Infusion of Thawed, Washed and Filtered Cord Blood for Pediatric Allogeneic Transplantation
PBMT-GEN-053
INFUSION OF THAWED, WASHED AND FILTERED UMBILICAL CORD BLOOD FOR PEDIATRIC ALLOGENEIC TRANSPLANTATION

1 PURPOSE

1.1 To outline the procedure for the infusion of thawed, washed and filtered umbilical cord blood cells. These products have been cryopreserved, thawed and washed to remove DMSO and other cryoprotectants in the Stem Cell Laboratory prior to transportation to the patient’s bedside and administration to the patient.

2 INTRODUCTION

2.1 Umbilical cord blood which has been cryopreserved is prepared in the Stem Cell Transplant Laboratory for infusion. On the scheduled day of infusion, the product is thawed and washed to reduce volume and cryoprotectants, and then filtered before transport to the patient’s bedside for administration. On the morning of the infusion, the Stem Cell Transplant lab contacts the patient’s care nurse to confirm the planned time of infusion and to calculate the timing of delivery of the product to the site of care. Thirty to sixty minutes prior to the infusion; the patient is pre-medicated with Benadryl, Tylenol, +/- steroids to prevent infusion-related reactions. As it is recognized that infusions of double cord units can be associated with a higher rate of clinical reactions, additional precautions are taken for these infusions. If a patient is to receive a double cord blood unit then after infusion of the first unit is completed and the patient is stable, the care nurse will call the Stem Cell Transplant Laboratory to instruct them to begin the process of thawing, washing, and preparation of the 2nd cord blood unit. The 2nd unit will be hung for infusion a minimum of 2 hours after completion of the infusion of the 1st unit. A repeat dose of pre-medications will be administered if more than 4 hours elapses over the period of time for the 2 infusions. No further pre-medications will be needed unless time lapse has been >4 hours from the administration of the first doses of pre-medications.

2.2 Special Precautions:

2.2.1 HSCT products must never be leukocyte filtered or irradiated.

2.2.2 When a double cord transplant will be performed, the second unit should not be thawed until the first unit has been infused and the lab has confirmed with the clinical team that the patient is stable.

2.2.3 There should be a minimum of 2 hours between the end of the infusion of the first unit and the start of the infusion of the second unit.

2.2.4 In a double cord transplant, the RBC, DMSO and volume loads of the combined infusions must be considered and adjusted to provide safe products to the patient.
2.2.5 Typically, the product arriving from the STCL has been filtered through a sterile 170uM filter set prior to placement into the final container for administration.

3 SCOPE AND RESPONSIBILITY

3.1 This procedure will be used in the infusion of thawed cord blood units in pediatric transplantation.

3.2 The Stem Cell Transplant Laboratory Manager, Pediatric Blood and Marrow Transplant Unit (5200) inpatient unit medical and nursing staff, the outpatient medical and nursing staff of the Pediatric BMT Clinic and Valvano Day Hospital (VDH), Children’s Health Center (CHC), Nurse Managers and attending physician on service are responsible for ensuring the requirements of this procedure are successfully met.

3.3 RNs may administer cellular therapy products after completing a demonstration of clinical competency with their preceptor.

4 DEFINITIONS/ACRONYMS

4.1 CHC Children’s Health Center
4.2 PPE Personal Protective Equipment
4.3 VDH Valvano Day Hospital

5 MATERIALS

5.1 Supplies needed upon arrival of product to the unit:
5.2 1 - 10mL normal saline syringe
5.3 1 – 5mL normal saline syringe
5.4 Alcohol prep pad
5.5 End cap
5.6 Sterile gloves
5.7 Masks
5.8 Specimen Requirements:

5.8.1 Thawed, filtered appropriately labeled, transplant product.

5.8.2 STCL-SOP-050 Infusion Form

5.8.3 Accompanying paperwork

6 EQUIPMENT

6.1 Alaris Syringe Pump

6.2 Cardiac Monitor

7 SAFETY

7.1 Use appropriate PPE when handling cellular therapy products.

8 PROCEDURE

8.1 Verify EPIC orders for re-infusion and notify on service attending physician that product has arrived to the unit. A physician or nurse practitioner must be present on 5200 for the duration of the infusion.
8.2 Verify that the product to be infused is indicated for the intended patient and that the patient received pre-medications for stem cell infusion 30-60 minutes prior to infusion.

8.3 Verify that product is for intended recipient by checking intended recipient tag of product against patient’s hospital identification bracelet.

8.4 Place electrodes for monitoring of heart rate during infusion.
8.5 Connect electrodes and pulse oximeter to patient and monitor and check that all connections are secure.

8.6 Insert 60mL syringe containing UCB product into a manual or automated Syringe Pump. The Alaris syringe pump is illustrated below.
8.7 Identify lumen of CVL to be used for infusion, check blood return and flush with normal saline.

8.8 Remove saline syringe from patient lumen and connect pre primed clamped transplant tubing by removing end cap from tubing and connect it to lumen of patient's CVL then remove Kelly clamp using aseptic technique.

8.9 Obtain vital signs before starting the infusion, then q5mins for 30mins, then q15mins until infusion is complete.

8.10 Infuse UCB at a rate of 5mL/kg/hour or per physician ordered rate on an Alaris pump (maximum infusion time WILL NOT BE LESS THAN 15 minutes).

8.11 After infusing the cells from the transplant syringe, turn stopcock off to the 60mL syringe and manually flush the tubing (using 5mL normal saline syringe) with 2.5 mL of normal saline flushing any residual cells out of the tubing and into the patient. Do not attempt to rinse the 60mL syringe with normal saline.
8.12 Disconnect tubing from patients CVL, flush lumen with normal saline and change cap per hospital protocol.

8.13 Document infusion on STCL-SOP-050 “Infusion Form”.

8.14 Document any adverse experiences on STCL-SOP-050 “Infusion Form” or if NMDP product, report per NMDP policy.

8.15 Maintain documents per hospital policy.

9 RELATED FORMS/DOCUMENTS

9.1 STCL-SOP-050 Infusion Form

9.2 PBMT-GEN-051 Infusion of Thawed and Washed Hematopoietic Stem and Progenitor Cells for Allogeneic or Autologous Transplantation

9.3 STCL-SOP-028 JA1 Thawing Job Aide for Patients

10 REFERENCE


10.2 Circular of Information for the Use of Cellular Therapy Products, Current edition

10.3 AABB Technical Manual, Current edition
## REVISION HISTORY

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| 05           | J. Allison | Added Section 11 Revision History. Formatted.  
SOP 8.1 Add EPIC  
Added Section 2.2 Special Precautions  
Changed title  
Combined PBMT-GEN-051 JA 2 and PBMT-GEN-JA3 as one procedure and changed the JA into an SOP number.  
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Added STCL-SOP-028 JA1 Thawing Job Aide for Patients to Section 9. |
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