PERIPHERAL BLOOD STEM CELL REINFUSION (PBSC) FOR AUTOLOGOUS TRANSPLANTATION IN JHCH

<table>
<thead>
<tr>
<th>Sites where Local Guideline applies</th>
<th>JHCH Wards, Oncology Day Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>This Local Guideline applies to:</td>
<td></td>
</tr>
<tr>
<td>Adults</td>
<td>No</td>
</tr>
<tr>
<td>Children up to 16 years</td>
<td>Yes</td>
</tr>
<tr>
<td>Neonates – less than 29 days</td>
<td>No</td>
</tr>
<tr>
<td>Target audience</td>
<td>Medical and Nursing Staff caring for paediatric oncology patients</td>
</tr>
<tr>
<td>Description</td>
<td>This guideline outlines process for arranging and administering PBSC to ensure patient safety.</td>
</tr>
<tr>
<td>National Standard</td>
<td>4, 5, 7</td>
</tr>
</tbody>
</table>

Go to Guideline

<table>
<thead>
<tr>
<th>Keywords</th>
<th>Autologous, blood, children, intravenous, IV, oncology, PBSC reinfusion, stem cell, transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document registration number</td>
<td>11.1</td>
</tr>
<tr>
<td>Replaces existing document?</td>
<td>Yes</td>
</tr>
<tr>
<td>Registration number and dates of superseded documents</td>
<td>11.13 JHCH Feb 2012</td>
</tr>
</tbody>
</table>

Related Legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:
- NSW Health Policy Directive PD2016_001 Donation, Use and retention of Tissue from Living Persons.
- NSW Health Policy Directive 2011_077 Recognition and management of a Patient who is Clinically Deteriorating
- Sydney Children’s Hospital Kids Cancer Centre (2016). Infusion of Thawed HPC Standard Operating Procedure.

Local Guideline note
This document reflects what is currently regarded as safe and appropriate practice. The guideline section does not replace the need for the application of clinical judgment in respect to each individual patient but the procedure/s require mandatory compliance. If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their unit manager/delegate and document the variance in the patients’ health record.

Position responsible for the Local Guideline and authorised by
Jason Simpson, General Manager/Director of Nursing CYPFS

Contact Person Details
Carol Doherty, JHCH Oncology CNC Carol.doherty@health.nsw.gov.au

Date authorised
This document contains advice on therapeutics
No

Issue date
October 2019

Review date
October 2022
# TABLE OF CONTENTS

- PURPOSE AND RISKS ............................................................................................................................ 3
- GLOSSARY ............................................................................................................................................. 3
- GUIDELINE .............................................................................................................................................. 3
- Staff Preparation ...................................................................................................................................... 3
- SPECIAL REQUIREMENTS ..................................................................................................................... 4
- Planning ................................................................................................................................................... 4
- BACKGROUND ........................................................................................................................................ 5
- ACCESS .................................................................................................................................................. 5
- EQUIPMENT ............................................................................................................................................ 5
- PROCEDURE .......................................................................................................................................... 5
  - Pre- Procedure ...................................................................................................................................... 5
  - Premedication ....................................................................................................................................... 6
  - Patient education prior to infusion ......................................................................................................... 6
  - Observations ......................................................................................................................................... 6
  - Preparation for infusion ......................................................................................................................... 7
  - Infusion of PBSC ................................................................................................................................... 7
  - Clumping and or Clotting ....................................................................................................................... 8
  - Infusion Reaction .................................................................................................................................. 8
  - Documentation ...................................................................................................................................... 8
- IMPLEMENTATION, MONITORING COMPLIANCE AND AUDIT ............................................................ 8
- FEEDBACK .............................................................................................................................................. 8
- CONSULTATION ..................................................................................................................................... 8
PURPOSE AND RISKS

Purpose
- Patient to receive PBSC safely and within guidelines
- PBSC are given within 20 minutes of thawing

RISKS
These risks are minimised by:
- Monitoring Vital Signs as described below
- Maintaining strict Fluid Balance Chart and notifying if urine output does not meet requirements.
- Monitoring patients urine for any red discolouration and urinalysis for blood if suspected, due to the presence of lysed RBC in the reinfusion product
- Monitoring patients weight
- Monitoring of blood electrolytes

Risk Category: Clinical Care & Patient Safety

GLOSSARY

<table>
<thead>
<tr>
<th>Acronym or Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMT</td>
<td>Bone Marrow Transplant</td>
</tr>
<tr>
<td>CVAD</td>
<td>Central Venous Access Device</td>
</tr>
<tr>
<td>DMF</td>
<td>Double Maintenance Fluids</td>
</tr>
<tr>
<td>DMSO</td>
<td>Dimethyl Sulfoxide</td>
</tr>
<tr>
<td>PBSC</td>
<td>Peripheral Blood Stem Cells</td>
</tr>
<tr>
<td>SRMO</td>
<td>Senior Resident Medical Officer</td>
</tr>
</tbody>
</table>

GUIDELINE

This Guideline does not replace the need for the application of clinical judgment in respect to each individual patient.

STAFF PREPARATION

It is mandatory for staff to follow relevant: “Five moments of hand hygiene”, infection control, moving safely/safe manual handling, documentation practices and to use HAIDET for patient/carer communication: Hand hygiene Acknowledge, Introduce, Duration, Explanation, Thank you or closing comment.
SPECIAL REQUIREMENTS

- Oncologist/Transplant Physician JHCH to complete the Notification of Cryopreserved Product Infusion Form (Obtained from the BMT Laboratory at the Mater) and sent to the BMT Laboratory at the Calvary Mater Hospital, Newcastle, 1 week prior to planned infusion date. This must be completed prior to commencing chemotherapy conditioning treatment. A cell integrity check must be completed prior to a ‘go-ahead’ being attended to commence conditioning chemotherapy and the results of this must be documented prior to starting conditioning.

- Please call The BMT Laboratory located at The Calvary Mater Hospital the day prior to the PBSC re-infusion to confirm the details and ensure that the infusion occurs at least 24 hours following the last dose of chemotherapy. Infusion maybe more than 24 hours after chemotherapy if dictated by the protocol. This will be detailed in the chemotherapy protocol completed by the Consultant Oncologist/Transplant Physician.

- The BMT Scientist/Technician will come from the Calvary Mater Hospital at a prearranged time.

- Ensure antibiotics are prescribed when the product is known to be positive for microbial contamination. Culture results and antibiotics choice must be discussed with the Consultant/Transplant Physician, open disclosure of the result and risks discussed with the family and this should be documented in the notes.

- Patient must be nursed with the ratio 1:1 during infusion.

- The BMT Scientist/Technician will bring the thawing bath and the PBSC and will be responsible for thawing PBSC.

- Have equipment ready, including anaphylaxis medications prescribed and drawn-up at the bedside prior to the technician’s arrival. Ensure the required staff (medical officer) is available for the expected time of infusion, and present prior to thawing.

- Arrange for Child Life Therapy to be present for preparation pre and during the infusion.

- The medical record number on the PBSC bags may be from Sydney Children’s Hospital and the Registered Nurses checking the PBSC will need to confirm the patient’s name, date of birth and cross reference with the accompanying documentation (which will include the details of the PBSC bags including bag identifiers, total cell dose and volume to be infused and the relevant patient details) to ensure the correct patient is receiving their own PBSC in the appropriate doses.

PLANNING

- Informed consent for Autologous Stem Cell Transplant must be obtained prior to commencing conditioning chemotherapy treatment.

- Please call the BMT Laboratory at The Calvary Mater Hospital the day prior to the PBSC reinfusion to confirm the details, including number of bags, and ensure that the infusion occurs at least 24 hours following the last dose of chemotherapy.

  NB: Infusion maybe more than 24 hours after chemotherapy if dictated by the protocol. This will be detailed in the chemotherapy protocol completed by the Consultant Oncologist/Transplant Physician.

- Consideration should be given to the blood pressure parameters (i.e. defining the 97th centile for hypertension for the child’s height and age) prior to infusion and prescription of an appropriate antihypertensive. Should the child become hypertensive above the parameter on manual blood pressures twice in 15 mins, administration of antihypertensive should be undertaken at the instruction of the Oncologist/Transplant Physician.
BACKGROUND

An autologous transplant involves the infusion of the patient's own haematopoietic stem cells which are collected in advance via Apheresis or Bone Marrow Aspirates. These cells are then reinfused after the patient receives high doses of chemotherapy. This is aimed to reduce their period of myelosuppression and ensure marrow regeneration.

ACCESS

- PBSC are preferably infused via central venous access device (CVAD). If CVAD unable to be used then a large bore cannula will need to be used.
- Documentation of access, including assessment, on CVAD/Peripheral IV care plan (HNE029200)

EQUIPMENT

- 2x 0.9% sodium chloride 100mls bags for priming the IV line and flushing after the completion of the PBSC.
- Intravenous giving set containing a 170-200micron filter (most standard giving sets contain appropriate filters). DO NOT USE a leukocyte depletion filter.
- 1x Extension piece
- 2x Yellow Kidney Dish
- Anaphylaxis medications drawn up and ready at bedside, in yellow kidney dish. Personal protective equipment (PPE)
- 4x 70% Isopropyl Alcohol swabs 2x 10ml luer lock syringes
- 1x Blunt drawing up needle
- 1x 10ml ampoule of 0.9% Sodium Chloride
- Oxygen mask and nasal prongs
- Resuscitation equipment
- Age appropriate observation chart
- Large trolley for thawing bath
- Contaminated waste bin

PROCEDURE

PRE-PROCEDURE

Premedication: hydrocortisone, loratadine and paracetamol charted and available for administration as per medication orders.
- Antiemetics: If possible to be timed to be administered 30 minutes prior to infusion PBSC.
- Prescribe adrenaline in case of anaphylactic reaction and have it drawn up ready at the bedside.
- Prescribe the PBSC on the Paediatric Blood Product Administration Form.
- Post hydration DMF should be pre-charted.
- Ensure the patient has correct identification bands on.
- Arrange for Child Life Therapy to be present for preparation pre and during the infusion.
- Arrange for the medical officer to be available and present on the ward for the duration of the infusion due to the risk of anaphylaxis.
- BMT Scientist/Technician will come from the Calvary Mater Hospital at a prearranged time.
PREMEDICATION

- Administer prescribed antiemetic: at least 30 minutes prior to planned time of PBSC infusion.
- Administer prescribed premedication: at least 20 minutes before planned time of PBSC infusion.

PATIENT EDUCATION PRIOR TO INFUSION

- Ensure the patient/parent/carer has been informed of the possible side effects by the Oncologist/Transplant Physician.
- Inform the patient/parent/carer that the cells are frozen in dimethyl sulfoxide (DMSO) which protects the cells during cryopreservation and thawing that it may cause;
  - Nausea and vomiting
  - Tickle in the throat
  - Abdominal cramps
  - Flushing, palpitations, tachycardia, hypertension or hypotension, all of which may be reduced by decreasing the rate of infusion and increasing the time interval between each bag.
  - Red discoloration of urine after the infusion (due to the presence of lysed RBC in the reinfusion product)
  - Shortness of breath
  - Rarely cardiac arrhythmia and arrest
  - Rarely anaphylaxis
  - Rarely neuro toxicity
- Inform patient/parents/carer to tell nursing or medical staff immediately if they feel sick or hot or they are experiencing palpitations.
- Inform patient/parent/carer that they will almost certainly experience:
  - An unpleasant taste which may be alleviated by chewing or sucking on a lollipop or ice-block, mints, smelling citrus fruits. They must, however, be aware that this could potentially be a choking hazard if the patient has a reaction.
  - A distinctive odour which will disappear after about 2 days – this will be more evident to people around the patient than to the patient themselves.

OBSERVATIONS

- Perform baseline observations. Temperature, pulse, respiration (TPR) blood pressure (BP), and oxygen saturation (SaO2) and record on the age appropriate Standard Paediatric Observation Form (SPOC). Ensure they are within normal limits for the child’s age.
- Monitor pulse rate and SaO2 at least every 5 minutes during infusion. N.B. Pulse rate must be monitored manually to detect any irregularity or changes in volume.
  - At the end of the infusion, full observations need to be monitored hourly for 4 hours. Note: If the patient is hypertensive at the end of infusion, alert Oncology SRMO/Registrar and administer anti-hypertensives if prescribed. Monitor BP every 10-15 minutes until normotensive.
  - Once normotensive, full observations need to be monitored hourly for 4 hours
  - Then 4 hourly full observations if stable.
- DMF to commence at the completion of PBSC infusion
- 6 hourly urine output totals with DMF
- Check U/A for blood and inform consultant or any urine discolouration or blood on urinalysis
- Daily Weight
- Report to Oncology SRMO/Registrar if any blood noted on urinalysis.

**PREPARATION FOR INFUSION**

- Check the labels on the frozen product against the patient’s identification band including name and date of birth. The medical record number on the PBSC bags may be from Sydney Children’s Hospital and the Registered Nurses checking the PBSC will need to confirm the patient’s name, date of birth and cross reference with the accompanying documentation (which will include the details of the PBSC bags including bag identifiers, total cell dose, volume to be infused and the relevant patient details) to ensure the correct patient is receiving their own PBSC in the appropriate doses.
- Once all checks have been performed the nursing staff and BMT Scientist/Technician will need to sign the Product Infusion Form brought over from the Calvary Mater Hospital and the Paediatric Blood Product Administration Form for the infusion of the PBSC.
- Nursing staff to sign off the Oncology Prescription/CHARM prescription (MAR) for the infusion of the PBSC.
- Don personal protective equipment (PPE).
- Prime the intravenous giving set with 0.9% sodium chloride. Do not infuse any other solutions concurrently with the PBSC unless the line has been adequately flushed (10-20ml 0.9% sodium chloride) before and after the medication.-DO NOT INFUSE ANY OTHER MEDICATIONS AT THE SAME TIME AT THE PBSC.
- Draw up 10mls sodium chloride with blunt drawing up needle into 10ml luer lock syringe.
- Scrub the hub of the needless connector with x2 70% Isopropyl Alcohol wipes for a total of 15 seconds and allow to dry.
- Connect 10ml syringe to needless connector and check for blood return from CVAD. Flush with 10mls 0.9% sodium Chloride using pulsating method and connect the giving set. When access to patient has been secured inform the BMT Scientist/Technician to commence thawing the cells.

**INFUSION OF PBSC**

- Once the BMT Scientist/Technician has thawed the cells, infuse the cells without delay to prevent clumping.
  1. Aseptically spike the bag after vigorously scrubbing the infusion access port with x2 70% Isopropyl Alcohol wipes for a total of 15 seconds and allow to dry.
  2. Open the roller clamp and any clamp on the line and infuse cells via gravity feed < 20 minutes per bag.
  3. Flush the line with minimum 20ml of 0.9% sodium chloride after each bag has been infused.
  4. If more than one bag is to be infused inform the BMT Scientist/Technician 5 minutes before the next bag is required so that there is enough time for the cells to be thawed.
- Follow the above steps 1-4 until all bags have been infused
- Commence Double maintenance fluid for 24 hours post PBSC, unless instructed otherwise by the Oncologist/Transplant physician.
- Notify transplant physician and BMT Scientist/Technician of any adverse events – including hypertension, tachycardia, fever or allergic response. Please complete the adverse reaction section of the Product Infusion Form, located in the patients’ chart, and return a copy to the BMT Laboratory.
CLUMPING AND OR CLOTTING

- If visible clumps begin to form during the infusion, the filter will prevent the infusion of large particles and hence the infusion can be continued.
- If visible clots are seen in the line below the filter, pause the infusion, inform the BMT Scientist/Technician and they will advise if any Acid Citrate Dextrose (ACD-A) is required to be added to the infusion.

INFUSION REACTION

- If the patient shows any signs of infusion reaction as aforementioned, immediately slow down the infusion and continue to monitor for worsening symptoms. If the infusion reaction becomes severe, stop the infusion, inform Oncology SRMO/Registrar and administer medications as prescribed. Re-commence the infusion as instructed by Oncology SRMO/Registrar once symptoms of subsided.
- Anaphylaxis or anaphylactoid reactions may be seen with stem cell reinfusions and appropriate escalation of patient care must be followed. This may include administration of anaphylaxis medications and calling a Rapid Response.

DOCUMENTATION

- Complete the Product Infusion Form supplied by the Processing Laboratory from the Calvary Mater Hospital with Thawing and Infusion details, including details of any adverse events.
- Record details in patient’s medical notes.
- Document any infusion reactions in the patient’s medical records and inform the Oncologist/Transplant Physician and BMT Scientist/technician. If multiple stem cell supported cycles are planned, provision for any change in management of future cycles if there were adverse events must be undertaken by the Oncologist/Transplant physician.
- Complete the fluid balance chart and administer fluids as prescribed. Please chart the stem cell infusion on the fluid order sheet after performing the bag check.

IMPLEMENTATION, MONITORING COMPLIANCE AND AUDIT

This document replaces current guideline with no change in practice. Oncology Clinical Nurse Educator will communicate with nursing and medical staff to ensure they are aware policy is available on Policy, Procedure and Guideline directory. Any related IIMS will be investigated.

FEEDBACK

Any feedback on this document should be sent to the Contact Officer listed on the front page.

CONSULTATION

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Frank Alvaro</td>
<td>Paediatric Oncologist/Haematologist/Transplant Physician</td>
</tr>
<tr>
<td>Dr Kristy McCarthy</td>
<td>Paediatric Oncologist/Transplant Physician</td>
</tr>
<tr>
<td>Carol Doherty</td>
<td>Paediatric Oncology/Haematology CNC</td>
</tr>
<tr>
<td>Name</td>
<td>Position/Activity</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Sandra Stone</td>
<td>Nurse Unit Manager Ward J1</td>
</tr>
<tr>
<td>Kate Baker</td>
<td>Paediatric Oncology/Haematology CNE</td>
</tr>
<tr>
<td>Linda Welschinger</td>
<td>BMT Laboratory Scientist Calvary Mater Hospital, Newcastle</td>
</tr>
<tr>
<td>Cathie Milton</td>
<td>Clinical Nurse Consultant Haematology Calvary Mater Hospital Newcastle</td>
</tr>
</tbody>
</table>