
Instigation of Haemopoietic Progenitor Cell Apheresis Collections

1. PURPOSE

This procedure describes a co-ordinated, consistent and systematic process for the facilitation of Haemopoietic Progenitor Cells by Apheresis (HPC-A) collection from donors for allogeneic and autologous bone marrow transplantation.

2. SCOPE

This document applies to all trained staff who are involved with the care and treatment of donors requiring HPC-A collection, processing with or without storage as required for transplantation. Staff of the Vaccine Study Laboratory; process HPC-A according to their Standard Operating Procedures.

3. RESPONSIBILITIES

This procedure applies to all trained staff involved with donors requiring HPC-A collection, processing with or without storage to ensure a co-ordinated, consistent and systematic approach to HPC-A harvesting.

It is the responsibility of the **requesting primary Consultant** to;

- explain apheresis to the donor and parents / caregiver as applicable.
- attain consent for the process. Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells.
- initiate donor-testing requirements as applicable for HPC-A collection.
- complete Haemopoietic Progenitor Cell Harvest Booking Form. CL-F-003.
- complete Request for Stem Cell Processing. CT-F-089.
- ensure that **ALL** completed documentation is signed and sent to Bone Marrow Transplant Clinical Nurse Coordinator (BMT CNC).
- oversee the care of the donor during HPC mobilisation.

It is the responsibility of the **Bone Marrow Transplant Clinical Nurse Coordinator (BMT CNC)** to;

- liaise with **ALL** key stakeholders interfaced with the HPC-A collection and processing procedure.
- confirm treatment bookings with the donor and parents / caregiver and associated Departments.
- ensure that **ALL** completed documentation is filed and distributed as required.
- liaise with the requesting primary Consultant as appropriate.

It is the responsibility of the **Apheresis Nurse (Ambulatory Care Centre)** to;

- liaise with the BMT CNC, processing laboratory(s) and the Head of the HSCT Programme or delegate for the duration of the collection(s).
- perform the HPC-A Collection(s) and labelling according to Standard Operating Procedures.
- hand over custody of care of the final HPC-A product to the respective laboratory.
- ensure the patient is stable throughout the collection and at completion of the HPC-A procedure before leaving the collection facility.

Instigation of Haemopoietic Progenitor Cell Apheresis Collections

It is the responsibility of the **Scientists of the Cell Therapy Flow Cytometry Laboratory** to;

- liaise with the BMT CNC, Apheresis Nurse and the Head of the HSCT Programme or delegate.
- accept custody of care of the final HPC-A product.
- process and store the HPC-A product according to Standard Operating Procedures.
- notify the Head of the HSCT Programme or delegate with the final HPC-A product CD34 yield.

It is the responsibility of the **Head of HSCT Programme or delegate** to;

- confirm optimum mobilisation regimen for the donor.
- confirm initiation of HPC-A collection.
- oversee the care of the donor during HPC-A collection(s).
- oversee the collection and processing of HPC-A products within the HSCT Programme.
- liaise with the requesting primary Consultant as appropriate.

It is the responsibility of the Quality Manager (QM) or equivalent to ensure implementation, maintenance and compliance with this procedure.

4. DEFINITIONS

CCC – Children's Cancer Centre within The Royal Children's Hospital

CD34 – Surrogate marker for haemopoietic stem cell

CFC – Colony Forming Cells

BMT CNC – Bone Marrow Transplant Clinical Nurse Coordinator.

Donor – A person who is the source of cells or tissue for a cellular therapy product.

G-CSF – Granulocyte Colony Stimulating Factor

HPC – Haemopoietic Progenitor Cell

HPC-A – Haemopoietic Progenitor Cells-Apheresis. Peripheral blood collected by apheresis as a source of haemopoietic progenitor cells. Mobilised unless otherwise stated.

HSCT – Haemopoietic Stem Cell Transplant

5. EQUIPMENT AND SUPPLIES

Not applicable.

Instigation of Haemopoietic Progenitor Cell Apheresis Collections

6. PROCEDURE

6.1 Completion of referral by the Primary Consultant

- All relevant documentation is compiled as a "HPC Collection Referral Pack"; these documents are available to treating Consultants from the BMT CNC and comprise of:
 - Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells.
 - Haemopoietic Progenitor Cell Harvest Booking Form. CL-F-003.
 - Request for Stem Cell Processing. CT-F-089.

- The Primary Consultant introduces the treatment of HPC-A Collection and subsequent transplantation (allogeneic / autologous) to the donor parents / caregiver as applicable. This is inclusive of providing relevant educational literature.

- Informed Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells, is obtained according to The Royal Children's Hospital Policy; Consent – Informed. Policy Number:RCH0040.

- It is a requirement that the Haemopoietic Progenitor Cell Harvest Booking Form (CL-F-003) and Request for Stem Cell Processing (CT-F-089) are completed and signed.

- Mandatory donor testing prior to HPC collection is initiated by the Primary Consultant and is according to requirements as documented in Standard Operating Procedures. The Head of the HSCT Programme **MUST** be notified of all donors with any positive virology marker.

- All completed signed documentation is forwarded to the BMT CNC as soon as possible. If there is an anticipated delay, the BMT CNC may commence liaising with all the relevant Departments, **BUT NO BOOKING IS CONFIRMED UNLESS ALL** documentation is received.

6.2 Receipt of Referral by the HSCT Programme

- The BMT CNC will liaise with all relevant key stakeholders, they may include;
 - the Apheresis Nurses of the Ambulatory Care Centre,
 - Paediatric Intensive Care Unit as required, and for **ALL** collections from **donors <15Kg**,
 - the Scientists of the Cell Therapy Flow Cytometry Laboratory,
 - Day Oncology Unit, (DOU)
 - Theatre,
 - CCC Fellow(s),
 - CCC Ward (NUM / AUM)
 - Pharmacy,
 - in addition, the Scientists of the CCC Vaccine Study Laboratory.

- Completed documentation will be filed or distributed as appropriate;
 - Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells in donor's history and a copy to donor parents / caregiver.
 - Haemopoietic Progenitor Cell Harvest Booking Form, CL-F-003. Completed copies circulated (as appropriate), the original will be filed by the BMT CNC.
 - Request for Stem Cell Processing (CT-F-089) original to Cell Therapy Flow Cytometry Laboratory, copy to Apheresis Nurse in Ambulatory Care Centre and a copy filed by the BMT CNC.

Instigation of Haemopoietic Progenitor Cell Apheresis Collections

- Anticipated date of collections is posted on a monthly planner as devised and circulated by the BMT CNC. The Primary Consultant is notified of the impending dates for collection.
- The appropriate CNC in consultation with the Primary Consultant will book chemotherapy admissions (in accordance with the mobilisation regime) and notify all the relevant Departments. This may involve inpatient and / or outpatient bookings.

NOTE the Head of the HSCT Programme will be available to advise on optimal mobilisation strategies.

6.4 Mobilisation

- Once the dates for the impending mobilisation chemotherapy (as required) and forthcoming HPC-A collection are confirmed, the BMT CNC notifies the donor parents / caregiver for future attendance(s) at the relevant Departments. If mobilisation is with G-CSF alone, the BMT CNC will arrange a time for education and receipt of the medication, vein assessment and orientation of the Apheresis area in the Ambulatory Care Centre.

NOTE ALL donors, parents / caregiver will have GCSF education (as applicable), vein assessment (donor) and orientation of the Apheresis area in the Ambulatory Care Centre preferably and if possible during the same hospital visit.

- At the next arranged appointment, the BMT CNC will meet with the donor parents / caregiver to ensure that they have received a copy of the signed Consent. Following vein assessment by the Apheresis Nurses, the BMT CNC will notify the CCC Fellow who will ensure a Theatre booking if Vascath insertion is required. The Primary Consultant or delegate must prescribe G-CSF and request post mobilisation FBE and peripheral blood CD34 enumeration monitoring as appropriate.
- If G-CSF is to be administered as an outpatient, nursing staff of the DOU will insert an Insulfon® port. DOU nurses and Pharmacy will give instruction regarding injection technique and education in relation to side effects of G-CSF.
- The Primary Consultant in association with the CNC and / or the BMT CNC monitors cell recovery and peripheral blood (PB) CD34 concentration.
- As a guide, based on in-house data;
 - For mobilisation by G-CSF alone, G-CSF dose of 10µg/kg/bd. If **NO** prior chemotherapy, harvest Day4 (D4) (following 7doses), if **PREVIOUS** chemotherapy, **BUT** recovered, harvest D5.
 - Mobilisation by G-CSF alone, median days to achieve desired PB CD34 concentration to initiate collection is 4 (range 3-5). (Chemo naïve – D4, otherwise – D5)
 - For mobilisation by chemotherapy+G-CSF, a G-CSF dose of 10µg/kg/day.
 - Mobilisation with chemotherapy+G-CSF, recommend to commence monitoring PB CD34 from D10, median days to achieve desired PB CD34 concentration to initiate collection is 13 (range 11-15) for the majority chemotherapy regimens.
 - Ideal PB CD34 concentration of $\geq 20 \times 10^3 / \text{ml}$ to initiate collection.

Instigation of Haemopoietic Progenitor Cell Apheresis Collections

NOTE the Primary Consultant oversees the care of the donor during HPC mobilisation. The Head of the HSCT Programme will be available to advise on mobilisation and authorise commencement of HPC-A collection.

6.5 HPC-A Harvest

- The Head of the HSCT Programme or delegate will assess the donor pre commencement of the HPC-A collection and ensure that the following Pathology Requests have been completed prior to the HPC-A collection:
 - Baseline FBE, ionised Ca²⁺, CD34 and clotting (as indicated, note ordered on day but prior to collection).
 - Valid crossmatched unit of Packed Cells is available, where machine blood prime is required.

- They are also responsible for ensuring that all medication orders are completed on the patients Medicine Chart, and that forms for Pathology Requests have been completed and accompany the patient as applicable for;
 - Mid-collection ionised Ca²⁺.
 - Medication order for Calcium Gluconate Infusion (to be actioned by phone consultation if indicated).
 - Post-collection FBE, ionised Ca²⁺ and clotting (if indicated).
 - Post collection transfusions (packed cells or platelets), cross match as required.
 - Medication order for post collection Heparin infusion for Vascath care as applicable.
 - HPC-A Processing (as applicable) – Cryopreservation / Fresh infusion, NCC, CD34 enumeration, CFC, Viability, Sterility and where applicable blood group and lymphocyte subsets.

- The Apheresis Nurse will confirm with the respective processing laboratory the commencement of HPC-A Collection and perform the collection according to Standard Operating Procedures.

- The HPC-A product will be labelled and custody of care of the product will be recorded and handed over to the respective laboratory according to Standard Operating Procedures.

- The donor **WILL NOT** depart the Ambulatory Care Unit unless assessed as clinically stable by the HSCT Physician or delegate and with specific instructions concerning future G-CSF dosing and confirmed contact details for notification of possible additional collections.

NOTE The Head of the HSCT Programme or delegate oversees the care of the donor for the duration of the HPC-A harvest process.

Instigation of Haemopoietic Progenitor Cell Apheresis Collections

6.4 HPC-A Processing

- The processing laboratory Scientist will accept custody of care of the HPC-A product and process the product according to Standard Operating Procedures.
- The Scientist will notify The Head of the HSCT Programme or delegate with the product CD34 yield as soon as possible.
- The Head of the HSCT Programme or delegate will authorise additional HPC-A collections as appropriate to achieve desired total yield as prescribed on CT-F-089.
- The Head of the HSCT Programme or delegate in communication with the BMT CNC will inform the donor parents/caregiver and the Apheresis Nurse with the applicable results and instructions as appropriate.

NOTE the Head of the HSCT Programme or delegate will liaise with the requesting Primary Consultant as appropriate.

7. ENDPOINT

Consented donor.

Eligible Donor fulfilling applicable criteria for HPC-A collection.

Donor with a PB CD34 concentration of $\geq 20 \times 10^3/\text{ml}$ to initiate HPC-A collection.

Haemodynamically stable patient pre and post HPC-A collection.

Sufficient total CD34 collected as prescribed by Primary Consultant on CL-F-003 and CT-F-089.

Documentation summary;

- Consent for Collection and Storage of Haemopoietic Progenitor Cells.
- Haemopoietic Progenitor Cell Harvest Booking Form. CL-F-003.
- Request for Stem Cell Processing. CT-F-089.

8. ATTACHMENTS

8.1 Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells.

8.2 Haemopoietic Progenitor Cell Harvest Booking Form. CL-F-003.

8.3 Request for Stem Cell Processing. CT-F-089

Instigation of Haemopoietic Progenitor Cell Apheresis Collections

9. REFERENCES

- 9.1 International Standards for Cellular Therapy Product Collection, Processing and Administration. FACT-JACIE. Fourth Edition. October 2008.
- 9.2 Requirements for Procedures related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells. National Pathology Accreditation Advisory Council. Australian Government Department of Health and Ageing. 2007.
- 9.3 Consent – Informed. Royal Children's Hospital Policies and Procedures Manual. Policy Number:RCH0040. Version 6. 2006.
- 9.4 Collection of Peripheral Blood Stem cells in Paediatric Patients. Andrew Fryga, Kerrie Jones, Nancy Messino, Dianne Tucker and Karin Tiedemann. Abstract presented at ASM of Bone Marrow Transplantation Scientists' Association of Australasia. 1999.
- 9.5 Medication Policy. Royal Children's Hospital Policies and Procedures Manual. Policy Number:RCH0291. Version 3. 2005.