Apheresis Training and Competency Manual

Lead Organisation: iMATCH

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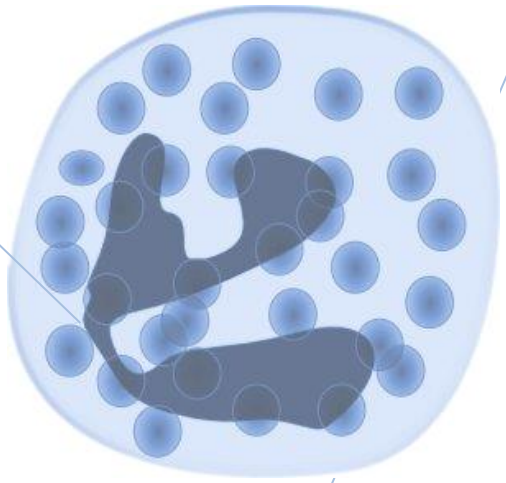


Apheresis Training and Competency Manual

Name:

Date of commencement:

Contents

Objectives

The aim of this training package is to provide nurses with the knowledge, skills and expertise to perform the specific apheresis procedures currently carried out within the CAU in a safe and professional manner as part of an extended nursing role. Patient and donor safety is paramount and the highest quality of holistic care is required.

The focus of this training will centre on cellular collection procedures.
Training in plasma exchanges and white cell depletions may require a longer period of time to complete due to the limited numbers of procedures undertaken within the CAU

The term competency refers to the knowledge, skills and behaviours required to perform a job, or an element of it, successfully. The objectives of this training are:

- Have a full understanding of apheresis terminology.
- Understand the rationale for each procedure
- Understand the nature of the centrifuge and the use of anticoagulants, including common adverse effects.
- Have the ability to describe the adverse effects associated with apheresis procedures and appropriate corrective actions.
- Demonstrate safe and appropriate operation of the Spectra Optia™ including knowledge of alarm conditions, troubleshooting and maintenance.
- Be able to demonstrate knowledge of required documentation, and patient assessment
- Be able to demonstrate knowledge of the relevant Standard Operating Procedure (SOP) and the location of the policy and procedure manuals for apheresis procedures (Q pulse)
- In addition to demonstrating practical competence you must be able to answer theoretical questions indicating your underpinning knowledge and understanding of the procedures and related topics.

Staff will also be required to be competent in blood transfusion and cannulation through the relevant Trust training and be competent in the use of the trust electronic prescribing system.

Apheresis assessments and training will be carried out by the Apheresis Co-ordinators/lead nurse. Additional guidance and education is available from the machine manufacturers Terumo BCT in form of e-leaning modules which can be accessed via Terumo BCT website**:**
https://www.terumobct.com/log-in-instructions

Assessment requirement includes: Final sign off with the Lead nurse for apheresis under the supervision of the Apheresis lead clinician. Eligibility to practice autonomously will also be defined by liaison with senior apheresis nursing staff and the Terumo representative.
Trainees will need to undertake a minimum of:

- A minimum of 10 supervised procedures plus 10 procedures independently.

- Complete competencies below
- Complete theory assessment below
- Completion of Terumo BCT MNC collection procedure Training checklist
- Terumo BCT apheresis quiz with the Terumo BCT Representative
- Completion of Terumo BCT e learning modules (1 2 3 7 for MNC procedures)
- Maintenance of competency for newly trained nurses will be 10 procedures per year

As part of the training process there are different resources you can access to help support your learning needs. At any point during your induction phase please highlight any extra needs to the Apheresis lead you may have identified.

*Lead Apheresis Nurses Cellular therapies/BMT coordinators Terumo e-learning modules. The HTA designated individual/*Terumo Representative/*SOP /Q pulse – Quality management team

Introduction

The Clinical Apheresis Unit (CAU) is part of the Haematology and Transplant Day Unit (dept 26) at The Christie. A full apheresis service for cellular collections is available between 0800 and 1600 during the normal working week with referrals accepted trust wide and from the network. The service is provided by the Cellular therapies and BMT coordinators and procedures are undertaken by an experienced team of haematology nurses based on the Haematology and transplant Day unit.

The Cellular therapies coordinators provide counselling, advice, follow up and medical assessment for patients, unrelated donors and related donors of those undergoing an apheresis and pre stem cell transplant procedures. All mobilisation chemotherapies and apheresis procedures are co-ordinated by the cellular therapies/BMT coordinators who will organise the timing of collections. They will also coordinate and conduct bone marrow harvest procedures in theatre if required. You will undergo a training period where you will work alongside one of the Lead Apheresis nurses and be supported by training opportunities with Terumo representatives.

The CAU currently has four Spectra Optia cell separators manufactured by Terumo BCT. The Terumo Optia system is a therapeutic apheresis, cell processing and cell collection platform. This system uses continuous-flow centrifugation and technology enabling operators to perform a wide variety of apheresis procedures. The Optia provides a semi-automated approach to collection that uses optical detection (Automated Interface Management system -AIM) to perform therapeutic apheresis and cell collections

Terumo BCT provide theoretical leaning support as outlined below on the operating procedures and Training of the Spectra Optia Apheresis System. These contain information and instruction on how to safely operate, troubleshoot and maintain the Spectra Optia Apheresis machines. The Terumo representative is contactable for advice and support on a daily basis.

You are encouraged to access all modules to enhance your overall knowledge of the apheresis system however assessment of competencies will be based on those modules relating to MNC and are encouraged to work through the student and new user electronic workbooks Terumo BCT provide.

Terumo BCT – e-Learning Modules Available

1) **The Principals of Apheresis on Spectra Optia (NEW)**
2) **Spectra Optia Apheresis System (V12) NEW**
3) **New User e-Learning Module (NEW)**
4) Spectra Optia TPE e-learning course
5) Spectra Optia TPE with Single needle e-learning course
6) Spectra Optia Red blood cell exchange (RBCx) e-learning course
7) **Spectra Optia MNC e-learning course**
8) Spectra Optia CMNC e-learning course
9) Spectra Optia White blood cell depletion (WBCD) e-learning course
10) Spectra Optia Granulocyte (PMN) e-learning course
11) Spectra Optia TPE (V12) e-learning course
12) Spectra Optia Exchange Tubing set – Instructional video
13) Spectra Optia Collect Tubing set - Instructional video
14) Spectra Optia IDL Tubing set - Instructional video
15) Spectra Optia Troubleshooting Tubing set Loading - Instructional video

Terumo BCT Training Materials

1) Student Workbooks for Each Spectra Optia Protocol – (electronic copy)
2) New User Workbooks - (electronic copy)
3) Training Checklist and Quiz for Each Spectra Optia Protocols.

Q-Pulse Document System

All Apheresis documentation and paperwork including Standard Operating Procedures (SOPs), forms and checklists are stored on the Q-Pulse document management system. The system is available on all computers on the HTDU. The purpose of the Q-Pulse system is to ensure that everyone has access to the most up-to-date version of all documentation. There are also computers with Internet access for research and relevant clinical articles, Hospital Policies, Standards and Procedure files relating to Apheresis.

SOP's relevant to Apheresis
Please familiarise yourself with each one during your training period.

1. SOP: APH-10" Collection Facility Staff Training and Competency SOP).
2. SOP: APH-159 "Optia Operator Cleaning and Maintenance"
3. SOP: APH-4 "Labelling of HPC and TC-T in the Clinical Apheresis Unit & RTX Theatres"
4. SOP: CLN-96 "Consent policy for stem cell transplant related therapies and procedures"
5. SOP: APH-157 "Patient/donor complications associated with the use of cell separators"
6. SOP: APH-151 "Clinical apheresis unit structure and referrals"
7. SOP: APH-150 "Cannulation Procedure for Apheresis Procedures"
8. SOP: SCL/POL/TSCH "Transport Policy (Lab and Collection Facility)"

Quality Management

The CAU has a quality management system which will allow the stem cell transplant program to achieve full accreditation by JACIE - Joint Accreditation Committee of International Cellular Therapy (ISCT) & European Society for Blood and Marrow Transplantation (EBMT) and to ensure compliance with the HTA Human tissue Authority. The main role of the quality function is to ensure the safety of products and patients, and that external accreditation is achieved and maintained. This is done by ensuring that:

- Standard Operating Procedures (SOPs) are correctly followed.
- Documentation is correctly and fully completed.
- Staff training is fully carried out.
- Staff competency is maintained.

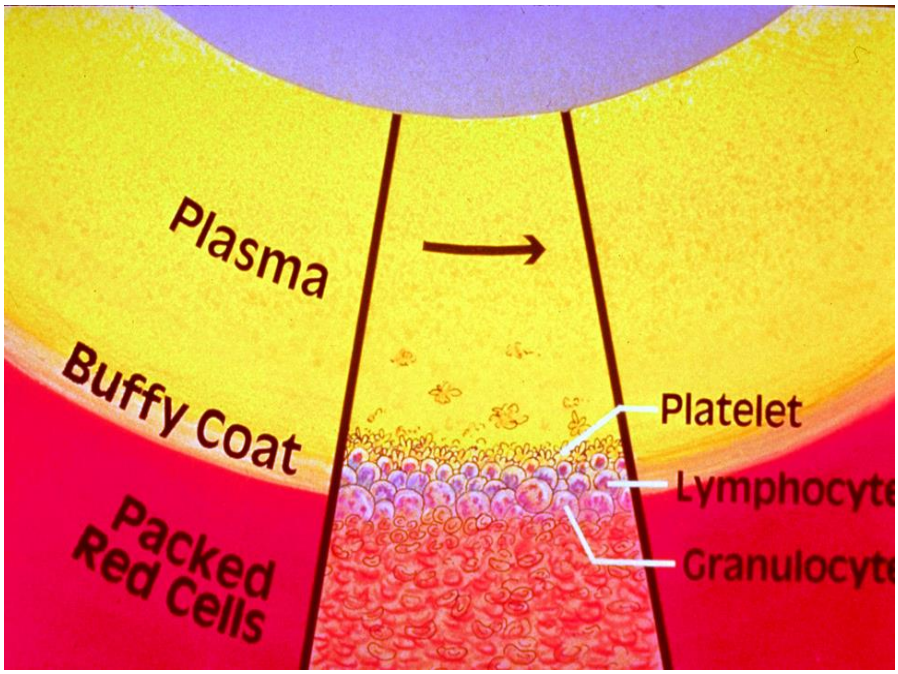
The CAU works in close conjunction with the Stem Cell Laboratory based in the Pathology department. They are responsible for the processing, cryopreservation and storage of any cellular stem cell /lymphocyte collection /trial product and for the analysis of predictive CD34+ve samples.

The Unit is accredited by the Human Tissue Authority (HTA) and the Join Accreditation Committee of ISCT and EBMT (JACIE) and operates under a strict quality management programme. This ensures that the clinical, collection and laboratory units are all working together to achieve excellent communication, effective common work practices and increased guarantees for patients.

Principles of Therapeutic /Donor Apheresis

Apheresis is derived from the Greek words “Apo” meaning “away” and “heresis” meaning “taking”. This process involves the removal of whole blood, followed by separating and collecting any of the components, returning the remaining blood components to the patient/donor.

The advance in sophisticated apheresis blood cell separators has dramatically changed the applications of apheresis procedures, with increasingly specific blood cells being able to be targeted.



Apheresis Mechanism of Action

Blood is drawn into a cell separator via an access line (peripheral or central) it is then separated by centrifugation according to size and density. The more dense elements, namely the red cells, settle to the bottom with less dense elements such as white cells and platelets overlying the red cell layer and finally, plasma at the very top. Apheresis involves an extracorporeal circuit through which whole blood travels with the aid of pumps through the machines, once separation has occurred. Remaining blood components are returned via the return line back to the patient

Anticoagulation

Anticoagulation is essential in maintaining the fluidity of extra corporeal blood in the apheresis circuit. The surface of the tubing can activate platelets causing clots/blockages in the disposable set requiring anticoagulation so the procedure can run without clotting complications. Although both citrate and heparin can be used a sugar-based Citrate is the preferred method for the majority of Apheresis procedures because of its safety and effectiveness. ACD-A (Anticoagulant Citrate Dextrose Solution A) is the Citrate product currently used in the Christie. Complications of Citrate are usually due to the physiological effects of hypocalcemia as it binds to ionized calcium. This can expose patients to electrolyte imbalances reducing the calcium, potassium and magnesium levels.

Patients/donors need to be closely monitored for signs of citrate toxicities and managed accordingly with oral or IV salt replacements.

Symptoms of Citrate toxicity

- Pallor
- Tetany
- Tingling lips and peripheries
- Body vibrations
- Cramps
- Chest pain

Management of citrate toxicities

- Pause Procedure

- Monitor patient – depending on severity does it indicate a medical review/ vital signs/ECG

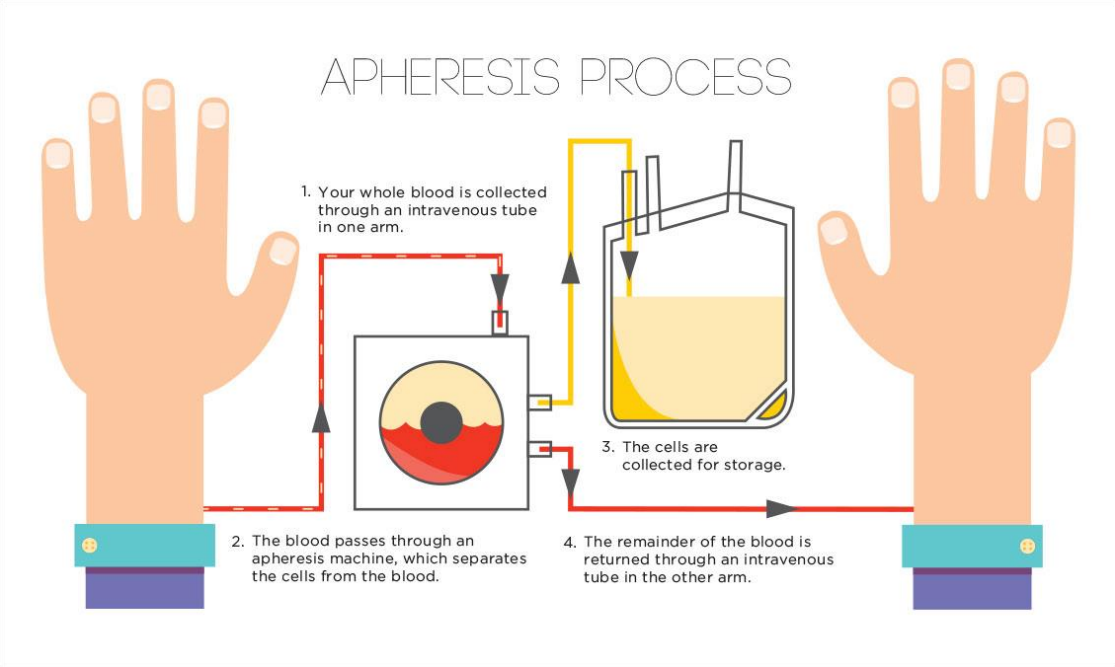
- Toxicity experienced through the use of an anticoagulant (ACDA)
  - GRADE 1 (Mild) Mild tingling/numbness around lips, periphery/ nausea
  - GRADE 2 (Moderate) Continuation / worsening of Grade 1 symptoms
  - GRADE 3 (Severe) Continuation of Grade 2 symptoms despite action taken

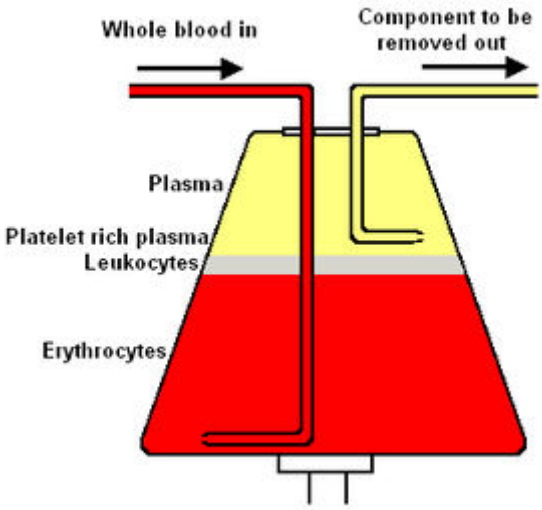
Therapeutic apheresis procedures broadly fall into the following categories:

Autologous apheresis = Performed on the patient.

Allogeneic apheresis = Performed on a volunteer donor.

Apheresis is used for the treatment of many diseases indications ASFA guidelines provides guidance on the efficacy of use for differing procedures in relation to disease type.





Types Therapeutic Apheresis Procedures

- HPC/lymphocyte collections
- Therapeutic plasma exchange
- Red blood cell exchange
- WBC depletion
- Platelet depletion
- Red cell depletion
- Donor granulocyte collections
- Platelet donations
- LDL apheresis and ECP

As specified in the Apheresis SOP for all collections patient/donors require a minimum Platelet count > 20 and HB > 8.0 pre procedure. Please discuss with medical team and Apheresis Lead if the results are below these parameters.

Cellular collections

Haematopoietic Progenitor cell (HPC)

The pluripotent stem cells (progenitor cells) are the basis of the haematopoietic system, essentially the parent cells of all bone marrow cells and of the immune system.

They possess excellent capacity of self-renewal and equal capacity of differentiation, i.e. it can reproduce itself quickly and in huge numbers and it can develop into any type of blood cell the body requires. They are extremely small (undetectable), mononuclear (one nucleus) and are hidden among other mononuclear cells. Most but not necessarily all are **CD34 positive.**

Stem cells form:

- 1.5% of bone marrow cells
- 1.5% of umbilical cord blood
- 0.2% of peripheral blood

CD34+ cells

CD34+ is a surface antigen expressed on haematopoietic stem cells. It is expressed most strongly on the most primitive cells. This is the marker used for detection of stem cells in the peripheral blood. A sample of peripheral blood can be tested using flow cytometry to measure the numbers of CD34+ cells present pre harvest. This is known as a predictive CD34+ test. It is estimated that there is a 90% chance that a predictive result within the range of 50 $x10^6$ LT will result in an overall HPC collect of 2 x 10^6kg CD 34+. Sufficient for one autologous stem cell transplant

The decision to undertake a HPC harvesting should not be based on the predictive result alone, the patient/donors clinical condition and circumstances should take priority.

Stem cell Mobilisation AUTOLOGUS

Under normal conditions the number of CD34+ circulating cells in the peripheral blood is insufficient to enable collection. The patient needs to be conditioned (mobilised) to encourage the bone marrow to generate larger numbers of stem cells and push them out into the bloodstream. This is usually a two-fold procedure:

1. The patient is given chemotherapy, e.g. cyclophosphamide. This helps to suppress the bone marrow for a short time. When it begins to regenerate it tries to compensate for its recent inactivity by manufacturing stem cells in a number more prolific than in the normal steady state.

2. The patient is given a **growth factor -** GCSF (Granulocyte Colony Stimulating Factor). These are naturally occurring substances which will be injected into the patient daily until harvesting takes place, and have the effect of stimulating the bone marrow to increase production of circulating immature stem cells.

3. The patient may also require the addition assistance of plerixafor to aide mobilisation if the PCD34 remains below the desired 20 but is about 10 on a rapidly rising white cell count

This two-fold conditioning usually stimulates the patient's bone marrow and hopefully results in an increase in the circulating CD34+ count. The first indication of marrow recovery is a rising WBC count. When the WBC rises to above **2**, a predictive CD34+ count can be taken to assess the patient's suitability for stem cell harvest. The patient may need to undergo a stem cell collection on several consecutive days depending on their predictive CD34 result and collect result. Patients are required to attend for predictive CD34 positive blood tests on

the designated day assigned by the Apheresis team at 8 am - 8:30 am to facilitate same day processing.

Procedure details:

1. These will involve mobilized autologous patients.
2. Confirm with patient they correctly received the indicated GCSF injections.
3. Await the CD34+ count on the day of harvest. Liaise with Apheresis Team
4. Triger collect at 2000mls followed by 1000mls if no automatic triggering occurred or if WCC above 40
5. If patient requires second day of collection make sure they have an additional dose of GCSF

Non Responders

There are a group of patients who do not respond to standard mobilisation regimes, i.e. whose CD34+ count never rises, and thus cannot be harvested Alkylinating agents such as fludarabine and chlorambucil can significantly affect an individual's ability to mobilise stem cells, as can radiotherapy. They will be referred back to the apheresis consultant who will decide on a further appropriate course of treatment. This may be re-conditioning using a more aggressive form of chemotherapy, referred for bone marrow harvest or for salvage mobilisation using plerixafor (a drug which aids stem cell mobilisation by working alongside GCSF ensuring the stem cells are released more efficiently).

Sibling Donors

Donors who have healthy normal bone marrow are mobilised using GCSF alone and usually respond well. GCSF is given in a dose of 10mcg/kg for 4 days prior with collection occurring on the 5th day. The donor may require harvesting over a period of days.

Procedure details:

1. These will involve mobilized allogeneic patients.
2. Confirm with patient they correctly received the indicated GCSF.
3. Donor can proceed **DO NOT** wait for on the day CD34+ count
4. Will require **two** oral calcium supplements pre procedure.
5. Triger collect at 2000mls followed by 1000mls if no automatic triggering occurred or WCC above 40.
6. If patient requires second day of collection make sure they have an additional dose of GCSF as per institutional policy.

Anthony Nolan Donors

These patients are volunteers who are registered with the Anthony Nolan register to be a match for someone requiring a Stem cell transplant. They would have been identified as a genetic match for a patient and will be attending the unit for their Apheresis/stem cell collection procedure. They may have specific Apheresis/harvest requirements so make sure to refer to the individual collection prescription and liaise with the Apheresis coordinators. During the procedure they may be visited by an Anthony Nolan volunteer to offer support.

Procedure details:

1. These will involve mobilized unrelated allogeneic patients.
2. Confirm with patient they correctly received the indicated GCSF injections.
3. Donor can proceed, don't wait for the CD34+ count on the day of harvest.
4. Will require pre glucose blood test.
5. Will require two oral calcium supplements pre procedure.
6. This collection may have specific sample/collect requirements please check collection prescription.
7. Triger collect at 2000mls followed by 1000mls if no automatic triggering occurred.
8. If patient requires second day of collection make sure they have an additional dose of Zarzio/Nivastem.
9. Will need post procedure full blood count.

Mononuclear/Dendritic cells - ATMPs

Advanced Therapy medicinal products (ATMPs) are medicines for human use that are based on cells, genes or tissues. Many new treatment opportunities are using the development of cellular immunotherapy therapies to treat patients such as CAR T. These treatments adapt and modify Autologous T cells in a laboratory so they are effective in immune response killing tumor/disease cells. Apheresis is the critical first step to the development of many of these products.

There is significant growth in the number of clinical trials for cell based gene and Immunotherapies. As many of these treatments are new, many will still be in research and trial phases. This will impact on the Apheresis procedure as they may have specific trial recommendations or requirements. Again it is vital to familiarize yourself with the collection prescription as each one may vary in its requirements. GCSF is not required for these collections.

Procedure details:

1. These procedures involve non mobilized Autologous Patients.
2. PCD34 not required
3. **DO NOT** wait on the day counts. Use the most recent full blood count
4. Collections may have specific sample/collect requirements please check collection prescription.
5. Triger collect at 2000mls followed by 1500 -2000 mls if no automatic triggering occurred.
6. 2 day collection may be required. Discuss with Apheresis Lead

Donor Lymphocyte Collections

The collection of sibling donor lymphocytes is used for the purpose of combating or preventing disease relapse. Lymphocyte donation does not require GCSF mobilisation. The product is divided into aliquots for reinfusion and cryopreserved the day following collection. Lymphocytes are also collected as part of several clinical trials.

Procedure details:

1. This procedure involves non-mobilized allogeneic Donors.
2. Can proceed with collection whilst awaiting todays result.
3. Use the most recent full blood count.
4. Trigger collect at 2000mls followed by 1500 – 2000 mls if no automatic triggering occurred.

There are specific procedures that require further training and education as they are not undertaken routinely on the CAU. If necessary a request will be made by the consultant haematologist and the procedure will be supervised by the Apheresis coordinators.

Plasma Exchange TPE

Indications for treatment include autoimmune or haematological diseases associated with an abnormal antibody, metabolic conditions, toxicity and hyperlipidaemia. Commonly conducted in our apheresis unit for:

- Thrombotic microangiopathy (TTP)
- Waldenstroms macroglobulinaemia
- High plasma viscosity (myeloma)
- Cryoglobulinaemia
- Platelet alloimmunisation and refractoriness

The pathway of these diseases is multifactorial and the use of TPE alone in their treatment is often a point of clinical debate. Replacement fluids for these procedures include Albumin4.5%, FFP, octoplas and normal saline. 1 to 1.5 x total plasma volume exchanges are common practice when carrying out a TPE procedure. Refer to SOP.

White Cell Depletion

WCDs are undertaken usually in cases of Leukaemia, when the patient presents with high WCC, and more importantly clinical symptoms of leukostasis Requests are only accepted from a Consultant Haematologist as these patients may be clinically very unwell. Replacement fluid may be required dependant on the amount of product to be removed. Refer to SOP.

Adverse Reactions

Therapeutic apheresis is a complicated medical procedure and the patient group that we are dealing with may have multiple co-morbidities. However there is a low incidence of procedural complication in daily practice. The minimization of any adverse effects requires a good understanding of the patient's clinical condition and any pre-existing issues. Good clinical monitoring and the early recognition of side effects is paramount in the safe management of individual undergoing apheresis.

Preparation of the patient on the day

As the Apheresis nurse you will need to assess and prepare the patient for the specific collection procedure they require. The patient/donor will have had a full medical assessment, pre harvest to ensure suitability for the procedure; this will include bloods and ECG. The patient may have undergone mobilization treatment ready for collection. Each patient/donor will have a designated plan and it is the part of you role to liaise with the Apheresis team to receive a hand over for the patients due for procedures that week and for the apheresis team to highlight any specific product requirements or concerns re the patient.

On day of the procedure meet with patient/donor and introduce yourself. Ensure that they are happy to go ahead with collection and have no outstanding questions or concerns.

Each patient will require:

- Consent for HTA.
- Consent for Apheresis procedure. DOH
- Any additional consent indicated by either trial or Anthony Nolan.
- Initial medical assessment fully signed off by a consultant.
- Prescription for Collection (HPC /BM /DLC /ATMP)
- Apheresis Nursing checklist – pre apheresis
- Venous assessment – referral for femoral line if required
- Procedural paperwork.

Consent

Before undergoing the Apheresis procedure the patient requires consenting. Training for this will involve you completing the Christie consent module as eLearning and completing the HTA consent training outlined by Diane Sweeny. Once you have been assessed and are passed as competent you will be able to undertake the consent process with the patient.

Consent for Apheresis collection process: including a description of the procedure and the need for it, highlighting any potential side effect or complications that could arise. Consent should be obtained in a private room giving the patient the opportunity to raise any concerns. Any concerns regarding the patient's capacity to obtain consent should be escalated to the apheresis team

HTA Consent: This form outlines the patient's wishes in relation to the collection, storage and testing of the cellular product as specified by the HTA guidelines.

Apheresis Nursing Checklist

On the day of collection the designated apheresis nurses undertake a standardized clinical checklist pre procedure. This allows you to highlight any on the day clinical concerns and that you are happy that the patient is fit to continue with the procedure on that day. Beware of sign or symptoms of infection or if observations are not within the patients normal range.

If you feel there are any significant clinical changes that may alters the patients/Donors suitability for this procedure DO NOT proceed await review by a member of the clinical team

The patient/donor weight (kilograms) and height (centimetres) will need to be confirmed on the day of collection, and that they have an up-to-date virology screen and pregnancy test if indicated. On the day blood tests will include a FBC, U&E (including a Christie profile) Coagulation and xmatch to go with the product.

It is the responsibility of the Apheresis nurse to review the blood results and action if they require any replacements

If on the day of collection the patient requires further medical assessment, has any requirements such as electrolyte replacement or further intervention for venous access please make sure this is documented clearly and the Apheresis Lead is informed.

Virology Screen

It is a legal requirement that any blood/tissue product that is collected for cryopreservation/storage, is accompanied by a virology screen obtained from the individual, taken within 30 days of donation. HIV, syphilis, and Hepatitis B and C. This will routinely be obtained when the patient is seen in clinic for medical assessment but may require repeating.

Collection Prescription

This will specify the target dose required for that collection and identify any additional blood tests or samples required. And identify any collection specific requirements. Please ensure that you refer to this when programming the machine.

Venous access for Apheresis collections

Effective Apheresis requires stable venous blood flow through the circuit. Peripheral vein cannulation is the approach of choice in most situations. Two points of cannulation (**ACCESS and RETURN**) are required. Vein assessment should always be performed by a competent apheresis operator to determine venous suitability and to ensure alternatives are implemented in a prompt fashion to minimize time delay and patient distress.

Venous access requirements

- **Inlet access** 16-18g back eye needles are short steel with plastic wings and extension tubing attached. They are designed to prevent vein collapse and placed in the anti-cubital fossa
- **Return access** 16-20g intravenous cannula. This can be placed in smaller distal veins of opposite forearm to the inlet access allowing patient flexibility and movement.

Ultrasound assessment /deep vein cannulation is a tool which can be used for patients who lack visible or palpable veins. It quickly identifies suitable veins and determines whether central access is required. Ultrasound-guided peripheral vascular access can increase the rate of successful cannulation attempts and decrease CVC use. Refer to the Christie CVC team if felt appropriate

If peripheral venous access is deemed unsuitable for cellular collection a short-term double lumen Central venous catheters (CVC) as in a **femoral line or vas cath** should be considered. Enabling high flow rates and uninterrupted blood flow. CVC are only used if venous access and other options have been excluded. Tunneled internal Jugular apheresis CVC lines may be considered if a long-term access is required or in the case of repeated procedures.

Note standard Hickman/CVC lines are in general not suitable for apheresis access which requires a **rigid walled catheter** to facilitate adequate flow rates which will not damage the catheter. Hickman lines can be used as an alternate site to return blood if already in situ.

PICC lines are currently not suitable to use in any way for an apheresis procedure

Please refer to hospital cannulation and CVC policy and to hospital line team for access advice/ultrasound guided deep vein placement.

Patient preparation for the acquisition and maintenance of peripheral access

Preparation

- Advise the patient to be well hydrated before procedure.
- Patient assessment, support and co-operation to mitigate potential challenges associated with peripheral access.

- Vascular assessment, visualize and palpate potential cannulation sites.
- Warming to assist vasodilation.
- Consider premedication (lorazepam 0.5mg s/l) pre procedure if the patient is particularly anxious or needle phobic

Acquiring peripheral access

- Placement of Inlet access should be placed last (i.e. after return cannula) and immediately before the start of the procedure to minimize blockage.
- If the patient has a Hickman line in situ this can be used for return access only.
- Consider use of **Veinplicity** devise to increase vasodilation **- Refer to user guidance and training competency**.
- Ultrasound guidance. – as above
- For CVC/femoral line - **Refer to Registrar for assessment.**

Maintaining peripheral access

- Vasoconstriction immediately after cannula insertion can result in inlet flow alarms the application of a gentle tourniquet or clenching of hand may assist in stabilizing the vein.
- Heat pack to upper arm may assist venous flow from the access needle
- Transient blockages can occur with Inlet and return access. If indicated the operator may need to pause the procedure to unblock/flush the access and or return lines.
- Decrease inlet pump speed.
- Compress arm.
- Adjust position of arm.
- Adjust angle of needle cannula.
- Flush with saline.

Things to consider if your patient requires CVC insertion.

- Patient consent.
- Appropriately trained doctor to carry out the procedure.
- Equipment required.
- Possible patient admission. Patients with femoral lines in situ will be admitted either over night or for 4-6 hours post line removal if only one collection day is required as per CVC SOP. It will be your responsibility to liaise with the bed management team to request the admission.
- Accessing/locking line in accordance with hospital policy.
- Line removal – **Refer to hospital policy**

Documentation

A very high standard of written documentation is required from everyone for each product collection. Documentation/monitoring of procedure should be carried out as the procedure progresses. It is vital that all forms of documentation are properly updated and completed before the end of the procedure, Complications, adverse reactions or events must be clearly highlighted and an IRF completed if needed – discuss with Apheresis team and HTA DI

If more than one procedure is taking place great care must be taken to ensure all documentation is for each procedure is kept separate and that products are correctly labeled pre detachment from the machine and patient

All patients should be fully handed over to the apheresis team and HTDU staff on completion of procedure

Procedural Paper work

- Standard Hospital / DOH consent form
- HTA Consent for testing, storage and discard
- Medical Assessment Form with cell prescription
- Procedural worksheet (WBC)
- Complications form to be completed at the end of the procedure
- HPC or TC-T Processing Request Form
- Labels

Completion of procedure

It is crucial to complete the procedural details on the label of the products as per individual collection requirements and SOP. Place each individual product in a clear plastic sample bag provided and seal ready for packing. Once the procedure is complete and when indicated disconnect the product bags, using the clamp provided and heat seal the line bellow ensuring it is secure as per MNC SOP. Place into the transportation box together with the necessary paper work and copies of the procedural worksheets.

The products will then be transported to the laboratory in accordance with the transport policy and SOP. The transport boxes contain two cool packs to ensure the HPC cells are transported at their optimum temperature. Liaison with the stem cell laboratory is required to coordinate the transport of the product from the CAU to the SCL

Once the product has been collected, remove the patient/donor peripheral access or manage central venous catheters as indicated in the CVC and cannulation SOP. Ensure Inlet and return access sites have clotted adequately. Perform patient observations on completion and refer to the medical team if any concerns are present and inform the Apheresis Lead the procedure is complete. All completed documentation should be filed or photocopied as per SOP outlines.

Post Procedure Advice

Please give the following advice to patients after collection is completed.

- Rest for 24 hours.
- Ensure good fluid intake of 2-3 litres per day.
- Avoid NSAI and Aspirin.
- Ensure the patient has the hotline details for any issues/advise needed out of hours.
- Ensure contact details are available and supplied to the apheresis team who will contact the patient if a second day of collection is required

The harvest result may not be available on the day or collection amount not adequate resulting in the patient having to return for a second day procedure. In this case the patient will require a further dose of GCSF if for HPC. . In cases where another GCSF dose is being considered and a peripheral white blood count > 40 the patient should be discussed with the medical team and splenic examination undertaken

- In all cases ensure the patient has a Follow up outpatient appointment for clinic.

The result of the harvest will be communicated by the Apheresis team via letter to the referring consultant/GP. Donors will be invited to attend for follow up blood tests in the Apheresis unit or at their GP surgery 4-6 weeks after donation or will follow donor advice as per individual organisations protocol. ANDP donors are followed up by the registry.

Induction check list

This document should be used in conjunction with relevant policies (Induction and essential training policy, medical devices training policy and Guidance for conducting a PDR Review and the development of a Personal Development Plan).

This checklist is intended to facilitate your introduction to the apheresis unit to make you familiar with your new role. The following points should be discussed between you and your trainer:

- Orientation to:
    - HTDU layout
    - Stem Cell Laboratory
    - Research Nurses
    - QM system
- View and discuss job description, objectives and responsibilities
- Discuss:
    - Therapeutic apheresis implications and practice on CAU

- Trust & local policies, procedures & protocols
    - Training Manuals
    - Competencies
    - Relevant Standard Operating Procedures
- Equipment training needs & equipment training record
    - TerumoBCT eLearning. Log-in instructions - https://www.terumobct.com/log-in-instructions.
- Once you have registered log in again enter email and password and click Support and the e-learning in the drop-down menu, scroll down to Spectra Optia and select the modules you wish to access.
    - Essential Training
- Communication
    - Patient information leaflets
    - Database
- Specific documentation requirements
    - Apheresis notes
    - Run sheets
    - Patient records
- Quality Management System
    - Apheresis SOP file
    - Q-Pulse
- Environmental Monitoring & Stock Control
- HTA consent and JACIE standards
- Consent training

Trainee Signature: _____ **Date:** _____

Trainer Signature: _____ **Date:** _____

Competencies

&

Theory Assessment

Please start to complete the competencies and theory questions at any point throughout your training period.

Competencies

1 – Preparation of a patient/ donor

On completion of this unit, nurses will be competent to prepare a patient or donor about to undergo apheresis procedures and be aware of the correct documentation and equipment required.

OBJECTIVES

	INITIAL INSTRUCTION		
	Date	**Trainee**	**Instructor**
• Demonstrate checking identity of patient.			
• Describe importance of patient's medical fitness to undergo procedure and value of baseline observations Describe the importance of pre procedural Baseline observations			
• Demonstrate explanation of procedure to patient			
• Demonstrate knowledge of levels and indications for cellular collection			
• Describe importance of obtaining patient consent to undergo procedure.			
• Demonstrate knowledge of blood results and their relevance to the procedure			
• Demonstrate knowledge of obtaining access and return lines to and from patient, and their importance.			
• Demonstrate good liaison with MDT.			
• Demonstrate use of correct documentation			
• Demonstrate the gathering together of appropriate equipment			
• Demonstrate knowledge regarding importance of an up-to-date virology screen			
• Ability to take HTA consent and procedural consent			

Competency 2 - Generic Equipment Skills Assessment

On completion of this unit, nurses will be able to correctly load, prime, run and dispose of equipment safely in accordance with SOP's, Operator Manual and training protocols, and prepare correct documentation. They will demonstrate safe management and monitoring of the patient /donor throughout the procedure as well as safe transfer of any product collected.

OBJECTIVES

	INITIAL INSTRUCTION		
	Date	**Trainee**	**Instructor**
• Assembles procedure specific supplies			
• Demonstrate loading of disposable set correctly			
• Demonstrates correct selection of procedure to be performed.			
• Demonstrate checking of IV fluids and recording of batch numbers.			
• Demonstrate machine prime correctly.			
• Establishes access and return lines effectively			
• Demonstrate entry of patient data into machine.			
• Demonstrate use of correct documentation during procedure			
• Demonstrates correct monitoring of patient and recording of parameters			
• Disconnects patient/donor correctly			
• Demonstrates safe disposal of equipment			
• Demonstrate aseptic technique at all times.			
• Demonstrate correct labelling of the product			
• Demonstrates returning products to stem cells labs			
• Demonstrates correct disposal of clinical waste			
• Demonstrates post procedure patient advice and education			
• Arranges post procedure follow up and investigations effectively.			

Competency 3 - Trouble Shooting: Dealing with Adverse Reactions

On completion of this unit, nurses will be able to undertake the safe management of the most commonly occurring adverse clinical reactions experienced during an apheresis procedure in accordance with SOP's, operator manuals and training protocols, and prepare correct documentation.

OBJECTIVES

	INITIAL INSTRUCTION		
	Date	**Trainee**	**Instructor**
• Demonstrate method of monitoring patients reaction to blood products			
• Demonstrate management of hypovalaemia in a patient			
• Demonstrates ability to deal with venous access problems			
• Demonstrates appropriate referral for femoral line insertion			
• Demonstrates ability to deal with allergic reactions			
• Recognises, grades and responds to citrate toxicity accordingly			
• Demonstrates correct action to be taken in event of citrate toxicity.			
• Demonstrates correct action to be taken in event of patient collapse.			
• Demonstrates ability to manage fluid balance issues			
• Demonstrates ability/knowledge of how to manage pre procedural electrolyte imbalances.			

Competency 4- Trouble Shooting: Dealing with Technical problems

On completion of this unit, nurses will be safely manage any mechanical /technical problems encountered during an apheresis procedure in accordance with SOP's, operator manuals and training protocols, and prepare correct documentation.

OBJECTIVES

	INITIAL INSTRUCTION		
	Date	**Trainee**	**Instructor**
• Demonstrates ability to deal with Return /or access pressure alarms			
• Describe action to be taken in event of machine failure.			
• Demonstrates accurate management of platelet clumping			
• Demonstrates ability to deal with various alarms as per operators manual instructions			
• Demonstrates appropriate management of the CP preference when chamber fills too slowly or too quickly(OPTIA)			
• Demonstrates appropriate management of CP when contents of collect line are too light or too dark			

Competency 5 - Stock keeping /storage /cleaning of equipment.

On completion of this unit, nurses will be able to deal with rotation of stock, ordering, batch records and storage details. And nurses will be able to clean machines and equipment safely and to a required standard.

OBJECTIVES

	INITIAL INSTRUCTION		
	Date	**Trainee**	**Instructor**
• Demonstrates cleaning of machines and equipment			
• Describe measures to be taken in event of missing/faulty equipment or stock.			
• Demonstrates use of personal protective equipment			
• Demonstrate ordering of stock as required.			
• Describe purpose of stock rotation.			
• Describe purpose of batch no records and expiry date records.			
• Describe action to be taken when finding time expired stock.			
• Describe function of temperature monitoring in cell separator room and ACDA storage site			
• Demonstrate recording of temperatures.			
• Demonstrates awareness of system maintenance requirements			

Trainee Signature: _____ **Date:** _____

Trainer Signature: _____ **Date:** _____

Theory Assessment

On completion of this unit, the trainee will be able to demonstrate a broad theoretical knowledge of how to safely perform a therapeutic apheresis procedure and manage potential complications

ASSESSMENT QUESTIONS

1. **Procedural collections**

Identify/discuss the key aspects of each collection procedure and what key actions to consider for each one.

HPC/Stem cell harvest:

Mononuclear/Dendritic cell collections:

Donor Lymphocyte collections:

1. General

1) What technical system do we use at the Christie?

2) Which parameters define the total blood volume (TBV) to be processed?

3) What are the default chase and harvest parameters?

4) What are our amended chase and harvest parameters?

5) Identify the importance of an accurate pre procedure haematocrit?

6) What impact would using an incorrect height or weight have on your procedure and the patient?

7) When configuring the system which parameters can we change to influence procedure outcome?

8) Identify several other factors which can affect the outcome of a procedure?

9) How is the interface established?

Patient Management

10) How would you manage a patient who experiences an episode of vasovagal syncope?

11) How would you manage a patient who experiences an episode of hypovolaemia?

12) How would you manage a patient who experiences an allergic reaction?

13) Discuss the importance of vascular access in apheresis.

14) How would you assess venous access/return before the start of the procedure?

2. ACDA management

1) Describe the role of ACDA

2) Describe the signs, symptoms and grade of a mild/moderate/severe citrate related reaction

3) What would your intervention be if your patient was developing signs and or symptoms of a citrate reaction?

4) Your patient complains of" tingling" so you increase the inlet AC ratio from 10:1 to 13:1. Will this alleviate the symptoms? Why or why not?

5) What is the default ACDA/inlet ratio?

6) When would you increase and decrease the ACDA ratio?

7) What happens to the flow rates?

8) What is the maximum advised ACDA infusion rate?

Trainee Signature: _____ Date: _____

Trainer Signature: _____ Date: _____

Practical Skills Assessment Sheet

Supervised Procedures	**Date**	**Assessor**	**Trainee**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
Independent procedures			
1.			
2.			
3.			
4.			
5.			

6			
7			
8			
9			
10			

Trainee Signature: _____ Date: _____

Trainer Signature: _____ Date: _____

Resources:

- Terumo BCT e-Learning Modules
- Terumo BCT Electronic student workbooks
- Terumo BCT New user workbooks (electronic)
    - Terumo BCT Spectra Optia Apheresis Systems Operators manual
- Standard Operating Procedures (SOP) for Clinical Apheresis Unit (Q pulse)
- Apheresis Principles and Practice (AABB)
- Therapeutic Apheresis Handbook – Physicians Handbook (ASFA)
- ASFA - Journal of Clinical Apheresis
- JACIE Standards
- Terumo BCT login link for e learning modules
  https://www.terumobct.com/log-in-instructions

References

1. Golestaneh , L. and mokrzycki, M. (2013) Journal of clinical apheresis. 28 (1), pp.64-62.
2. Kaplan, A., 2012. Complication of Apheresis. Seminars in Dialysis, 25(2), pp. 152-158.
3. Kay, L.A. (1988) Essentials of haemostasis and thrombosis Churchill Livingstone.
4. Weinstein, R., 2001. Hypocalcemic toxicity and atypical reaction in therapeutic plasma exchange. Journal of clinical Apheresis, 16(4), pp. 210-211.
5. O'Grady, N., Alexander, M. & Burns, L., 2011. Guidelines for prevention of intravascular catheter related infections. American journal of Infection Control, 39(4), pp. S1-S34.
6. Butcha, C. et al., 2003. Reduction of adverse citrate reaction during autologous large volume of PBSC Apheresis by continuous infusion of calcium gluconate. Transfusion, 43(11), pp. 1615-21.
7. Dougherty, L., 2015. Vascular Access device: Insertion and Management. In: Manual of clinical nursing procedure. Oxford: Wiley -Blackwell Publishing.
8. Golestaneh, L. & Mokizycki, M., 2013. Vascular Access in therapeutic Apheresis: update. Journal of Clinical Apheresis, 28(1), pp. 64-72.
9. Humpe, A., Rigger, J., Munzel, U. & Kholer, M., 2000. A prospective randomized, sequential crossover trial of large volume leukapheresis procedure: effects on serum electrolytes, platelets counts and other coagulation measures. Transfusion, Volume 40, pp. 368-74.
10. Malachowski, M., Comenzo, R. & Hillyer, C., 1992. Large volume Leukapheresis for peripheral blood stem cell collection with haematologic malignancies. Transfusion, Volume 32, pp. 732-735.
11. Mcleod, B. .., 2012. Plasma and plasma derivatives in Therapeutic plasmapheresis. Transfusion, Volume 52, pp. 38-44.
12. Nursing and Midwifery Council (2015) Standards to support learning and assessment in practice

13. Perry, L. & Sands, J., 1999. Vascular and degenerative Problems of Brian: Medical-Surgical nursing. Missouri: Mosbys.
14. Raphel, J., Chervret, S. & Hughes, R., 2012. Plasma exchange for Gullian Barre syndrome. Cochrane database.
15. Scales, K., 2010. Central Venous access device: Part 2 for Intermediate and Long Term Use. British Journal of Nursing (Intravenous Supplement), 19(5), pp. S20-S25.
16. Szczepiorkowski, Z. et al., 2010. Guidelines on the use of Therapeutic apheresis in clinical practice- evidenced based approach from the Apheresis Application committee of the American Society for Apheresis. Journal of Clinical Apheresis, Volume 25, pp. 83-177.
17. Terumo BCT Spectra Optia Apheresis System - http://www.terumobct.com/location/emea/products-and-services/Pages/spectra-optia-apheresis-system.aspx
18. Tortora, G. J. & Derrickson, B., 2011. Principles of Anatomy &Physiology. Asia: John Wiley&Sons pte Ltd.
19. Weinstein, R., 2001. Hypocalcemic toxicity and atypical reaction in therapeutic plasma exchange. Journal of clinical Apheresis, 16(4), pp. 210-211.

Appendix

Terumo Spectra Optia® Apheresis System Mononuclear Cell (MNC) Collection Procedure Training Checklist

MNC Training Checklist - 306620870.

Terumo Spectra Optia® Apheresis System Mononuclear Cell (MNC) Collection Student Handbook

MNC v8 Handbook-Student.pdf

Terumo Spectra Optia® Apheresis System New User Workbook

New User Workbook - Student A4.pdf