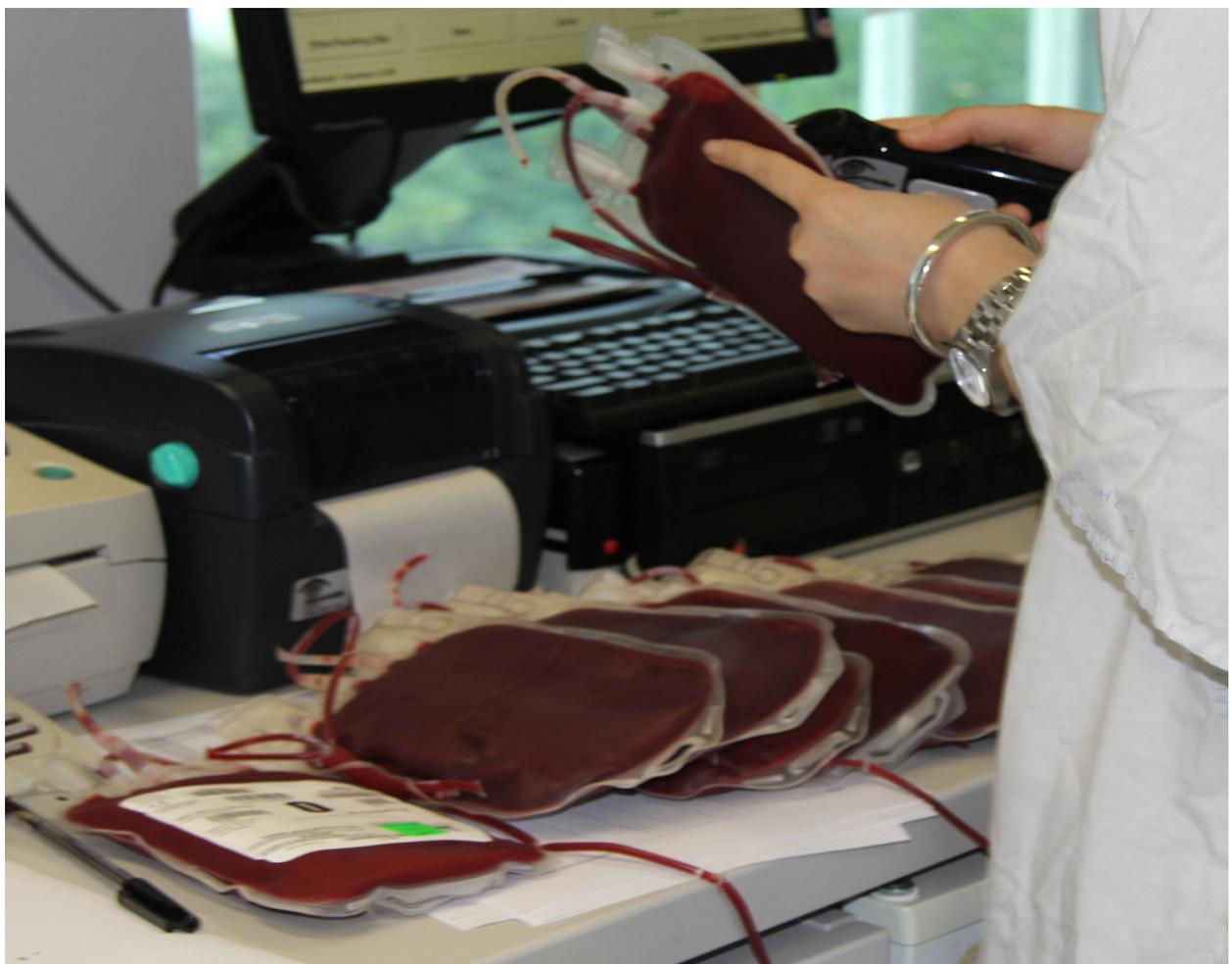
There are a number of elements to consider when transferring or receiving blood and blood product. Below are suggestions you *may* wish to include in your MOU.

TRANSFERRING OUT BLOOD AND BLOOD PRODUCT

It is important to allow sufficient time for receiving facilities to utilise blood and blood products before expiry. The recommendations below are given to ensure the receiving site has the highest likelihood to use the product before expiry;

- 7 - 14 days before expiry for red blood cells,
- >5 days before expiry of supplier irradiated blood cells,
- 24 hours, or as short as agreed to with the receiving site, before expiry for platelets,
- 1 - 3 months before expiry for manufactured products.

You may wish to introduce a system to improve utilisation of short expiry products. For example, the sending laboratory should phone the receiving laboratory to see if they can use the product prior to expiry.



The receiving health provider should be notified of an impending delivery within a time frame agreed between sites in the MOU [e.g. 24 hours' notice]. This notification will allow sufficient time for receiving facilities to adjust their own inventory orders from the supplier. If relevant, outline in your MOU multiple hub and spoke arrangements to ensure that if one health provider is unable to accept a transfer another arrangement is in place.

Details of blood and blood product transfers should be recorded in BloodNet prior to transport for facilities with access to BloodNet. The BloodNet transfer receipt form, or equivalent, should then be printed and added to the shipper for transportation with packing date, time and signature of packer. Health providers without access to BloodNet should complete the transfer form in [Appendix 6](#) to accompany their shipment.

It is important to inspect all blood and blood products for prior to packing. You should consider documentation of the inspection in your MOU. A checklist to check blood and blood products is available for receiving sites in [Appendix 6](#).

Your MOU should include the agreed shipping configurations and container specifications for the varied climates your locations will face. This should assure all participating health providers in the MOU that blood and blood products are maintained within the recommended manufacturer's temperature specifications.

A record of the storage temperature of the products must be available on request at the facility that shipped the product. NATA accredited health providers may need to provide this documentation during their accreditation process. This documentation will assure all participating health providers are storing blood and blood products within the current *AS3864 Medical refrigeration equipment – For the storage of blood and blood products*⁵. It will also provide assurance that blood and blood products are maintained within manufacturer's temperature specifications and prevent discards due to unknown storage conditions.

Consider what documentation will be required with transfers in the MOU. Recommended documentation and information is:

- name of shipping health provider and receiving health provider
- identification of components/products shipped (donor numbers) and description of component/product and total number of units transferred
- date and time transfer entered into BloodNet, where applicable
- date and time packed
- identification of person who packed the shipment
- inspection of product appearance attended
- transfer procedure checklist, see [Appendix 4](#)
- shipper Packing Slip for sites without BloodNet, example available in [Appendix 7](#)

* The above documentation can be recorded on the printout from the BloodNet transfer episode or on the Blood and Blood Product Transfer Form available in [Appendix 6](#) of this document.

LABELLING OF TRANSPORT SHIPPERS

It is important to label blood and blood product transport shippers appropriately. See [Appendix 8: Shipper Label](#) for an example. Consider including the following details as a minimum;

- name and phone number of contact person at the receiving site,
- name and address of intended receiving site,
- dispatch time and date,
- dispatching health provider, staff member name and contact details,
- clear and precise instructions to the courier contractor.

RECEIVING BLOOD AND BLOOD PRODUCT

When receiving blood and blood product transferred from another health provider, consider the following:

- Review your current inventory and routine stock orders to account for expected transfers into your facility. This may require you to reduce your routine order. For example, if you know you are receiving 20 units of red blood cells, reduce your order by 20 units unless you know that more is required that day.
- Document the time and date the transferred blood and blood product was received on [Appendix 6: Blood and Blood Product Transfer Form](#) and whether temperature specifications have been met. This will ensure you have completed records for accreditation purposes.
- It is the responsibility of the receiving facility to ensure the blood and blood product has been maintained within the manufacturer's required temperature range before accepting it into your inventory. If in doubt, the product must be quarantined until storage and transport conditions have been verified.¹¹ Please refer to the Australian & New Zealand Society of Blood Transfusion *Guidelines for pretransfusion laboratory practice*.¹¹
- It is good practice to inspect the shipper and blood product upon receipt as per [Appendix 6: Blood and Blood Product Transfer Form](#). This ensures the integrity of each unit and that patient safety is maintained.
- Enter the acceptance or non-acceptance of product into your laboratory information system as required. To ensure traceability, it is important that all laboratories with access to BloodNet must enter their transfers and discards.
- You should maintain a record of transferred products for auditing and accreditation purposes. This can be completed through BloodNet or manually if the transferring and/or receiving site does not have access to BloodNet. This will allow you to review the transfer arrangements and track if transferred products are utilised, if discards rates of expired product decrease and so on.

REMOTE SITES WITHOUT A LABORATORY OR BLOOD FRIDGE

For non-laboratory remote sites with a blood fridge consider who is responsible for maintaining the fridge. The receipting site is responsible for ensuring that all product received has been kept within manufacturer's temperature specifications and will need to include access to temperature records in the MOU. You may also want to consider including any maintenance records. Alternatively, you may choose to opt for a signed declaration that all blood and blood product has been maintained within manufacturer's temperature specifications, by the transferring out site.

For remote sites or facilities without a laboratory you may like to include the following additional documentation with the transferred blood and blood products as an assurance for the receiving facility that blood and blood product have been stored according to manufacturers' temperature requirements;

- completed paperwork outlining the daily storage temperature checks of the blood fridge or storage area, see *Appendix 5: Blood Fridge Maintenance Record*;
- a photocopy of the objective graph recorder from the blood fridge demonstrating the temperature range of the place of storage; or
- information from the health provider responsible for maintaining the blood fridge, for example temperature graphs, maintenance records. You may be satisfied with a declaration from the sending health provider.

For remote sites without a blood fridge consider how blood and blood products are stored while onsite and include specific storage methods in your MOU. Examples of inclusions include, but are not limited to;

- the product must remain in a sealed shipper until used,
- the product must be accompanied by a data logger or temperature indicator,
- transfer of patient specific product only for immediate use.

For remote sites without a blood fridge, storage and transport requirements and documentation must be detailed in the MOU.

Staff at the remote site should undertake the BloodSafe eLearning "Transporting Blood" module. The receiving laboratory could also consider undertaking additional training for ward/nursing staff at the remote site.

APPENDIX 1: TRANSFER ESTABLISHMENT AND REVIEW CHECKLIST

PROCEDURE	✓
Identify sites you could transfer to/from.	<input type="checkbox"/>
Review what blood and blood product you could transfer in/out.	<input type="checkbox"/>
Review courier or transport possibilities.	<input type="checkbox"/>
Contact potential participating sites to gauge interest.	<input type="checkbox"/>
Set up initial meeting with managers and scientists in charge to discuss transferring options.	<input type="checkbox"/>
Go through the MOU to make it specific for your situation.	<input type="checkbox"/>
Agree to storage, transport, package, documentation and training requirements.	<input type="checkbox"/>
Outline acceptable days until expiry that units should be identified for transfer.	<input type="checkbox"/>
Sign off on agreed MOU.	<input type="checkbox"/>
Educate staff on arrangements.	<input type="checkbox"/>
Set start date for transfer arrangement to commence.	<input type="checkbox"/>
Set date to meet and review transfer arrangement.	<input type="checkbox"/>
Review MOU arrangement to ensure working for all health providers involved.	<input type="checkbox"/>

APPENDIX 2: VALIDATION PLAN

1. PURPOSE / SCOPE

This document describes the validation of:

- Shipper [enter shipper name] for the use in the inter-hospital/laboratory transport of [Enter components as required].

Responsibilities

Position	Responsibility
Senior Scientist	Design validation; analyse results; prepare the report; perform the validation; compile results
Quality Manager	Authorise validation and approve for implementation

2. REFERENCES

A reference you may like to review is the Council of Europe's "Guide to the Preparation, Use and Quality Assurance of Blood Components", 16th edition.¹⁸

[List references you outline in this document]

3. MATERIEL (add/delete below as required)

- 3.1 3x Shipper [enter shipper name].
- 3.2 Room temperature coolant packs (conditioned at +20 to +24°C for 24hrs prior to use).
- 3.3 Chilled coolant packs (conditioned at +2 to +6°C for 24hrs prior to use).
- 3.4 Frozen coolant packs (conditioned at approximately -19°C for 24hrs prior to use).
- 3.5 Tamper evident labels.
- 3.6 Cardboard dividers.
- 3.7 Expired red cells with defaced label "Research Only" or empty dummy packs filled with 275ml saline.

4. EQUIPMENT

Temperature Data Loggers (TDL): [Enter Company Name], [Enter Model No].

Temperature Data Logger	Serial Number	Asset Number
TDL1		
TDL2		
TDL3		

Note: Performance Qualifications for the data loggers have been included in Attachment [X].

Cool Room [Enter name e.g. CR001]

Incubator [Enter name e.g. CR001]

Note: Records for Cool Room [CR001] and Incubator [I001] are located in [Enter location e.g. Engineering Department]

5. ACCEPTANCE CRITERIA

- 5.1. Temperature maximum does not exceed 10 °C.
- 5.2. Temperature minimum does not fall below 2 °C.
- 5.3. There should not be a temperature range difference of ± 1 °C between the lowest and highest values for the maximum temperature recorded for each of the data loggers and each of the replications when determining maximum transport time.
- 5.4. There should not be a temperature range difference of ± 1 °C between the lowest and highest values for the minimum temperature recorded for each of the data loggers and each of the replications when determining minimum transport time.

6. PROCEDURE (add/delete below as required)

6.1. *Description / Background Information*

- 6.1.1. This laboratory will be validating/revalidating the [enter shipper name] for the transport of red blood cells [or other component] between the following health providers [insert names].
- 6.1.2. Routine transfer of blood components is undertaken by [enter name]
- 6.1.3. A review of Bureau of Meteorology for local climatic conditions indicates that minimum environment temperatures do not drop below [enter minimum temperature e.g. 10°C].
- 6.1.4. Validation time was set at [x] hours as a review of transport arrangements and non-compliance reports indicate that this would be the worst case scenario the laboratory would experience in the transfer of components.

6.2. *Key Variables* (add/delete below as required)

- 6.2.1. Staff will be accessing cool room during low temperature qualification period.
- 6.2.2. Building air conditioning is switched off from [enter time e.g. 10pm] to [enter time e.g. 6am] during ambient temperature qualification period.

- 6.3. *Samples* (add/delete below as required, set temperature levels to represent your requirements)
- 6.3.1. Data logging sample rate set at [x] minute intervals.
 - 6.3.2. Sampling was undertaken over [x] hours for [10 °C - 14°C] low temperature qualification period.
 - 6.3.3. Sampling was undertaken over [x] hours for [20 °C - 24 °C] ambient temperature qualification period.
 - 6.3.4. Sampling was undertaken over [x] hours for [32 °C - 42 °C] high temperature qualification period.

6.4. *Data logger Parameter Settings*

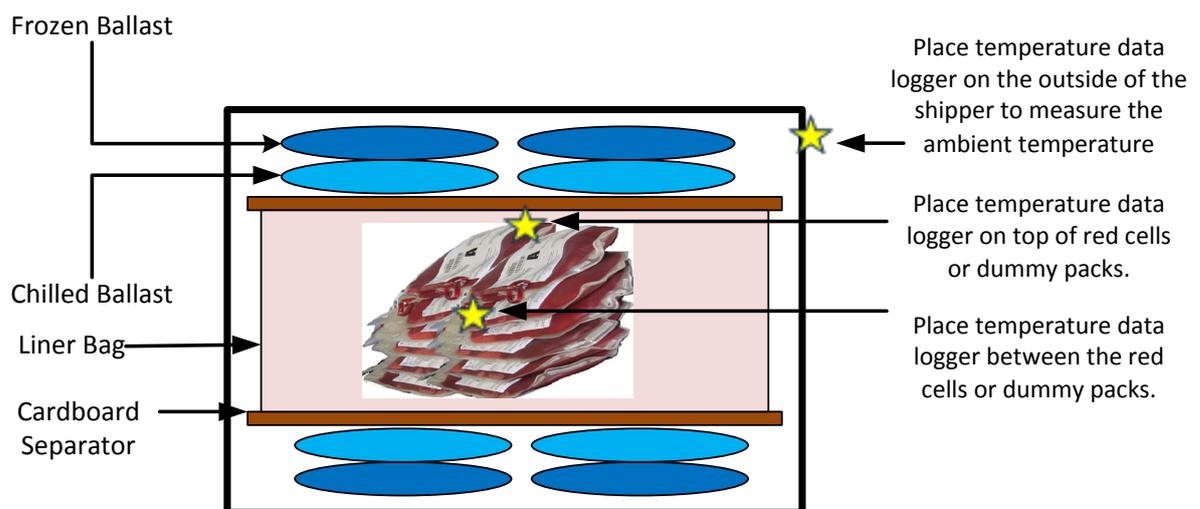
- 6.4.1. Data logger delay setting set to 15 minutes to allow equilibration.
- 6.4.2. Data logging sample rate set at [x] minute intervals.
- 6.4.3. Data logger sample points set at [number of readings to reach 30 hours].

6.5. *Participating centres & personnel*

[Enter Health Provider/Laboratory Name/s], [Enter Location], Senior Scientist, Quality Manager

6.6. *Packing Configuration*

Packing configuration as outlined in **Figure 1** below. For each configuration you will need to determine the minimum and maximum number of packs allowed for each configuration to be validated.



*Figure 1 adapted from the Australian Red Cross Blood Service *Receipt and Use of Blood Service Shippers by External Institutions to Transport Blood and Blood Products* Red Cell Configuration R1.

6.7. Temperature Data Loggers and Placement

- 6.7.1. Data loggers equilibrated to required temperature e.g. 10 °C - 14 °C, 20 °C - 24 °C, 32 °C and 52 °C.
- 6.7.2. Place one logger in-between the red cells or dummy packs.
- 6.7.3. Place one logger above the red cells or dummy packs.
- 6.7.4. Attach one logger to the outside of the shipper to measure the environment temperature.
- 6.7.5. Refer Figure 1 above.

6.8. Temperature Validations

- 6.8.1. Shipper packed in accordance with Figure 1 was placed in Cool Room CR001 for [as per 6.1.4] for minimum temperature validation. This was repeated on three separate occasions.
- 6.8.2. Shipper packed in accordance with Figure 1 was placed in Blood Bank Laboratory for [as per 6.1.4] for ambient temperature validation. This was repeated on three separate occasions.
- 6.8.3. Shipper packed in accordance with Figure 1 was placed in Incubator I001 set at 32 °C for [as per 6.1.4] and then at and at 42 °C for maximum temperature validations. This was repeated on three separate occasions.

7. RESULTS

7.1. Data logger Performance Qualification

Performance testing was undertaken and completed by [Enter detail e.g. Engineering Department] on [Enter date]. Results of performance testing against a reference thermometer are outlined in the **Table 1** below.

Table 1 Reference thermometer performance testing

Temperature Data Logger	Recorded Temp °C	Ref Thermometer Recorded Temp °C	Difference °C
TLD1	23.6	23.5	- 0.1
TLD2	23.6	23.6	0.0
TLD3	23.6	23.5	- 0.1

Note: Reference Thermometer [Enter Serial No] records can be obtained from [Enter Engineering Department]

7.2. Minimum Temperature Validation

7.2.1. Raw data of data logger download is included in Attachment 1.

7.2.2. Summary of results of data logger mapping is in **Table 2** below:

Table 2: Data logger mapping results

Position	Date	Data Logger	Minimum	Maximum
Position 1	[Enter date]	TDL1	[4.9] °C	[6.8] °C
Position 1	[Enter date]	TDL1	[5.7] °C	[7.9] °C
Position 1	[Enter date]	TDL1	[5.2] °C	[7. 2] °C

[Enter other tables as required]

8. DISCUSSION AND RECOMMENDATIONS

The performance testing of the four data loggers was undertaken and completed by [Enter name e.g. Engineering Department], an ISO9000 accredited facility, on [enter date]. The results against a reference thermometer showed that no data logger had a variance greater than \pm [enter variation e.g. 0.1] °C.

The minimum temperature validation occurred on three separate occasions over a 7 day period from [enter date] to [enter date]. Cool room CRO01 decommissioned for maintenance was recommissioned and set to 10 °C - 14 °C for this validation study. The packing configuration and data logger placement is outlined in Figure 1.

The results show that the shipper stored at 10 °C - 14 °C for [x] hours did not drop below [x] °C for the validation period. The variation of minimum temperature across the three validations for each of the data loggers is [0.8] °C within the allowable $\pm 1^\circ\text{C}$ acceptance criteria. The results show that the shipper stored at 10 °C - 14 °C for [x] hours did not exceed 10 °C until [x] hours. The maximum temperature variation across the three validations for each of the data loggers is [enter variation e.g. 1.1] °C and is within the allowable $\pm 1^\circ\text{C}$ acceptance criteria.

[Discuss ambient temperature validation]

[Discuss maximum temperature validation]

It is recommended that Shipper [Enter name] is suitable for the transport of red cells as inter-hospital/laboratory for up to [x] hours. If the transport is expected to exceed [x] hours or if non-contracted transport such as a taxi is required then consignments should include a data logger as part of the packing configuration, to be positioned next to the red cell packs.

9. APPENDICES

Attachment [1]: Raw data download of [data logger] for minimum temperature validations.

Attachment [2]: Cool Room Temperature Map

Attachment [3]: [other documents as required]

10. APPROVALS

	Name	Signature	Date
Report prepared by:			
Quality Manager Approval			

End of document

Repeat the process below for each configuration, product and possible temperature exposure range, for example: 0 °C to 4 °C, 4 °C to 24 °C, 24 °C to 40 °C, 40 °C to 52 °C

APPENDIX 3: EXAMPLE MEMORANDUM OF UNDERSTANDING (MOU):

MEMORANDUM OF UNDERSTANDING

for the

Transfer of blood and blood products between the below listed health providers

<ENTER HOSPITAL OR PATHOLOGY SERVICE (PROVIDER)>

1. PARTICIPATING HOSPITALS OR PATHOLOGY SERVICES

The Memorandum of Understanding (MOU) is endorsed by the [e.g. Senior Haematologist/ Senior Scientist/ Laboratory Manager] from each participating facility. The signatories agree to abide by the contents of this MOU.

<Enter Hospital or Pathology Service (Facility)>
Signature_____
Name_____
Position_____
Date_____

<Enter Hospital or Pathology Service (Facility)>
Signature_____
Name_____
Position_____
Date_____

<Enter Hospital or Pathology Service (Facility)>
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Position_____
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<Enter Hospital or Pathology Service (Facility)>
Signature_____
Name_____
Position_____
Date_____

2. CONTACTS

<ENTER HOSPITAL OR PATHOLOGY SERVICE (FACILITY)>

List names, position, contact

List names, position, contact

<ENTER HOSPITAL OR PATHOLOGY SERVICE (FACILITY)>

List names, position, contact

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<ENTER HOSPITAL OR PATHOLOGY SERVICE (FACILITY)>

List names, position, contact

List names, position, contact

3. PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to establish cooperation between the above signed health providers for facilitating blood and blood product transfer arrangements between identified facilities. The MOU relates to the *Managing Blood and Blood Product Transfers*.

The intention for this MOU is to:

- Assist in the reduction of blood and blood product wastage due to expiry or non-use through the transfer of blood and blood products before expiry to enhance the likelihood of usability.
- To provide a uniform process for the transfer of blood and blood products between the participating facilities.
- To ensure that acceptable temperature ranges for blood and blood products are maintained and are demonstrable during storage and transportation.
- That AS3864 compliant blood refrigerators are used for the storage of blood.
- To provide a uniform process for tracking transferred blood and blood products.

4. COORDINATION

The original document and technical and administrative coordination of this MOU will reside with <enter facility name and contact details>.

The coordinator will be responsible for the MOU and will communicate with all participating health providers on the activities conducted and information related to the MOU.

5. DEFINITIONS

Sending Health Provider: the health provider that is transferring blood and blood product out of their site.

Receiving Health Provider: the health provider that has agreed to receive the blood and blood product transfers into their site.

Blood product approaching expiry: any product shipped should not have less than the following remaining of the shelf life, unless specifically agreed to by participating health providers in this MOU or in special situations;

- 7-14 days for red blood cells,
- > 5 days before expiry for irradiated blood cells,
- 24 hours or as short as agreed to with the receiving site before expiry for platelets,
- 1-3 months before expiry for manufactured blood products.

6. MEMORANDUM OF UNDERSTANDING REVIEW

< Identify the MOU review responsibilities and timeframe>

For example:

- Review timeframe is every two years,
- Responsibilities include a review of;
 - updated accreditation documents and Australian Standards,
 - MOU participant inventory holdings and blood and blood product usage patterns,
 - inclusion of additional health providers,
 - <list review responsibilities as agreed>.

7. IMPLEMENTATION

Roles and Responsibilities of participating health providers

7.1. Responsibilities for all MOU Participants

Participating health providers are responsible for following the guidance outlined in *Blood and Blood Product Transfers* including the following:

- Maintaining standards and accreditation, where appropriate.
- Meeting all necessary standards and legislation for the storage, handling and transport of blood and blood products as outlined in *Managing Blood and Blood Product Transfers*.
- Participating health providers will ensure that blood components are handled, stored, distributed and transported in a manner that prevents damage, limits deterioration, and meets required standards.
- <Enter additional responsibilities agreed by the participating health providers>

7.2. Sending Health Provider

The sending health provider must: <Identify sending site responsibilities>

For example:

- Contact receiving provider for approval prior to transfer, minimum timeline agreed to is <enter agreed minimum time> hours before arrival of transfer.
- Ensure blood and blood products must have the minimum agreed specified time to expiry as per Section 5. Definitions, unless explicit agreement is acknowledged from receiving site
- Enter transfer into BloodNet (where applicable).
- Enter transfer into your Laboratory Information System (LIS) (where applicable), or manually log where no laboratory is onsite.

- Visually inspect all products prior to transferring.
- Comply with agreed packing and shipping configuration, specifically:
- <enter agreed validated packing configuration>.
- Include the Transfer Checklist with either the transfer receipt from BloodNet, OR the Blood and Blood Product Transfer Form (Appendix 6).
- For sites without a laboratory include the following documentation as agreed;
 - completed Blood Fridge Maintenance Record form, OR
 - completed paperwork outlining the daily storage temperature checks of the blood fridge or storage area, AND
 - a photocopy of the objective graph recorder from the blood fridge, OR
 - information from the health provider responsible for maintain the blood fridge with temperature records, maintenance records or signed declaration.

7.3. *Receiving Health Provider*

The receiving health provider must: <Identify receiving site responsibilities>

For example:

- agree to receive the transferred blood or blood product;
- review your current inventory and routine stock orders to account for expected transfers in;
- inspect all packaging of received blood and blood product and do not accept the transfer unless it is intact and packed according to agreed validated shipper configuration;
- document the time and date the product was received;
- document evidence that manufacturer's temperature specifications have been maintained. If in doubt, quarantine all products until storage, packing and transport conditions can be verified;
- check temperature data logger, if used;
- visually inspect all blood and blood products received;
- record transferred in units into your LIS;
- complete all other documentation as required e.g. group check if transferred from a non-laboratory setting;
 - maintain record of product received by transfer.

8. TRANSPORT LOGISTICS

<Enter transport logistics as agreed by the participating health providers>

For example:

- The agreed packing configuration is as per the Blood Service Validated Shippers.

Refer to:

- *Receipt and Use of Blood Service Shippers by External Institutions to Transport Blood and Blood Products,*
- *Transport Times,*
- *Transportation of blood components and fractionated products. OR*
- The agreed packing configuration is <enter agreed validated packing configuration>.
- Data loggers or temperature monitoring must be used when transport is outside validated shipper times.
- The agreed transport method is:
- <Enter agreement for courier/transport method>.
- <Enter agreement for courier/transport cost>.

APPENDIX 4: TRANSFER PROCEDURE CHECKLIST

PROCEDURE	✓
1. Routine check for products close to expiry.	<input type="checkbox"/>
2. Identify and contact possible receiving health provider/s to negotiate transfer of close to expiry product.	<input type="checkbox"/>
3. Record blood or blood product transfer in BloodNet. Print transfer record and include with the product.	<input type="checkbox"/>
4. Record transfer information on Blood and Blood Product Transfer Form** ** only if BloodNet is not available	<input type="checkbox"/>
5. Record blood or blood product transfer in the Laboratory Information System (LIS)*. *If your LIS is interfaced with BloodNet then record entry is not required in BloodNet.	<input type="checkbox"/>
6. Inspection of blood and blood product for abnormal appearance, package integrity, leakage and expiry date.	<input type="checkbox"/>
7. Check blood or blood product is packed according to MOU agreement, include date and time packed on transfer form.	<input type="checkbox"/>
8. Copy of the Blood Fridge Maintenance Record form or temperature graph included as per MOU (to be sent when required/requested).	<input type="checkbox"/>
9. Transport shipper labelled.	<input type="checkbox"/>
10. Notify recipient health provider by telephone or email of impending delivery.	<input type="checkbox"/>

Checklist completed by:

Name: _____ Signature: _____

Date and Time: __/__/____

APPENDIX 5: BLOOD FRIDGE MAINTENANCE RECORD

Blood fridge maintenance procedures must be performed according to the schedule above.

Record all results on the form

Fridge location / identification:		Hospital Name:					Asset No.:					Month:					Year:																				
Daily maintenance checks		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31					
Record blood fridge temperature from digital display or internal thermometer (Acceptable Range 2-6°C) (Record temperature)																																					
Check temperature recording chart for out of range spikes (✓)																																					
Document reasons for spikes on temperature chart and in Problem Log below.																																					
Check fridge for blood that can be returned to the transfusion provider.																																					
Segregate blood and contact transfusion service for return (including advice on packing and transportation of blood as required). (✓)																																					
Initials of staff member performing check (Initials)																																					
Maintenance checks (define period with a minimum requirement as outlined in AS3864) (See procedure on right)		Week	1	2	3	4	5	BLOOD FRIDGE MAINTENANCE PROCEDURES																													
Change temperature chart (✓)		Date						TEMPERATURE CHART																													
Test all alarms to ensure correct functioning		Audible (✓)						Weekly temperature chart (circular type): Open cover, remove old chart. Check chart for conformance during previous 7 days, date and sign. Date new chart, identify fridge/hospital, sign and place on recorder. Ensure that day and time are correct with pen recorder position. Adjust if necessary. Ensure pen tip is touching chart. Close and lock cover. Other types of temperature chart—Check chart conformance daily and change as required.																													
		Visible (✓)						ALARM TEST																													
		Power Loss (✓)						Audible: Push test button and ensure audible alarm (e.g. beep or siren) is functioning. Visible: Push test button and ensure visible alarm (e.g. flashing light) is functioning. Power loss: Turn power off at wall switch or main switch if accessible. Ensure alarms function. Remote alarm: Push test button and ensure remote alarm system(s) is functioning.																													
		Remote Alarm (✓)						ALARM HIGH AND LOW TEMPERATURE ACTIVATION CHECKS																													
Initials of staff member performing check (Initials)								Some newer fridges have an automated process for these tests. Older fridges require a manual checking process as detailed below. Please refer to the fridge manufacturer's manual on how to do this. Please handle probes carefully for the following checks (once completed carefully replace probes)																													
Maintenance checks (define period with a minimum requirement as outlined in AS3864) (See procedure on right)		Task	Date	Pass(✓)/Fail(✓)	By (Initials)	<ul style="list-style-type: none"> High temperature alarm: Remove probe from container. Insert into a small container of room temperature water. Ensure alarm is activated as temperature rises above 5.5°C. Low temperature alarm: Remove probe from container. Insert into a small container of iced water. Ensure alarm is activated as temperature falls below 2.5°C. 																															
Battery backup check				Pass...../Fail.....		BATTERY BACKUP CHECK – refer to manufacturer's instructions																															
High Alarm activation check				Pass...../Fail.....		CORRECTIVE ACTION MUST BE TAKEN IF ANY BLOOD FRIDGE MAINTENANCE TEST FAILS																															
Low Alarm activation check				Pass...../Fail.....																																	
Check door seals & clean internally				Performed:.....																																	
Problem log (Record problems, dates and corrective actions taken (continue on reverse if required))		Copy Sent to Partner Transfusion Laboratory		Name	Sign	Date																															
		Reviewed by Laboratory		Name	Sign	Date																															

APPENDIX 6: BLOOD AND BLOOD PRODUCT TRANSFER FORM

For facilities without BloodNet access only

From:		Contact phone:	
To:		Date:	Time:
Donation Number (if applicable)	Blood Group (if applicable)	Comments (These include any temperature or storage non-compliance issues e.g. outside the 30 minute rule, problems with the blood fridge, any physical damage to the unit)	
1.			
2.			
3.			
4.			
5.			
6.			
STORAGE CONFIRMATION (COMPULSORY)			
Indicate the following checks have occurred by ticking the appropriate box.			
Red Blood Cell Units:			
<input type="checkbox"/> Check the Blood Fridge Register to ensure each red cell unit being transferred has been stored appropriately:			
<ul style="list-style-type: none"> red cell units have not been removed from the blood fridge longer than 30 minutes at any given time 			
<input type="checkbox"/> Check the Blood Fridge Maintenance Record to ensure compliance of storage criteria:			
<ul style="list-style-type: none"> blood fridge temperature has remained stable within 2° - 6°C degrees during the storage period that the temperature recorded is complete with no missing data 			
Other Blood Products:			
<input type="checkbox"/> Check that other blood and blood product have been stored as per manufacturer's temperature specifications			
If there are any problems with handling and storage of any of these blood or blood products:			
<ul style="list-style-type: none"> these MUST be documented in the above comments section next to the appropriate blood or blood product contact the laboratory and inform them of the details 			
I declare to the best of my knowledge, the above information regarding the handling and storage of the blood and blood product listed above is correct.			
Name:	Signature:	Position:	
RECEIVING LABORATORY USE ONLY			
<input type="checkbox"/> Temperature check on receipt: _____ °C		Passed <input type="checkbox"/>	Failed <input type="checkbox"/>
<input type="checkbox"/> The above documentation has been completed verifying correct handling and storage of blood and blood products [boxes ticked, signature present]		Passed <input type="checkbox"/>	Failed <input type="checkbox"/>
<input type="checkbox"/> Tamper-proof port is intact and no blood is present in the port, for red cells only		Passed <input type="checkbox"/>	Failed <input type="checkbox"/>
<input type="checkbox"/> The blood and blood product is intact, not discoloured or has unusual particulate matter [check against other units if necessary]		Passed <input type="checkbox"/>	Failed <input type="checkbox"/>
<input type="checkbox"/> Only blood and blood product stored conforming to AS3864 and manufacturer's temperature specifications have been accepted back into inventory		Passed <input type="checkbox"/>	Failed <input type="checkbox"/>
<input type="checkbox"/> Blood and blood products that are not compliant are to be destroyed via medical waste and recorded in LIS and BLOODNET, where available and appropriate		Passed <input type="checkbox"/>	Failed <input type="checkbox"/>
Checked by:	Signature:	Date:	Time:

APPENDIX 7: SHIPPER PACKING SLIP/ BLOOD CONSIGNMENT RECORD

<Insert logo or
hospital name
here>

Consign-
ment
Number:

To:	From:

SENDER TO COMPLETE

No. of Shippers:	Blood Product:	Qty:
Patient Name:		Packed Date: Time:
Sent via:	YOUR Lab courier <input type="checkbox"/>	Taxi <input type="checkbox"/>
	Bus <input type="checkbox"/>	Airline <input type="checkbox"/>
	Other Courier <input type="checkbox"/>	
Details:		
Other Courier Company Name:		
I have packed this consignment in accordance with the packing configuration:		
Signature:	Dispatched Date:	Time:

RECIPIENT TO COMPLETE *Please return completed form to Sender*

No. of shippers received:	Shipment received unopened and undamaged? YES <input type="checkbox"/> NO <input type="checkbox"/>
For products listed below Is the temperature within the acceptable range? YES <input type="checkbox"/> NO <input type="checkbox"/> <i>If product is outside specified temperature range, contact sender immediately for advice.</i>	
Received	Date: Time:
Unpacked	Date: Time:
Signature:	Date:

 <p>WARNING DO NOT USE products if: The shipper arrives open The product is outside the specified temperature range</p>	<p>ACCEPTABLE TEMPERATURE RANGE Red cells..... 2°C to 10°C Autologous Blood 2°C to 10°C Platelets..... 20°C to 24°C Manufactured products as per Product Information</p>
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Laboratory Notes

APPENDIX 8: SHIPPER LABEL

<p>DELIVER IMMEDIATELY</p> <p>HUMAN BLOOD PRODUCTS FOR TRANSFUSION</p> <p>Do Not Refrigerate This Shipper</p>	<p><u>Deliver To:</u></p> <p>Attention to: [Insert Name and Position]</p> <p>[Insert name of Transfusion Laboratory]</p> <p>[Insert location/building name]</p> <p>[Insert name of Hospital][Insert address]</p> <p>[Insert Phone Number]</p> <p>[Insert Fax Number]</p>
<p>CONTENTS</p> <p><input type="checkbox"/> Autologous Blood</p> <p><input type="checkbox"/> Red Cells</p> <p><input type="checkbox"/> Platelets</p> <p><input type="checkbox"/> Thawed FFP</p> <p><input type="checkbox"/> Frozen Plasma Components</p> <p><input type="checkbox"/> Clotting Factors</p> <p><input type="checkbox"/> Immunoglobulins</p> <p><input type="checkbox"/> Albumin</p> <p>Packed Time: Valid to Time:</p> <p>Packed Date:</p> <p>Despatch Date: Time:</p> <p>Signed:</p>	<p><u>Delivered From:</u></p> <p>[Insert Name and Position]</p> <p>[Insert Hospital Name]</p> <p>[Insert Address]</p> <p>[Insert Phone Number]</p> <p>[Insert Fax Number]</p>



NATIONAL BLOOD AUTHORITY
AUSTRALIA

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