health

Report on the blood storage and handling survey 2010

Blood Matters – better safer transfusion program

State Government Victoria

Australian Red Cross BLOOD SERVICE

Department of Health

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Acknowledgements

Thank you to the many people who contributed to this audit of blood storage and handling in Victorian hospitals. Their efforts to collect and analyse data make it possible for us to present this cumulative report. We trust that making such data accessible will allow its use to help improve the safety of transfusion for the ultimate benefit of our patients.

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Authorised by the State Government of Victoria, 50 Lonsdale Street, Melbourne.

July 2011

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Introduction

The delivery of a safe blood product to patients is vital. From collection to transfusion, the care of blood and blood components according to established guidelines ensures a safer product is provided to the patient. Although Victoria does not collect data on serious transfusion events related to handling and storage errors, such cases are collected as part of the UK Serious Hazards of Transfusion (SHOT) program and provide useful insights for Victorian health services.

In the *2009 annual SHOT report* (Taylor 2010), 196 cases were reported under the handling and storage error category, an increase of 41 per cent from the previous year. There was no mortality and no major morbidity arising from these incidents. The largest group was related to cold chain errors (84 cases) of which the majority (62 cases) related to inappropriate storage of components; followed by excessive time to transfuse (69 cases). The majority of handling and storage errors (78 per cent) arose outside the laboratory and were the responsibility of clinical, portering and transport staff. Consequently, SHOT has recommended that all staff involved in the transfusion process must understand the basic storage requirements of blood components. The cases in the SHOT report are those where the component was transfused, thereby posing a risk to a patient, but an additional concern is the many components wasted due to insufficient care being taken of cold chain requirements.

Blood Matters – better safer transfusion program conducted a blood storage and handling audit in 2005 with 15 selected regional centres and smaller metropolitan private hospitals. A series of recommendations were made as a result of the survey and are shown below.

Recommendation 1: All hospitals should identify the person with responsibility for management of designated blood fridges, including preventative maintenance and calibration (AS 3864-1997).

Recommendation 2: The minimum number of fridges be used as designated blood fridges outside of pathology (AS 3864-1997) and be labelled ‘blood fridge only’ (Council of Europe [2005] guidelines).

Recommendation 3: Designated blood fridges with only local alarms should be located in areas that are staffed at all times (NATA ISO/IEC 15189 2005).

Recommendation 4: All organisations should have an emergency plan in the event of a designated blood fridge failure. Short term battery backup is only one aspect of an overall emergency response and recovery plan.

Recommendation 5: All hospitals need to be aware of all of the relevant Australian Standards for designated blood fridges.

Recommendation 6: Fresh frozen plasma (FFP) should be thawed under controlled conditions by appropriately trained staff. There needs to be local policies and procedures governing the use and maintenance of equipment used to thaw FFP.

Recommendation 7: Packaging and transit times need to comply with Council of Europe (2005) guidelines. Temperature assessment on receipt of transported blood products should be considered for those deliveries at higher risk.

In 2010, Blood Matters revisited storage and handling practices to find if previous recommendations were being implemented and to identify opportunities for improvement.

The 2010 audit invited all Victorian hospitals (n = 136) to contribute data.

Facilities involved in transfusing blood should adhere to a number of standards and guidelines to ensure a safe product. These standards and guidelines were considered when developing the audit tool and making recommendations.

The references used to frame best practice were:

- Australian Standard AS 3864-1997 *Medical refrigeration equipment – for the storage of blood and blood products*
- Australian and New Zealand Society of Blood Transfusion (ANZSBT) *Guidelines for pretransfusion laboratory practice*, 5th edition, 2007
- National Association of Testing Authorities (NATA) Application Document ISO/IEC 15189, *Supplementary requirements for accreditation in the field of medical testing 2005*
- National Association of Testing Authorities (NATA) *AS 4633 (ISO 15189) Field Application Document Amendment Sheet Medical testing 2009*
- *Guide to the preparation, use and quality assurance of blood components*, 15th edition, Council of Europe Publishing 2009
- The Australian Council on Healthcare Standards (ACHS) EQuIP 4 guide (Criterion 1.5.5: The system for prescription, sample collection, storage and transportation and administration of blood and blood components ensures safe and appropriate practice).

Since the previous audit took place in 2005, new standards and accreditation requirements have taken effect and should be considered when making a comparison between the two years.

The storage and handling of blood and blood products is highly regulated during transportation between the Australian Red Cross Blood Service (the Blood Service) and pathology. However, there is limited regulation and control of these products once they leaves pathology and enter the clinical area. The Therapeutic Goods Administration requires the Blood Service to adhere to the Council of Europe guidelines for storage and handling of all blood products; laboratories are regulated by NATA. In the clinical setting, EQuIP 4 (in its blood management standard) outlines policies required for education of staff, storage and handling, and monitoring of any equipment involved in storage and handling. (New EQuIP 5 standards for ACHS accreditation of hospitals are available and will take effect on 1 July 2011.)

Survey aims

The survey aims to improve the quality of care provided to patients by ensuring the appropriate storage and handling of blood and blood products (red blood cells and fresh frozen plasma) after issue from a laboratory/pathology service.

Objectives

The objectives of the survey were:

- to identify current storage and handling practices in hospitals
- to identify barriers (if any) to the implementation of appropriate storage and handling standards in hospitals.

Method

A letter of invitation to participate was forwarded to the Chief Executive Officer of 136 regional and metropolitan hospitals within Victoria. The survey proforma was made available on the Blood Matters website. The survey proforma was created as a fillable Word form so that facilities could enter data electronically and email the completed form, allowing the responses to be imported without manual data entry.

A copy of the proforma and related information sheet is attached (Appendix 1).

The 2010 proforma contained a number of additional questions to further assess facilities' compliance to guidelines and follow up on recommendations made in 2005. (Appendix 2 outlines the changes, as well as commentary throughout the report.)

Results and conclusions

General information

The audit was sent out to 136 Victorian hospitals, both regional and metropolitan, and public and private. The return rate was 65 per cent (89 sites). Nursing or scientific staff completed the survey.

In 2005, the survey was sent to 15 hospitals with a return rate of 87 per cent (n = 13). In 2010, the survey was sent to the same hospitals with 12 hospitals submitting data (80 per cent return rate).

Table 1: Return rate of audit, 2010

	Number sent	Number returned	Return rate
Regional	70	53	76%
Metropolitan	16	15	94%
Private	50	21	42%
Overall	**136**	**89**	**65%**

One (small rural) hospital returned the survey stating that blood transfusions were never performed at their facility.

Storage and handling of red blood cells

Of the hospitals transfusing blood, the majority (82 per cent) stored blood for periods longer than four hours. Most of the hospitals storing blood for a prolonged period had designated blood fridges or a pathology department onsite. However, two reporting hospitals had no fridge storage (designated or general) for blood products and stored such products in an esky for periods longer than four hours.

Five hospitals reported storing blood in an esky, with up to three red blood cell units at one time. Three hospitals reported monitoring the temperature of the blood stored in eskies. In the 2005 audit, no hospital reported using an esky for blood storage.

Recommendation: Blood and blood products must be stored in an appropriate temperature-controlled and monitored environment; this may be a validated blood fridge or an alternative storage system that has been validated for that purpose. Infusion should commence within 30 minutes of being taken from a blood fridge (or validated container) and completed within four hours of removal.

Designated fridge

A designated blood fridge ensures blood products are stored at the correct temperature, are not contaminated through storage with other substances and that access is limited to authorised staff. This supports adequate record keeping and reduces the risk of errors, such as collection of wrong blood products.

Table 2: What equipment do you use to store red blood cells upon initial receipt in the hospital?

	All 2010 data (n = 88)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
Designated blood fridge	62 (70%)	8 (73%)	13 (100%)
Esky	5 (5%)	0 (0%)	0 (0%)
General use fridge	4 (5%)	0 (0%)	0 (0%)
Released directly from hospital pathology*	19 (22%)	5 (45%)	n/a
Other (vaccine fridge, ARCBS shipper)	6 (7%)	0 (0%)	0 (0%)

Note: A small number of responses included information for more than one site, therefore, percentage may add up to greater than 100 per cent.

* 'Released directly from hospital pathology' was not provided as an option in the 2005 survey.

One of the reported designated blood fridges used for initial receipt of blood was in fact an 'everyday bar fridge dedicated to specimens', while two other facilities reported using vaccine fridges. This was occurring in regional services where transfusions were occurring at a low frequency.

National guidelines for vaccine storage recommend that a vaccine fridge is not used for storing food or any other goods (*National vaccine storage guidelines: strive for 5,* Department of Health and Ageing 2005).

Of the 81 organisations that reported blood is stored upon initial receipt in a designated fridge or is released directly from the hospital pathology department, 31 (38 per cent) had additional fridges where blood products are stored.

Table 3: Are there any other fridges where blood or blood products are stored such as theatre, emergency departments or wards?

	All 2010 data (n = 88)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
Yes	**31 (35%)**	**5 (45%)**	**3 (27%)**
1 additional fridge	18	3	1 (Freezer)
2 additional fridges	8	1	2
3 additional fridges	5	1	0
No	**57 (65%)**	**6 (55%)**	**10 (77%)**

The majority of the additional storage fridges ('remote fridges') were considered to be designated fridges, except in five reporting facilities. Of the 49 remote fridges reported in 2010, 43 (88 per cent) were designated blood fridges, of which 69 per cent are labelled as 'blood fridge only'. These remote fridges were most commonly located in theatre, as well as oncology units and emergency departments. The large metropolitan and large regional hospitals tended to have multiple remote fridges.

Limiting the number of remote blood fridges increases the likelihood that all blood fridges will be monitored and managed appropriately. EQuIP 4 recommends that where a health care organisation has a blood refrigerator which is not situated within the pathology laboratory, the hospital is responsible for ensuring that a maintenance and quality control program for the refrigerator is in place in accordance with Australian Standard 3864 and any amendments: *Medical refrigeration equipment – for the storage of blood and blood products*.

The number of remote fridges beyond initial receipt continues to be high. The 2005 recommendations included keeping the number of fridges used as a designated blood fridge to a minimum and where designated fridges exist ensure that they are clearly labelled as 'blood fridge only'.

Recommendation: The number of fridges used as remote blood fridges outside of pathology are minimised and labelled 'blood fridge only'.

Temperature monitoring

Temperature monitoring of fridges is important to ensure fresh blood products are maintained at the required 2° to 6°C. ANZSBT guidelines (2007) state that blood products must be stored in an appropriate temperature controlled (and monitored) environment (4.5.1.1). Refrigerators and deep freeze cabinets used to store blood products must conform to Australian Standard AS 3864 *Medical refrigeration equipment – for the storage of blood and blood products*. This applies not only to blood banks but also the external locations that they supply within their hospital campus(es), other satellite locations and other healthcare facilities. Compliance with the standard is the responsibility of the organisation that owns the equipment (4.5.1.2).

Table 4: Are all your fridges temperature monitored?

	All 2010 data (81 facilities with at least one fridge to store blood)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
Yes	80 (99%)	12 (100%)	13 (100%)
No	1 (1%)	0	0

Only one facility reported that their fridge was not temperature monitored. This particular audit respondent had been under the impression that it was monitored; however, on review for the purpose of this audit, discovered that no temperature probe was in place.

Facilities reported that a combination of hospital and pathology staff is responsible for temperature monitoring.

Fridges need to be alarmed so that operational failure is apparent and staff can then take action.

Alarm systems, according to the AS 3864 (standard 2.7.2) whether central or local, should incorporate a battery-operated local aural and visual alarm and be activated when the temperature of the lagged probe falls to 2.5°C or reaches 5.5°C and/or if there is an interruption of electrical supply to the refrigeration cabinet. However, NATA (2005) recognises that there is a large variation in age, design and construction of blood bank refrigerators in use around Australia, and thus states a minimum requirement for a continuously monitored alarm with an audible signal.

NATA recommendation: Facilities with older refrigerators must ensure when a new replacement is planned that it conforms to the standard not only structurally and functionally but also with the monitoring recommendations.

In the clinical setting, a plan is required to ensure that there is a clear chain of responsibility for responding to fridge alarms, initiating appropriate response/s and taking corrective action (EQuIP 4).

Table 5: Do you have fridge alarms (local/central/none)?

	All 2010 data (112 fridges reported on)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (13 fridges reported on)	2005 data (14 fridges reported on)
No alarms	5 (4%)	0 (0%)	0 (0%)
Alarmed locally and centrally	38 (34%)	6 (46%)	6 (43%)
Alarmed locally only	46 (41%)	2 (15%)	4 (29%)
Alarmed centrally only	23 (21%)	5 (38%)	4 (29%)

Considering 41 per cent of fridges are alarmed locally only, it is important to ensure that such fridges are located in areas that are staffed at all times so an activated alarm can be actioned. The survey did not determine alarm locations.

There was a small number (n = 5, 4 per cent) of facilities which reported that fridges storing blood were not alarmed either locally or centrally. These facilities were located in regional areas and performing either less than six transfusions per year (n = 3) or less than one transfusion per week (n = 2).

Recommendation: All blood fridges should be alarmed and those with only local alarms should be located in areas that are staffed at all times.

Emergency plans

In the event of a refrigeration failure it is important that an emergency plan is enacted immediately so that the integrity of the fresh blood products is maintained by storage at 2° to 6°C.

Emergency plans for refrigeration failure were in place at 59 out of 81 (73 per cent) facilities (considering some facilities did not have refrigeration for blood storage). Of these plans, the majority were reviewed in the past three years or planned to be reviewed within the coming three years. One facility noted that the plan review date was overdue.

Table 6: Do you have an emergency plan/policy for refrigeration failure?

	All 2010 data (n = 81)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
Yes	59 (73%)	8 (67%)	11 (85%)
No	22* (27%)	4† (33%)	2‡ (15%)

*Four facilities indicated refrigeration for blood products located in hospital pathology department.

† Three facilities indicated refrigeration for blood products located in hospital pathology department.

‡ One facility did not have an emergency plan but reported that the fridge had battery back up.

Of the 22 facilities with no emergency plan, 18 reported that they had at least one fridge to store blood. One facility noted that although they did not have an official emergency plan, an informal plan was posted on the fridge.

The decline in reported emergency plans present between the years 2005 and 2010 cannot be easily explained based on the data collected.

Recommendation: All hospitals should have an emergency plan in the event of a blood fridge failure.

Refrigeration maintenance

ANZSBT (2007) provides general recommendations on guidelines for maintenance of equipment, including daily temperature checks for refrigeration.

The EQuIP 4 standards state that 'hospitals also need to be responsible for the correct functioning of the equipment; that is, the appropriate staff must respond to identified problems of the equipment'.

Only one hospital was unable to identify who is directly responsible for the routine maintenance and trouble shooting of the remote fridge.

Recommendation: All hospitals should identify the person with responsibility for management of blood fridges, including preventative maintenance and calibration.

Group O, Rh(D) negative blood for emergency supply of red cells

Only 9 per cent of donors in the population have group O, Rh(D) negative (O neg) blood type (Hollingsworth et al. 2004). As the universal donor blood group, demand for O negative blood is proportionally higher due to emergency use prior to recipient blood group availability and contingency holdings. It is important to ensure this rare and valuable resource is managed carefully.

Table 7: Do you have an O negative blood supply for emergency use?

	All 2010 data (n = 88)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
O neg on- and offsite	47 (53%)	7 (58%)	10 (77%)
O neg onsite only	12 (14%)	0 (0%)	2 (15%)
O neg offsite only	21 (24%)	5 (42%)	1 (8%)
No access to O neg	8 (9%)	0 (0%)	0 (0%)

Of the facilities reporting no access to an emergency blood supply either on- or offsite, four were facilities with an acute care service including emergency department, two facilities had an acute care service with no emergency department, and two were palliative care facilities.

Facilities reported a broad spectrum of utilising emergency O negative blood with 28 facilities not using any in the last two years, although it should be noted that it was difficult for some facilities to respond accurately due to pathology data collection methodology which often does not allocate blood for use as emergency versus non-emergency.

Table 8: How many times in the last two years have you required emergency O negative units?

	All 2010 data (n = 88)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
None	28 (32%)	1 (8%)	2 (15%)
Less than 10	30 (34%)	9 (75%)	9 (69%)
Between 10 and 100	14 (16%)	1 (8%)	1 (8%)
Greater than 100	1 (1%)	0 (0%)	0 (0%)
Unknown – used but unable to quantify	12 (14%)	1 (8%)	1 8%)
Missing data	3 (3%)	0 (0%)	0 (0%)

Note: This question was difficult for facilities to respond to accurately; pathologies frequently do not always allocate blood use as emergency versus non-emergency use, or the data system does not readily allow such allocation to be made.

If a hospital does not have access to O negative blood (or an appropriate emergency blood supply), there is a real potential risk to patients. In a 2008 coroner's report (State Coroner of Victoria, Case No. 1137/04) the lack of access to O negative blood was directly attributable to the death. Specifically, 'one particularly unedifying aspect of the evidence was the lamentable lack of knowledge of the ready availability at [the hospital] of two units of "O negative" or universal donor blood suitable for emergency use either in the absence of, or in anticipation of cross-matching. Significantly neither [doctors] were aware of its existence… [The hospital] should ensure that all doctors with practising rights are aware what facilities and resources for transfusion are available at the hospital' (p.14).

Recommendation: All appropriate staff, in facilities that provide emergency services or acute care services where there is a potential risk for bleeding, should be made aware of the availability and location of emergency blood and how to access such products.

Storage and handling of fresh frozen plasma

When thawing fresh frozen plasma (FFP) it is important that it is handled appropriately and in line with the recommendations in place by ANZSBT (2009).

ANZSBT states minimum requirements for the process of thawing FFP to include:

- dedicated waterbath or plasma thawer maintained between 30–37°C
- clip-lock (press seal, snap-lock, resealable bags)
- approved refrigerated storage equipment (refrigerator or freezer) that meets the requirements of, and is maintained in accordance with, AS 3864.

There are risks associated with thawing the product which should not be underestimated. These risks can impact either on bacterial contamination or the efficacy of the component.

Potential risks with thawing FFP and strategies to reduce harm

Potential risk	Strategies to reduce risk/harm
Pinholes or cracks in plastic	Place in a clean sealable plastic bag during thawing if not in vacuum sealed bags
Thawing temperature fluctuations	Monitor temperature of plasma thawer
Duration of thawing exceeded	Remove from thawer as soon as the entire contents are visibly liquefied
Dirty thawing equipment	Use clean well-maintained thawing equipment
Leaking or burst bag	Discard product as biohazard

Once thawed, FFP must either be infused or maintained in continuous refrigerated storage (at 2–6°C) for up to 24 hours.

In addition, the ANZSBT (2009) identifies quality control requirements:

- daily temperature quality control of storage and thawing equipment
- weekly cleaning (or more frequently if required) of plasma thawing waterbath or equipment
- ensure that water bath or thawer temperature stays within specifications (30–37°C) during thawing.

Of the hospitals reporting, 55 (63 per cent) stated that they received fresh frozen plasma.

Table 9: Do you receive fresh frozen plasma thawed or frozen?

	All 2010 data (n = 55)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 9)	2005 data (n = 11)
Thawed	32 (58%)	3 (33%)	3 (27%)
Frozen	22 (40%)	6 (67%)	8 (73%)
Thawed and frozen	1 (2%)	0 (0%)	0 (0%)

The pathology department was typically responsible (74 per cent) for thawing the FFP when it was received frozen from the Blood Service. When thawed by the pathology department, it was stated that an appropriate waterbath was used. In the remaining situations, ward staff or others were reported as thawing the FFP. One hospital reported thawing FFP by ‘leaving it on the bench at room temperature’ and another by ‘thawing in a sink of water 20 minutes’. The majority (70 per cent) of facilities reported that the frozen FFP was supplied by the Blood Service, whilst the remaining facilities stated that it was supplied by an onsite pathology. It should be the responsibility of the pathology supplying blood products to provide FFP in a form ready to transfuse. If FFP is received in a frozen state, the pathology provider should give advice on the correct procedures to thaw FFP.

Of the hospitals receiving FFP frozen, 88 per cent of hospitals report having a policy governing the use and maintenance of equipment used to thaw FFP.

Recommendation: FFP should be thawed under controlled conditions (ANZSBT 2009). There needs to be local policies and procedures governing the use and maintenance of equipment used to thaw FFP.

Blood product registry

It is essential to be able to trace products entering and leaving storage fridges so that individual donated blood products can be traced to individual transfused patients.

Blood and blood products used by hospitals need to be traceable from donor to recipient and from recipient to donor (Department of Health, Victoria, *Hospital circular* 32, 2008). Hospitals which fail to keep adequate records run greater legal risks should tracing be necessary. Consequently, all issues of blood and blood products must be adequately recorded to enable product recall in cases of:

- potential blood contaminated by bacteria or viral infections
- contamination occurring during manufacture
- labelling or testing errors
- other events which compromise the quality of the product and have the potential to put the recipient at risk.

An effective traceability system involves both keeping a register of blood products issued in the hospital, and recording transfused product details on the patient's file. The Australian Health Ministers' Conference (12 November 2010) issued a statement of stewardship including the expectation that health providers have an ordering and receipt verification process in place.

For hospitals with some form of blood refrigeration outside the pathology department (n = 69), 94 per cent stated that they maintain a register of products entering and leaving the fridge.

Recommendation: All hospitals with fridges storing blood or blood products located outside the pathology shall maintain a register of products entering and leaving the fridge.

Transport

General information

Transport of products to hospitals occurs by a variety of means. It is important to carefully control product temperature and prevent damage to these products during transport.

Fifty-five per cent of hospitals reporting had a blood bank or laboratory that supplies blood on site, therefore they did not require blood products to be transported as such. Of the 41 hospitals requiring transport of blood and blood products to their facility, the majority relied on a private pathology courier (either alone or in combination) to transport blood (71 per cent), followed by taxi (39 per cent), the Blood Service (29 per cent), voluntary drivers (15 per cent), bus (5 per cent), and other (12 per cent), including rail.

Of the 41 hospitals requiring transport, seven relied on methods other than a private pathology courier and the Blood Service.

Table 10: How are blood and blood products transported to your facility? (Tick all that are appropriate)

	All 2010 data (n = 41)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 5)	2005 data* (n = 13)
Blood service courier†	12 (29%)	2 (40%)	5 (38%)
Private pathology courier	29 (71%)	3 (60%)	7 (54%)
Voluntary drivers	6 (15%)	2 (40%)	1 (8%)
Taxi	16 (39%)	2 (40%)	3 (23%)
Bus	2 (5%)	0	3 (23%)
Plane	0 (0%)	0	1 (8%)
Train‡	n/a	n/a	9 (69%)
Other	5 (12%)	2 (40%)	0 (0%)

* All hospitals in 2005 were requested to answer this question, whereas in 2010, hospitals with a blood bank or laboratory that supplies blood onsite were not required to answer the question.

† Direct delivery by ARCBS to hospitals is isolated and discouraged. It is possible that the question was misinterpreted by the responding hospitals.

‡ Train was not provided as an option in 2010.

For hospitals with no onsite blood supplies (n = 41), 63 per cent reported the dispatch time between the Blood Service and their facility was less than an hour, 24 per cent took between one and two hours, and 20 per cent had a dispatch time of longer than two hours (including one hospital stating greater than 3 hours).

Reporting of unacceptable products

Products received not at the correct temperature must be reported, quarantined and/or returned to the supplier. It is critical that blood products are handled and stored in a manner to preserve their integrity. This includes maintaining the products at an appropriate temperature. According to ANZSBT guidelines, blood products, which during storage have reached a temperature outside of specification, have been stored in non-conforming equipment or where there is any doubt regarding the conditions of storage, must not be used for transfusion (except at the discretion of the Laboratory Director). Any such occurrences must be clearly documented and the product held in quarantine until a decision is made (ANZSBT 2007).

For hospitals requiring blood delivery from offsite, 46 per cent (19 of 41) reported assessing the blood product on arrival. Of the 22 hospitals not assessing temperature on arrival, 18 hospitals relied on private pathology couriers and/or the Blood Service, while another four hospitals were reliant on taxi or other.

Two hospitals reported that temperature has been unacceptable on at least one occasion. These hospitals also reported dispatch times greater than two hours. In those situations, the hospitals stated that they reported and/or returned products in such incidents.

Recommendation: Packaging and transit times of blood need to comply with guidelines. Temperature assessment on receipt of transported blood products should be considered for those deliveries at higher risk, for example use of a data logger in conjunction with validated transport times and logging delivery time. Your local pathology provider or the Blood Service <http://www.transfusion.com.au/blood_products/storage/blood_transport> can provide advice.

Other

Standards and overview for blood refrigeration

In Australia, standards for blood refrigeration are prescribed by NATA and ANZSBT for designated blood fridges in laboratories and Australian Council on Healthcare Standards (ACHS) for designated blood fridges in other locations within hospitals.

Sixty-four facilities (79 per cent) reported that they had accreditation requirements pertaining to blood and blood product storage. These facilities were correctly able to state NATA, ANZSBT, and EQuIP standards (1.5.5) as the accreditation requirements. Recognition of accreditation requirements increased in the hospitals participating in 2005 and 2010. Some of the hospitals reporting no accreditation requirements pertaining to blood and blood product storage may be accredited under ISO 9000, which has no standards for blood. Although only in draft and yet to be finalised, the Australian Commission on Safety and Quality in Health Care has developed National Safety and Quality Health Service Standards (ACSQHC 2010) which will potentially have a positive impact on such accreditation requirements. The draft standards include a 'blood and blood product safety standard'.

Table 11: Do you know whether you have any accreditation requirements pertaining to blood and blood product storage? If yes, what are they?

	All 2010 data (n = 81)	Hospitals submitting 2010 and 2005	
		Subset 2010 data (n = 12)	2005 data (n = 13)
Yes	64 (79%)	10 (83%)	8 (62%)
NATA/ANZSBT	38	5	8
ACHS	39	7	1
NATA/ACHS	20	4	1
No	17 (21%)	2 (17%)	5 (38%)

Recommendation: All hospitals need to be aware of all of the relevant Australian Standards for remote blood fridges.

Hospital committees

The majority of facilities (91 per cent) were able to nominate a hospital committee to which blood storage, handling and use is reported. Specialised transfusion committees were reported in 42 per cent of facilities. Other facilities stated that blood storage, handling and use issues are reported through committees such as patient safety, infection control, and quality. One facility noted that prior to having a transfusion trainer employed, blood product issues were not reported to any committee.

Variables potentially impacting hospitals' ability to correctly store and handle blood products.

The following three variables ranked most highly among all responding hospitals as negatively impacting the ability to adequately store and handle blood products:

- staff education
- staffing levels and mix
- distance from blood product supplier.

The issues impacting on the hospitals tended to differ based on the hospital category, although there was a common theme of staff education.

Table 12: Rank the following variables which negatively impact on your ability to appropriately handle and store blood and blood products, 2010

All hospitals	Metropolitan hospitals	Regional hospitals	Private hospitals
staff education	staff education	distance from blood product supplier	staff education
staffing levels and mix	staffing levels and mix	staff education	staffing levels and mix
distance from blood product supplier	financial constraints	financial constraints	lack of clinical governance

Overall, private hospitals tended to weight the variables as having a lower negative impact than the public hospitals.

Not surprisingly, regional hospitals stated that the distance from the blood product supplier had the greatest negative impact on their ability to appropriately handle and store blood and blood products.

In addition to the above variables, hospitals highlighted other concerns such as lack of documented informed consent, location of remote blood fridges (resulting in restricted access, or isolated from clinical staff to hear alarms), and poor compliance to blood registry completion.

A number of hospitals noted that the BloodSafe e-Learning had made education of staff more accessible; although a number of hospitals stated that ‘there was no funding to take the staff off the ward so that they can be trained in transfusion issues’.

Wastage was also raised as a concern due to poor practice, such as product being left out of the refrigerator for longer than standards allow, low compliance to completion of blood product registry, or unreliable equipment resulting in the temperature of blood components not being maintained within the acceptable temperature range.

Some of the hospitals noted that financial constraints had an impact on the ability to purchase equipment for appropriate storage of blood products that meets standards, and the ability to provide adequate training.

It should be the responsibility of the hospital’s clinical governance system to address the issues impacting on the safe delivery of blood and blood products. Variables impacting negatively on the ability to appropriately handle and store blood and blood products should be reviewed by appropriate committees, such as specialised transfusion committees, patient safety and quality committees.

Summary

Overall, hospitals across Victoria have a good understanding of basic blood product storage and handling procedures. It was evident that hospital types (metro versus regional versus private) had different barriers to ensuring the delivery of a safe blood product. Staff education was a common theme for all hospital categories. Regional hospitals identified distance from blood product supplier as a significant barrier to easily handle and store blood and blood products appropriately, while the private hospitals identified lack of clinical governance as having a negative impact.

It is pleasing to see that the majority of facilities (91 per cent) were able to identify a hospital committee to which blood storage, handling and use is reported to. It is appropriate that the oversight of transfusion issues such as storage and handling should occur within the hospitals' clinical governance framework. This can be achieved, in part, by having a standing agenda item on an existing quality review committee or having a transfusion committee that reports into the hospitals clinical governance framework.

The survey was also able to serve as an audit tool to highlight areas which may need improvement for individual hospitals. For example, one hospital had thought that all remote fridges were being temperature monitored, but in fact on review, became aware that it was no longer occurring.

A series of recommendations have been made as a result of the survey and are shown below.

Recommendation: Blood and blood products must be stored in an appropriate temperature-controlled and monitored environment; this may be a validated blood fridge or an alternative storage system that has been validated for that purpose. Infusion should commence within 30 minutes of being taken from a blood fridge (or validated container) and completed within four hours of removal.

Recommendation: The number of fridges used as remote blood fridges outside of pathology are minimised and labelled 'blood fridge only'.

Recommendation: All blood fridges should be alarmed and those with only local alarms should be located in areas that are staffed at all times.

Recommendation: All hospitals should have an emergency plan in the event of a blood fridge failure.

Recommendation: All hospitals should identify the person with responsibility for management of blood fridges, including preventative maintenance and calibration.

Recommendation: All appropriate staff, in facilities that provide emergency services or acute care services where there is a potential risk for bleeding, should be made aware of the availability and location of emergency blood and how to access such products.

Recommendation: FFP should be thawed under controlled conditions (ANZSBT 2009). There needs to be local policies and procedures governing the use and maintenance of equipment used to thaw FFP.

Recommendation: All hospitals with fridges storing blood or blood products located outside the pathology shall maintain a register of products entering and leaving the fridge.

Recommendation: Packaging and transit times of blood need to comply with guidelines. Temperature assessment on receipt of transported blood products should be considered for those deliveries at higher risk, for example use of a data logger in conjunction with validated transport times and logging delivery time. Your local pathology provider or the Blood Service <http://www.transfusion.com.au/blood_products/storage/blood_transport> can provide advice.

Recommendation: All hospitals need to be aware of all of the relevant Australian Standards for remote blood fridges.

References

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Appendix 1: 2010 survey

Blood Matters - Better Safer Transfusion Program

Blood Storage & Handling Survey

This survey is not a critical assessment of your facility and will not compromise your ability to access blood products.

The grey fields and/or checkboxes on the form need to be completed by you. Use the mouse or the TAB key to move the cursor from one field to another. It is estimated this survey will take between 30 minutes and 1 hour to complete.

When answering the questions consider how blood is stored and handled once it enters the hospital from the providing laboratory.

Hospital code

General

1. How often (approximately) do you transfuse blood or blood products (red cells, platelets, plasma, plasma derived products etc) in your facility?

☐ Never ***(This questionnaire is not applicable to you. Please go to Question 39).***
☐ <6 x /year ☐ less than 1/week ☐ greater than 1/Week ☐ 1 or more per day

2. Do you store blood and blood products for periods greater than 4 hours? ☐ Yes ☐ No

Storage and Handling of Red Blood Cells (RBC)

3. What equipment do you use to store RBC upon initial receipt in the hospital?

☐ designated blood fridge ☐ esky ☐ general use fridge (e.g., also holds tissues, specimens, drugs, food, etc)
☐ RBC are released directly from hospital pathology department
☐ Other, *please specify*

4. If you use an esky, how may RBC units do you usually store at one time? *Insert number*

5. If you store RBC in an esky or other container (which is not a fridge) do you monitor the temperature of blood products?

☐ Yes *if yes, how?* ☐ No

6. If you use a fridge to store RBC, who owns the fridge?

☐ hospital ☐ private pathology ☐ don't know

7. Does the fridge receive preventative maintenance?

☐ Yes *if yes, by whom and their position title?* ☐ No

8. Are there any other fridges where blood or blood products are stored such as theatre, Emergency Department or wards?

☐ Yes
1. *Please list* Designated Blood Fridge ☐ Yes ☐ No Is it labelled "Blood Fridge Only" ☐ Yes ☐ No
2. *Please list* Designated Blood Fridge ☐ Yes ☐ No Is it labelled "Blood Fridge Only" ☐ Yes ☐ No
3. *Please list* Designated Blood Fridge ☐ Yes ☐ No Is it labelled "Blood Fridge Only" ☐ Yes ☐ No

☐ No

9. Are all your fridge(s) temperature(s) monitored? ☐ Yes ☐ No

Comments: ____

Page 1

10. Who is responsible for temperature monitoring of the fridge(s)?

Fridge (from Qu 8)			
1. *Please list*	☐ hospital staff (other than Pathology)	☐ pathology staff	☐ don't know
2. *Please list*	☐ hospital staff (other than Pathology)	☐ pathology staff	☐ don't know
3. *Please list*	☐ hospital staff (other than Pathology)	☐ pathology staff	☐ don't know

11. Do you have fridge alarms?

Fridge (from Qu 8)			
1. *Please list*	☐ local	☐ central	☐ none
2. *Please list*	☐ local	☐ central	☐ none
3. *Please list*	☐ local	☐ central	☐ none

12. Do you have an emergency plan/policy for refrigeration failure? ☐ Yes, *if yes, review date?* ☐ No

13. Who is directly responsible for the routine maintenance and trouble shooting of the designated blood fridge?
Position Title:

14. Do you have an O negative blood supply on-site for emergency use?
☐ Yes, If Yes, how many units? & kept in which fridge(s) referred to in question 8? .
☐ No

15. Do you have access to O negative blood off-site for emergency use (even if you have an on-site supply)?
☐ Yes, If Yes, how long does it take to access (minutes/hours)
☐ No

16. How many times in the last 2 years have required emergency O negative units? *insert no. of times*

Storage and Handling of Fresh Frozen Plasma

17. Do you receive/transfuse Fresh Frozen Plasma (FFP)? ☐ Yes ☐ No (If NO, go to Qn.26)

18. Who supplies your FFP? (Please tick one or more responses)
☐ Australian Red Cross Blood Service (The Blood Service) ☐ Pathology on-site ☐ Pathology off-site
☐ Other *Please provide details*

19. Do you receive FFP thawed or frozen?
☐ Thawed ☐ Frozen ☐ Both thawed & frozen

20. If you receive FFP frozen, who is responsible for thawing it?
☐ Pathology ☐ Ward Staff ☐ Other

21. If you receive FFP frozen, how do you thaw it?

22. Does your facility have a policy governing the use and maintenance of equipment used to thaw FFP?
☐ Yes ☐ No

23. If you receive FFP frozen, how do you store it?
☐ Freezer ☐ Dry ice ☐ Other

24. If you store FFP in a freezer, is it temperature monitored? ☐ Yes ☐ No

25 If you store FFP in a freezer, do you have an emergency plan for freezer failure? ☐ Yes *if yes, review date?* ☐ No

RBC and FFP

26. If you store products in a fridge, do you maintain a register of products entering and leaving the fridge?
☐ Yes ☐ No ☐ Don't know

Transport

27; Does you facility have a blood bank or laboratory that supplies blood on site?
☐ Yes go to question 35
☐ No

28. How are blood and blood products transported to your facility? (Tick all that are appropriate)
☐ The Blood Service courier ☐ Private pathology courier ☐ Voluntary drivers
☐ Taxi ☐ Bus ☐ Plane
☐ Other

29. What is the approximate time between dispatch from The Blood Service and arrival at your facility?
☐ <1 hour ☐ 1-2 hours ☐ 2-3 hours ☐ >3 hours

30. Is the blood product temperature assessed on arrival? ☐ Yes ☐ No (If NO, go to Qn.35)

31. Is blood product temperature ever unacceptable on arrival? ☐ Yes ☐ No (If NO, go to Qn.35)

32. How often is the product temperature unacceptable? (% of delivery occasions)
☐ <1% (Rarely) ☐ 1 to 20% (sometimes) ☐ 21 to 50%(commonly)
☐ >50% (more often than not)

33. Is this more frequent with certain modes of transportation?
☐ Yes *if yes, which ones?* ☐ No

34. What do you do when you have temperature unacceptable blood products? (Tick all that are appropriate)
☐ Use them as normal ☐ Report ☐ Return to supplier
☐ Discard

Other information

35. Are you aware that there is a Standard for blood refrigeration? ☐ Yes ☐ No

36. Do you know whether you have any accreditation requirements pertaining to blood and blood product storage?
☐ Yes *if yes, what are they?* ☐ No

37. Which hospital committee are blood storage, handling and use reported to?

38. Which, if any, of these variables impacts negatively on your ability to appropriately handle and store blood and blood products (if possible please rank in order of impact where 1 = MOST negative impact and 9 is LEAST negative impact)?
Availability of information on standards
Staff education
Staffing levels and mix
Executive support
Lack of clinical governance (eg transfusion committee)
Financial constraints
Distance from blood product supplier
Storage facility size and type
Other

Can you provide examples for illustrative purposes?

Organisation/Respondent Details

39. Respondent's position held

40. Who is/are the pathology service(s) that provide you with blood products (excluding The Blood Service)?

(to help us determine all parties involved in the transfusion process at your site).

Please complete above form, filling information in the grey shaded boxes and check boxes, save report and email completed report to Jo.Perillo@health.vic.gov.au

If unable to send electronically, print completed report and mail to:

Blood Matters Program
Quality, Safety & Patient Experience Branch
Department of Health
GPO Box 4541
MELBOURNE VIC 3001

Please contact 9096 1303 if you have any difficulties.

Blood Matters - Better Safer Transfusion Program

Blood Storage & Handling Survey

Background

Adequate transportation, handling and storage of blood and blood products has an important impact on the safety and quality of blood products. Evidence suggests that there is variation in how products are transported and stored in hospitals.

The Blood Matters Program works with Victorian hospitals to ensure that products are transported handled and stored appropriately.

The Blood Matters: Patient Blood Management Working Group under the governance of the Blood Matters Advisory Committee (BMAC), has identified the need to repeat the survey to determine current practice following Report on *Blood Storage and Handling Survey 2005*, http://www.health.vic.gov.au/best/news/survey.htm .

Survey aims

To improve the quality of care provided to patients by ensuring the appropriate storage and handling of blood and blood products (Red Blood Cells and Fresh Frozen Plasma) after issue from a laboratory.

Objectives

i. To identify current storage and handling practices in hospitals
ii. To identify barriers (if any) to the implementation of appropriate storage and handling standards in hospitals.

Methodology

The methodology involves the completion of a survey of current storage and handling practices at your hospital. The survey questions consider how blood is stored and handled once it enters the hospital from the providing laboratory.

Individual hospital results will be kept confidential. Blood Matters will produce a report presenting aggregate results.

A designated member of hospital staff will complete the survey and return to the Blood Matters secretariat. The Blood Matters secretariat will coordinate the survey, taking responsibility for the distribution of the survey tools, data entry and analysis, and will collaborate with the members of the Patient Blood Management Working Group and BMAC in formulating the report.

Time frame

Please return the survey form by 30th November 2010

If the survey tools are misplaced, or further information is required please contact:

- Jo Perillo Transfusion Education Nurse Blood Matters on Tel: 90961303 or email: jo.perillo@health.vic.gov.au
- or Debra Birznieks Program Manager, Blood Matters on Tel: 90969037 or email: debra.birznieks@health.vic.gov.au

Appendix 2: Comparison of 2005 and 2010 survey

Survey differences between 2005 and 2010:
Additional questions are shown by yellow highlight; deletions are shown by ~~red cross out.~~

Blood Storage & Handling Survey

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Hospital code

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☐ designated blood fridge ☐ esky ☐ general use fridge (e.g., also holds tissues, specimens, drugs, food, etc)
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5. If you store RBC in an esky or other container (which is not a fridge) do you monitor the temperature of blood products?

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7. Does the fridge receive preventative maintenance?

☐ Yes *if yes, by whom and their position title?* ☐ No

8. Are there any other fridges where blood or blood products are stored such as theatre, Emergency Department or wards?

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☐ No

9. Are all your fridge(s) temperature(s) monitored? ☐ Yes ☐ No

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☐ Taxi ☐ Bus ☐ Plane
☐ Other ☐ ~~Train~~

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