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Heroes in red

Refrigeration's vital role in our blood banks

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HEROES IN RED

According to the Australian Red Cross Blood Service, demand for blood and blood products will grow by 100 per cent over the next 10 years.

Sean McGowan investigates the vital role refrigeration plays in the blood bank – and meets a fridgie whose personal experience led to a professional passion.

In 2013, qualified commercial refrigeration technician Nathan Wallace had just entered the medical refrigeration industry. He was working as a technician and sales manager for a local manufacturer of blood and plasma refrigeration units.

Little did he know that he would soon have a personal connection to this vital equipment.

In July that year, his then three-year-old son Hunter was diagnosed with a congenital heart disorder.

"As you can imagine this was quite a shock to my wife and I, and we weren't really sure how to handle it," recalls Wallace.

After multiple visits to Melbourne's Royal Children's Hospital (RCH), a date was set for surgery.

"It was at this time that we were given a consent form that we could choose to sign," Wallace says. "It dealt specifically with the permission, should Hunter require it during surgery, to administer a blood transfusion of some kind.

"I read the form, took a sigh of relief, and signed it with the utmost confidence that my son was in the best hands. You see, the company I worked for at the time was responsible for the supply, maintenance and ongoing service of the blood fridges and plasma freezers at the RCH's blood bank division."

Wallace knew the strict legal requirements and thorough systems in place at the RCH blood bank. If his son needed a transfusion, the blood contained within the fridges would be of the highest quality available.

"Most people sign that form with blind confidence and trust in our medical system," he says. "But they can have the same level of assurance as I did, whether they know it or not."

For Wallace, it was a defining moment. Since then he has been committed to applying his knowledge and technical capabilities in the field of medical refrigeration. He currently operates Medical and Commercial Refrigeration (MCR) Solutions in Melbourne.

"My 'why' is my son," he says. "But it's also your son, your daughter and your family."

> Medical and blood refrigeration is a specialised field that utilises equipment few of us would ever come across

A SPECIALISED FIELD

Just like other sectors of the refrigeration industry, medical and blood refrigeration is a specialised field that utilises equipment few of us would ever come across.

Although it's not as visible as the commercial refrigeration industry, the size of the sector is significant, and it plays a vital role in public health. Every hospital, university, medical establishment, pharmacy – and even local council – will rely on at least some form of medical refrigeration system.

Each requires a level of special care and maintenance above and beyond the usual standards. Common refrigeration systems in this sector include:

- Pharmaceutical refrigerators (Quality Care Pharmacy Program, or QCPP-certified purpose-built fridges) that are compliant for use in accredited pharmacies, GPs and council offices (often for school vaccinations).

> Failure to store blood correctly can make transfusions less effective, and even harm the patient

- Reagent refrigerators, which operate at the same temperatures as QCPP fridges (2°–8°C) but are not directly certified by the QCPP.
- Laboratory reagent or sample freezers, offering a temperature range from -120°C up to 0°C cryogenic systems.
- Blood fridges and plasma freezers – a very specific group of equipment that must comply with AS 3864-2012 and be listed on the Australian Register of Therapeutic Goods (ARTG).
- Custom processing refrigeration equipment that exists for a precise purpose such as processing apheresis or plasma in their transfusion bags, from the room ambient temperature to -30°C core temperature in under 50 minutes.
- Refrigerated incubators and environmental chambers used in the science sector for testing, study and simulation.

"Just about every hospital, nationwide, has at least one blood fridge – usually maintained by the pathology lab that occupies that particular hospital," says Wallace. "Plasma freezers are marginally less common, but they still have a large presence."

Although this equipment creates a refrigerated environment in much the same way as any other fridge, the controls are much stricter. Additionally, they must be able to record and report events to ensure they operate within the requirements of the relevant standards.

The storage of blood and blood components is covered by AS 3864-2012 Medical refrigeration equipment – For the storage of blood and blood products. This includes the requirements for manufacturers of the medical refrigeration equipment used. Blood is generally separated into components such as red cells, platelets and plasma (see breakout), so the standard indicates the temperatures the different components should be stored at.

According to the Australian Red Cross Blood Service, one in 30 Australians give blood each year (3 per cent).

This is critical, because failure to store blood correctly can make transfusions less effective, and even harm the patient.

INSIDE THE TECHNOLOGY

Refrigerants are undergoing big changes, and that includes those used within blood refrigeration and freezer equipment.

According to Wallace, R134a has been a commonly used refrigerant in the field. Some blood fridges and plasma freezers also use R507.

"Cabinets requiring -80°C temperatures (for the long-term storage of samples, or for experimental storage) have a two-stage cascade arrangement," he says. "These can use R507 in the first (high) stage and a blend of R508B and R290 (propane) in the low stage."

The energy efficiency of this equipment is increasingly coming under closer scrutiny, and lower-GWP natural refrigerants are also being considered.

Blood fridges and freezers must be listed on the ARTG, as administered by the Australian Government Department of Health's Therapeutic Goods Administration (TGA). The TGA describes this equipment as "Medical Device Class 2B", which has very stringent operational requirements and requires ongoing performance verification and calibration, as outlined in AS 3864.2.

Specialist service companies must be accredited with the National Association of Testing Authorities (NATA), as well as compliant with ISO9001 – the international standard that specifies requirements for a quality management system (QMS).

In line with AS 3864.2, the alarms of the refrigeration unit must be tested every six months.

"The requirement is to verify that the refrigeration unit has operating alarms at 2.5°C and 5.5°C to ensure correct operation between these temperatures," says NATA sector manager – inspection, Julian Wilson.

A spatial temperature distribution check also has to be carried out to ensure there are no significant variations in temperature across the interior space of the equipment. The check is performed when the cabinet or room is installed, and after relocation or significant repairs or other significant alterations to the internal space.

Wallace says that to meet this requirement, a spatial map (3D temperature mapping of each shelf and location of blood product storage) is created.

"A NATA-accredited temperature data logger is used for this task," he says. "The testing company maps the temperature distribution across the blood product storage space, on every shelf, for a minimum of eight hours as per AS 3864-2012."

The spatial map must be performed to the standard of AS ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.

Such precise temperature control presents real challenges for both equipment operators and service providers.

FROM DONOR TO PATIENT

Step 1 At donation

A whole blood donation is approximately 470mL (an adult has from 5–7L of blood in their body). This donation is collected over 5–10 minutes and the first 30mL is diverted into sample tubes for testing.

Step 2 The blood

Once donated, the whole blood is centrifuged and separated into red cells, buffy coat (white cells and platelets) and plasma, so that recipients can receive the most appropriate treatment. It is very rare for a patient to need whole blood.

All red cells and platelets are filtered to remove white cells. All platelets are screened for bacterial contamination.

Step 3 The samples

Blood service laboratories test for ABO and Rh (D) blood type, and perform viral screening, red cell antibody screening and syphilis screening.

When required, additional donor testing is performed including confirmatory testing, malarial antibody screening and CMV (Cytomegalovirus) antibody screening.

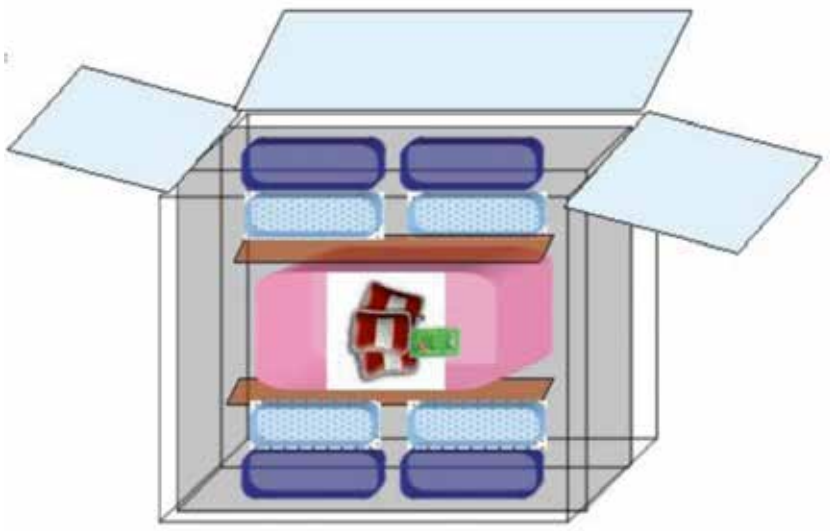
Step 4 After testing

Blood components are labelled for release and made available in the Blood Bank stock inventory.

Step 5 Transport and delivery

Orders are packed into shippers according to pack type and component temperature requirements, and transported to hospitals and laboratories using a consignment tracking system.

Source: tranfusion.com.au

<table>
<tr><th rowspan="2">R1</th><th>Number of components per shipper</th><th>Validated transport time*</th><th>Legend</th><th>Name</th><th>Quantity</th><th>Note</th></tr>
<tr><td>4 to 8 red cell units (if <4 use ballast)</td><td>2 hours 40 minutes</td><td></td><td>Foil pouch</td><td>1</td><td>Used to line box and contains all other items</td></tr>
<tr><td colspan="3" rowspan="8">  </td><td></td><td>Frozen -19°C</td><td>2</td><td></td></tr>
<tr><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td></td><td>Cardboard divider</td><td>1</td><td>Used to stop contact with ballast</td></tr>
<tr><td></td><td>Extra chilled ballast (as per table)

Place ballast outside the plastic bag liner</td><td colspan="2"><table><tr><th>Number of red cell units</th><th>Number of ballast packs</th></tr><tr><td>4 to 8</td><td>0</td></tr><tr><td>3</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>1 (or full paediatric set)</td><td>3</td></tr><tr><td>1 to 3 paediatric units</td><td>4</td></tr></table></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td>Used to contain red cells and logger if added</td></tr>
<tr><td></td><td>Cardboard divider</td><td>1</td><td>Used to stop contact with ballast</td></tr>
<tr><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td colspan="3">Notes: *If anticipated transport time exceeds the maximum transport time a data logger must be placed in with the shipment.</td><td>Frozen -18°C</td><td>2</td><td>Place on bottom</td></tr>
</table>

Source: Blood Service Shippers – Receipt and Use by External Institutions, Australian Red Cross Blood Service, 2018.

"Some fridges are larger spaces – including walk-in spaces – that may be accessed regularly, while others are quite small," says Wilson. "Cooling a filled fridge is part of the challenge, while maintaining that temperature across the space when loads are varied is another part."

He says temperature is possibly the most difficult SI quantity to measure with confidence; slight variations in temperature are not easy to identify.

"All temperature-controlled enclosures will show natural variation across their spatial range, and this changes with loading, use and the condition of the equipment."

The standard compensates for rapid changes in the air temperature (for example, when the door is opened) by putting sensors in bags that mirror the bulk and properties of stored blood.

But ultimately, such variability means there is a lot to consider in establishing that a fridge is performing as specified.

BLOOD ON THE MOVE

As well as storing blood in stationary refrigeration, Australia's health service must transport blood components to wherever they are needed using a consignment tracking system.

According to the Australian Red Cross Blood Service, blood components are usually transported under similar temperature conditions as when they are stored. To maintain these temperatures, specially designed cardboard boxes with thermal insulation inserts are used, along with a variety of frozen and chilled coolant packs arranged in different configurations.

These configurations depend on the blood component type being transported, the number of components, the ambient temperature and the expected transit time.

For instance, red cell configurations are designed to maintain components within 2–10°C, while platelet configurations are used maintain components within 20–24°C.

Nathan Wallace and his (healthy) son Hunter.

Data loggers are also used to continually record the internal temperature of the packaged configurations if the transport time is expected to exceed the maximum transport time. And if the data logger shows the temperature specifications have been exceeded, the data is analysed to decide whether the components can still be used.

MAKING A DIFFERENCE

For many of those who work in the medical and blood refrigeration sector, including Wallace, the ability to have a direct impact on the health of the community is a big appeal.

"I have always wanted my profession to be more than just a job – more than just a way to provide for my family," says Wallace.

"The jump from commercial refrigeration and the food services industry to medical was very interesting, and I learned a lot about the way the health industry works – both positive and negative. But in the end, I've found what I want to do with my skill set."

Patients like young Hunter Wallace – who five years after his surgery is a fit and healthy eight-year-old boy – have not just the donors to thank, but also the refrigeration systems that transported the blood safely to them. According to the Australian Red Cross Blood Service, one in three Australians will need blood or blood products in their lifetime. ■

CLINICAL CONTROL

The Australian Red Cross Blood Service separates blood into different components – red cells, platelets and plasma. Patients can then receive the blood component they need. According to the Blood Service, components should be stored as follows:

Red cells

Must be stored from 2–6°C. Red cell components have a shelf life of 42 days – although paediatric red cells last only 35 days and washed red cells just 28 days. Red cell components must not exceed 30 minutes at room temperature.

Platelets

Must be stored within a temperature range of 20–24°C. They have a shelf life of just five days, and require gentle, continuous agitation in a single layer on a platelet agitator. Therefore, the storage devices used to store platelets are very specific in their design.

Fresh frozen plasma, cryodepleted plasma and cryoprecipitate

Must be stored at or below -25°C, and have a shelf life of 12 months.

Source: mytranfusion.com.au