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# Based on World Marrow Donor Association (WMDA) Guidelines for couriers and the transportation of haemopoietic progenitor cells (HPC-(M), HPC (A) and therapeutic cells- T Cells)

# INTRODUCTION

The World Marrow Donor Association (WMDA) is a worldwide network of stem cell registries and cord blood banks that provide haemopoietic progenitor cells (HPC) from voluntary unrelated donors to those in need of bone marrow transplantation. Over 49% of the HPC collected from unrelated donors are transported across international borders[1].

## 1. COURIERS

The courier has sole responsibility for the safe and timely transport of HPC from the collection centre to the transplant centre. Selection and assignment of courier responsibility is a collaborative process between NZBMDR, Transplant Centre and Collection facility.

NZBMDR will organize the courier training, travel, insurance and accomodation. A folder containing all paperwork required will be forwarded to the courier at least 4 days prior to departure. **Form C04 Courier paperwork**

### 1.1. Courier requisites

Couriers must be trained and equipped to fulfil the responsibilities as described below. The Transplant centre is responsible for providing any extra/special transport specifications.

To be selected as a courier, the person **must:**

- not be related to the donor or patient;
- be an experienced independent international traveller;
- have no other obligations until after the HPC have been delivered;
- have access to a credit card with a reasonable limit;
- be trained in all policies and procedures required for the transportation of HPC;
- must have adequate command of the English language or the language(s) used in the countries to be visited for international transport.
- Have a mobile phone with international roaming
- Have access to a credit card with a minimum of $2000

It is preferable that the courier has experience in transporting HPC within NZ and Australia prior to acting as an international courier.

**NZ Couriers must sign C 02 Courier Authorisation prior to commencing each collection.**

### 1.2. Commercial Courier companies

If a commercial courier company is used, there needs to be a direct committed relationship between the transport company and the registry/transplant centre. The company needs to understand that their "normal" business/ transport procedures will not apply to the transportation

of HPC products and the company must be able to customise the service they provide to meet these needs.

The company must be able to provide trained couriers that meet NZBMDR guidelines. NZBMDR must be involved with the company in the development of the service and the training of the couriers.

### 1.3. Courier responsibilities

The courier is responsible for ensuring that the HPC is transported safely from the collection to the transplant centre in the shortest possible time and at the temperature requested by the transplant centre.

NZBMDR recommends that non-cryopreserved peripheral blood stem cells (PBSCs) are transported between +2 and +8$^{o}$ C[2].

The courier **must**:

- remain in possession of the HPC product at all times;
- carry documentation relating to transportation of the HPC product;
- verify accuracy of information on HPC labels on the product and accompanying tubes;
- place the product bags and samples properly in the cooler ( see section 4 );
- make every possible effort to ensure that the HPC does not pass through Xray screening at security checkpoints;
- deliver the HPC directly to the designated person at the transplant centre or processing laboratory;
- inform the transplant centre of possible delays;
- not consume or be under the influence of alcohol or sedative drugs while transporting the HPC;
- always maintain patient and donor confidentiality (see 1.7).

If transport of the HPC would be jeopardised by refusal to allow X-ray screening of the HPC, the courier should permit the cells to pass through the X-ray screening device in a single instance. This incident must be recorded on the Transport Stem Cell Audit Form C06

Note that the effect of cumulative X-ray screening on HPC product viability has not been determined[3].

### 1.4. Equipment:

All couriers should carry the following equipment:. Cooler boxes and thermometers must be validated

- An isothermal transport box or a rigid puncture proof thermally insulated cooler for transport of non-cryopreserved HPC
- Cooler and coolant packs or isothermal temperature shells;
- Programmed data loggers or thermometers with an exterior temperature display if required by the TC;
- Disposable gloves for assistance with inspection of HPC.

### 1.5. Documentation

NZBMDR will organize travel, accommodation and travel insurance.
A folder containing all paperwork required will be forwarded to the courier at least 4 days prior to departure

The documentation may consist of:

- Airline ticket or electronic ticket information;
- Train ticket (or instructions on how to purchase train ticket);
- Passport – must be valid for a minimum of 6 months
- Visa/ entry permits;
- Information on reservation of accommodation;
- Travel insurance;
- Verification of Prescription for HPC collection;
- Donor infectious disease marker testing (most recent results within 30 days of collection);
- Letters to airport security at departure, transit and arrival airports as required;
- HPC product accompanying documentation (provided at collection centre).

**C01 Transplant, Collection and Courier details**

### 1.6. Luggage

Most airlines, especially on international sectors, strictly enforce the limit on the number, size and weight of items that may be carried as cabin baggage including the cooler used for transportation of HPC. Therefore couriers should be aware that although carriage of personal items as cabin baggage is recommended, many international airlines will require couriers to check in their personal luggage. When not used for the transportation of HPC, unfrozen coolant packs must be checked in. The HPC product must **never** be placed inside checked luggage or inside the courier's personal cabin baggage. It is recommended that the HPC product be placed under the seat in front of you.

### 1.7. Confidentiality

The courier must accept the policies and procedures of the relevant national registries and/or the transplant and collection centre regarding courier, recipient and donor interaction. Couriers must not disclose to the recipient's family or staff of the transplant centre or collection centre, details that could result in identification or location of the donor or recipient. The courier must ensure that labels on the outer transport container do not compromise donor/ recipient confidentiality.

### 1.8. Insurance

Couriers will be covered by NZBMDR travel insurance for international destinations.

### 1.9. Flight arrangements

NZBMDR will book and prepay for all flights and accommodation

- Flights will be booked with minimum stopovers;
- Appropriate aisle seat allocation will be requested .
- The courier must be aware of alternative modes of transport if substantial delays arise;

- NZBMDR will notify airline and security staff at airports when required;
- For long haul flights the courier must make contact with the collection centre at least one day prior to the scheduled collection;
- All changes in original transport arrangements must be communicated immediately to NZBMDR
- NZBMDR will provide the Collection Centre registry with the itinerary and contact numbers of the courier at least 4 days prior to departure of the courier.

## 2. LABELLING

Labelling should adhere to IATA (International Air Transport Authority) and national regulations concerning the safe handling and transport of biological material at all times (www.iata.org).

### 2.1. Labelling of HPC product and blood samples

Labelling of the HPC and accompanying blood samples must comply with any regional, state or national regulatory/ legal requirements or manufacturing license requirements of the collection centre and/ or transplant centre and with current FACT/JACIE standards .

Labels must be legible and printed using waterproof ink labels and can contain the following information:

- unique numeric or alphanumeric product code
- donor identification code
- recipient identification code
- type/ proper name of product
- ABO group and Rh type of donor
- collection date, time and time zone at end of collection
- product volume / cell count
- bag number and total number of bags
- mandatory statements if applicable in accordance with Appendix I (FACT/JACIE standards )[4]

### 2.2. Labelling of transport container

The outside of the cooler must be labelled with appropriate wording (with regard to local regulations), for example:

**MEDICAL SPECIMEN – HANDLE WITH CARE**

**DO NOT X-RAY**

**WARNING: Contains human tissue for transplantation**

**Do not place near heat**

**Do not freeze**

**Do not delay delivery**

When transporting the cooler without HPC, the label should be covered by the courier and allowed to pass through all security checkpoints including X-ray machines if required.

Address labels for the transplant centre including institution, address, contact details and phone numbers should be affixed to the cooler in accordance with current FACT/JACIE standards[4] or other local regulations but ensuring donor/ recipient confidentiality during transportation.

### 2.3. Documentation

In addition to details on the HPC product label, the accompanying documentation can contain the following information:

- Recipient name;
- Name, address and 24 hour phone number of contact at the collection facility/ donor registry;
- Name, address and 24 hour phone number of contact at the transplant centre;
- Results of donor infectious disease testing;
- Results of preliminary testing (cell counts as appropriate for product release);
- Circular of Information (AABB) or equivalent;
- Letters for security at departure and transit airports or train stations.

## 3. PACKING HPC FOR TRANSPORTATION

### 4.1 Containers

- Packaging and shipping containers should be validated to hold at the required temperature for in excess of the anticipated transit time, under the expected range of external temperatures;
- Data loggers should be used to record the temperature of the HPC during transportation but thermometers with a protected probe and exterior temperature display may be used;
- The courier must be familiar with instructions for using the container and datalogger:

**C 10 Credo Box Instructions**

### 4.2 Cooler and Coolant Packs

- Attach the probe of a thermometer or data logger if available to the outer bag;
- Arrange bags, pre-frozen coolant packs and any insulating material as specified by transplant centre for adequate temperature control over the estimated transit time into the cooler;
- Bags of HPC must be thermally insulated from frozen coolant packs to avoid spot freezing;
- Check the temperature every 1 to 2 hours from the external data display if not using data loggers and record the temperature. The temperature of the HPC should be maintained at no less than +2°C;. There is no need to open the cooler.

**C 07 temperature monitoring**

### 4.3 Additional Specimens

Additional peripheral blood or bone marrow specimens should be placed inside specimen transport containers or plastic bags prior to placing in cooler or isothermal transport box with the HPC.

## 5 TRANSPORT OF HPC

If the scheduled departure time is late in the day, the transplant centre may request the collection centre via the relevant registry to store the cells at +4°C for collection by the courier at a time suitable for flight connections.

Collection centres should wherever possible, depending on availability of equipment, provide HPC in bags:

- without spikes or access sites inserted;
- with lines heat sealed rather than clipped and of sufficient length to allow the use of a sterile connecting device to access the bag if required; and
- with at least one port available for use at the transplant centre.

### 5.1 Transportation of HPC, marrow

The collection centre should ensure that the collection media has been validated according to local protocols to provide sufficient anticoagulation and viability of bone marrow during the estimated transit time. NZBMDR requests the addition of ACD to marrow in the ratio of 1:5 for transport over 8 hours duration. Bone marrow collected for adults and large paediatric recipients should be divided into at least two blood collection / transfer packs.

### 5.2 Transportation of HPC, apheresis and therapeutic -T cells

Although this may vary according to local protocols, anticoagulant will be added to apheresis products during collection on the cell separator and as programmed by the apheresis machine.

For long distance transportation and/ or overnight storage of HPC, Apheresis, the final concentration of nucleated cells in the collection is important for viability. To minimise the loss of viability, the concentration of nucleated cells should be reduced by the addition of autologous plasma in the processing laboratory. Apheresis products are usually transported in the collection pack of the cell separator kit (i.e. 1 bag per apheresis collection).

The majority of HPC collections by apheresis require a single day of collection, so the courier should anticipate leaving after the first scheduled day of collection depending upon flight availability. If a second collection is required, the first collection should be stored at +4°C without agitation in a blood product refrigerator at the collection centre.

## 6 COURIER TASKS DURING ASSIGNMENT

### 6.1 Arrival at the city where the collection centre is located

On arrival at the city where the collection centre is located, the courier must contact the designated person in order to:

- confirm arrival, contact and travel details;.
- Place the coolant packs at –4°C or –20°C (freezer) as instructed by transplant centre
- Coolant packs may be placed inside a labelled bag in a freezer at the hotel . If this is not possible deliver the cooler and coolant packs to the collection centre
- confirm the time and location for collection of the HPC;
- confirm transportation from the hospital to the airport or train station.

### 6.2 On the day of collection

On the day of collection, the courier must:

- arrive at collection centre at the arranged time and location;
- make contact with the designated contact person;
- carry personal identification (eg. passport) and the documentation required for the transport of HPC;
- crosscheck with the collection centre representative, the type, number and labelling of bags containing HPC, the cell count and the addition of anticoagulant against the request for HPC;
- pack HPC and additional specimens into the cooler (refer to section 4) according to instructions provided by the transplant centre;
- collect and check all accompanying paperwork (refer to section 1.5);
- **DO NOT add** heparin, antibiotics or any other additive to the HPC during transportation;
- declare the HPC on all customs/ immigration and quarantine forms for inspection as required;
- supervise any visual inspection of the HPC;

**C06 Transport of Stem cell Product audit**

### 6.3 Arrival at city where the transplant centre is located

On arrival at the city where the transplant centre is located, the courier must:

- travel immediately to the transplant centre or processing laboratory according to instructions;
- contact the designated staff member at the transplant centre or processing laboratory for hand over;
- record the time of delivery and temperature of the HPC upon arrival;
- cross check the HPC and specimen tubes against the details provided by the collection centre and the request for HPC;
- visually inspect the bags and the HPC for anomalies such as visible clumping;
- record any events or incidents during transport.
- sign for delivery of the HPC to the transplant centre
- Alert transplant centre staff regarding documents requiring completion and return to the collection centre post delivery and/ or post transplant.

**C05 Collection and Verification of HPC**

## 7. Courier Incident Management

### 7.1 Introduction

The transportation of HPC by a courier is a critical step in transplantation using voluntary unrelated donors. Any incidents or deviations in transport can have a significant impact on patient outcome; this is particularly important for long distance transport. An incident is defined as an unplanned event that occurs during the transportation of HPC that results in, or has the potential for, injury to the recipient or damage, delay or other loss to the HPC.

### 7.2 Active management

- The 'first point of contact' must be clearly communicated to, and understood by, the courier in advance of travel;
- A courier must notify their 'first point of contact' as soon as they are aware of any incident or potential incident, although the requirement for notification should not delay resolution of the incident;

### 7.3 Analysis and Corrective Action

- Any organisation involved in transport of HPC must conduct a thorough review of all incidents using appropriate methodologies
- The review of each incident should outline both the corrective actions taken either immediately or after the event to remedy the incident and preventive actions taken to prevent recurrence of the incident;
- All corrective and preventive actions must be followed-up to ensure that changes have been effective and lead to process improvement;
- a SPEAR shall be submitted to WMDA when a reportable incident occurs.

## 8. REFERENCES

[1] WMDA Annual Report Stem Cell Registries 2014 and WMDA Annual Report Unrelated Cord Blood Banks/Registries 2014
[2] Antonenas, V. Fresh PBSC harvests, but not BM, show temperature-related loss of CD34 viability during storage and transport. Cytotherapy (2006) Vol 8, No 2, 158-165
[3]Petzer et al. (2002) Breaking the rules? X–ray examination of haematopoietic stem cell grafts at international airports. Blood 99: 4632-4633
[4]FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration.

## ADDITIONAL REFERENCES

Goldman JM (1994) 'A Special Report: Bone Marrow Transplants Using Volunteer Donors - Recommendations and Requirements for a Standardised Practice Throughout the World – 1994' Update Blood 84: 2833 – 2839
Cleaver SA, Warren P., Kern M. et al., (1997) 'World Marrow Donor Association (WMDA) Special Report: Donor Workup and Transport of Bone Marrow' (Website: www.worldmarrow.org)
Code of Federal Government Regulations, Title 21-Food and Drugs, Part 1271 Human

Cells, Tissues and Cellular and Tissue Based Products (USA) Circular of Information for the Use of Cellular Therapy Products (AABB)

## 9. WEBSITES Referred to in the preparation of these guidelines

World Marrow Donor Association - www.wmda.info
Bone Marrow Donors Worldwide - www.bmdw.org
American Association of Blood Banks – www.aabb.org
International Society for Cellular Therapy – www.celltherapysociety.org
National Marrow Donor Program – www.marrow.org or www.network.nmdp.org/
Australian Bone Marrow Donor Registry - www.abmdr.org.au
Japanese Marrow Donor Program - www.jmdp.or.jp
Anthony Nolan Trust – www.anthonynolan.com
ZKRD – www.zkrd.de
IATA – www.iata.org