



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

DOCUMENT NUMBER: PBMT-GEN-051

DOCUMENT TITLE:

Infusion of Thawed and Washed Hematopoietic Stem and Progenitor Cells for Allogeneic or Autologous Transplantation

DOCUMENT NOTES:

Document Information

Revision: 12

Vault: PBMT-General-rel

Status: Release

Document Type: PBMT

Date Information

Creation Date: 23 May 2022

Release Date: 10 Jun 2022

Effective Date: 10 Jun 2022

Expiration Date:

Control Information

Author: MOORE171

Owner: MOORE171

Previous Number: PBMT-GEN-051 Rev 11

Change Number: PBMT-CCR-349

PBMT-GEN-051

INFUSION OF THAWED AND WASHED HEMATOPOIETIC STEM AND PROGENITOR CELLS FOR ALLOGENEIC OR AUTOLOGOUS TRANSPLANTATION

1 PURPOSE

- 1.1. To outline the procedure for the infusion of thawed and washed transplant products (PBPCs, bone marrow, umbilical cord blood cells). These products have been cryopreserved, thawed and washed to remove dimethyl sulfoxide (DMSO) and other cryoprotectants in the Stem Cell Laboratory (STCL) prior to transportation to the patient's bedside and administration to the patient.

2 INTRODUCTION

- 2.1. Peripheral blood stem/progenitor cells, umbilical cord blood, autologous or allogeneic bone marrow, which have been cryopreserved and stored after collection are thawed and prepared for infusion in the Stem Cell Laboratory. The product is thawed and washed to remove cryoprotectants before being transported to the patient's bedside for administration to the patient. On the morning of the infusion, the Stem Cell Laboratory 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. An infusion set is provided for use at the patient's bedside. This set is comprised of the bag of cells to be infused which has been sterile docked to a bag of normal saline. The saline will be used to rinse the transplant bag and tubing after the cells are infused. Syringes are attached to stopcocks to allow for aspiration of the product from the bag if flow does not occur easily. Thirty to sixty minutes prior to the infusion, the patient is pre-medicated with diphenhydramine, acetaminophen, +/- corticosteroids to prevent infusion-related reactions.
- 2.2. Special Precautions:
 - 2.2.1. Hematopoietic Stem Cell Transplant (HSCT) products must never be leukocyte filtered or irradiated.
 - 2.2.2. When multiple products are scheduled to be infused, wait a minimum of 2 hours between products.
 - 2.2.3. 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 as confirmed with the clinical team that the patient is stable
 - 2.2.4. In a double cord transplant, the red blood cell, DMSO and volume loads of the combined infusions must be considered and adjusted to provide safe products to the patient.

3 SCOPE AND RESPONSIBILITIES

- 3.1. The Laboratory Manager and medical and nursing staff of the Pediatric Transplant and Cellular Therapy (PTCT) inpatient and outpatient units are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1. BMT Blood and Marrow Transplant
- 4.2. CHC Children's Health Center
- 4.3. DLI Donor Lymphocytes
- 4.4. DMSO Dimethyl sulfoxide
- 4.5. HSCT Hematopoietic Stem Cell Transplant
- 4.6. PBPC Peripheral Blood Progenitor Cells
- 4.7. PTCT Pediatric Transplant and Cellular Therapy
- 4.8. STCL Stem Cell Laboratory

5 MATERIALS

- 5.1. Transplant bag from STCL
- 5.2. Normal Saline Attachment in Satellite Bag
- 5.3. Gravity Blood Set with Standard Blood Filter (170-260 micron filter)
- 5.4. 60 mL Luer-Lock Syringe
- 5.5. 250 mL Normal Saline bag
- 5.6. SmartSite Infusion Set
- 5.7. Double 3-way stopcock Extension tubing
- 5.8. Two (10 mL) Normal Saline Syringes
- 5.9. Alcohol Preps
- 5.10. STCL-SOP-050 Infusion Form
- 5.11. Accompanying paperwork
- 5.12. Materials

Specimen Requirements:



5.13.

- 5.13.1. Thawed, appropriately labeled, transplant product docked to 50 mL bag of normal saline.



6 EQUIPMENT

- 6.1. NA

7 SAFETY

- 7.1. Appropriate PPE must be worn when handling cellular therapy products.

8 PROCEDURE

- 8.1. Verify the orders for infusion in the electronic medical record and notify the attending physician that product has arrived to the unit. A physician or nurse practitioner must be present on the inpatient unit or clinic 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 within the 30-60 minutes prior to infusion.



- 8.3. Assemble bag of normal saline to SmartSite infusion set and prime tubing with normal saline and have available in case of an emergency. Prime double stopcock and extension tubing with normal saline.



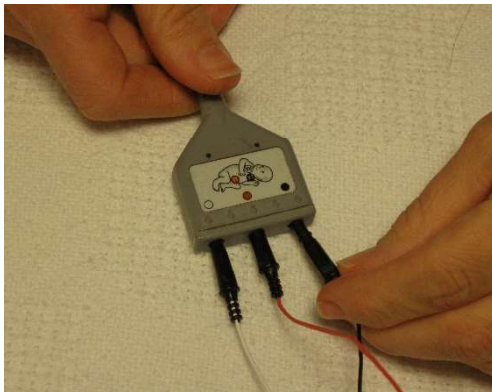
- 8.4. Verify that the product is for intended recipient by checking intended recipient tag of product against patient's hospital identification bracelet.



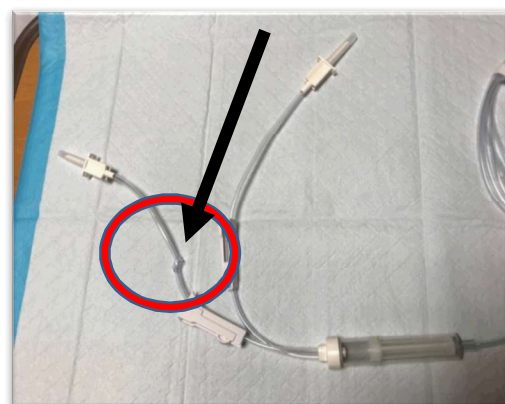
- 8.5. Place electrodes for monitoring of heart rate during infusion.



- 8.5.1. For auto reinfusions in outpatient infusion area, only heart rate and O2 saturations are monitored.
- 8.6. Connect electrodes and pulse oximeter to patient and monitor.



- 8.7. On Gravity Blood Set tubing, first roller clamp one of the two double spikes and roller clamp the primary line of the blood tubing. Do not tie a knot in one end of the double spike.



- 8.8. Spike product with Gravity Blood set and place a Kelly Clamp between the product bad and the saline rinse bag (be sure that the seal is closed between the saline rinse bag and product bag).



- 8.9. Hand prime Gravity Blood Set with the progenitor cell product. Do not back-prime Saline up into Gravity Blood Set.



- 8.10. Connect primed Gravity Blood Set to the Double 3-way stopcock tubing at the end.



- 8.11. Notify the attending physician on service of the patient's weight and the volume of the transplant. The attending physician will give an order for how long to infuse the product. Check patient's central venous line (CVL) for blood return and flush

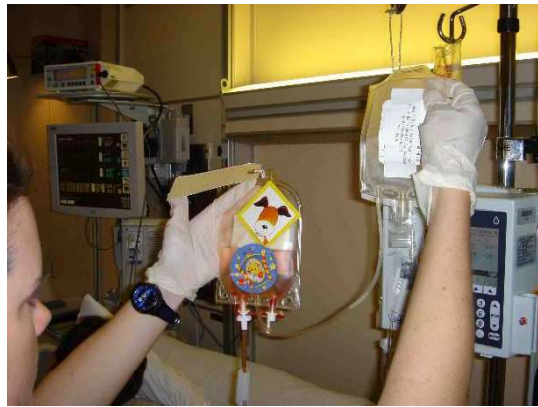
patient's central line with normal saline and connect tubing to patient's central line. Turn both stopcocks so they are open to the patient and infuse product per physician order. If product fails to flow after opening clamps, attach a 60 mL syringe to the stopcock and use the push pull method to complete the transplant per the physician's orders.



- 8.12. Obtain vital signs every 5 minutes for 30 minutes then every 15 minutes until the infusion is complete.
- 8.13. After infusing the cells from the transplant bag (when the bag is empty and very little remains in the drip chambers so as to not get air in the line) rinse the empty bag with saline to rinse any residual cells out of the bag and into the patient. To accomplish this:
 - 8.13.1. Clamp off the line to the patient.
 - 8.13.2. Open the clamp on the bag of saline (if available) or open the Kelly clamp on the tubing running from the bag of normal saline to the transplant bag and break the seal formed when sterile docking the tubing.



- 8.13.3. Allow approximately 1/4 of the 50 mL bag of normal saline to rinse into the transplant bag, and then re-clamp line with Kelly clamp or claps on tubing set.



- 8.13.4. Gently mix the transplant bag that contains residual cells and normal saline.
- 8.13.5. Open the line to the patient and infuse the saline product.
- 8.14. Repeat steps 8.13.3 thru 8.13.5 one more time, when the last bit of saline from the previous rinse is in the chamber, infusing approximately ½ of the normal saline bag (50 mL).
- 8.15. Document infusion on STCL-SOP-050 *Infusion Form*
- 8.16. Document any adverse experiences on STCL-SOP-050 *Infusion Form*. Alternately, if the product is a NMDP product, report per NMDP policy.
- 8.17. Maintain documents per hospital policy.

9 RELATED FORMS/DOCUMENTS

- 9.1. STCL-SOP-050 Infusion Form
- 9.2. PBMT-GEN-053 Infusion of Thawed Filtered Cord Blood for Pediatric Allogeneic Transplantation.
- 9.3. STCL-SOP-028 JA1 Thawing Job Aid

10 REFERENCE

- 10.1. Buchsel, PC and PM Kapustay, Eds. Stem Cell Transplantation: A Clinical Textbook. Oncology Nursing Press, Pittsburgh PA. 2000
- 10.2. Circular of Information for the Use of Cellular Therapy Products, Current Edition
- 10.3. AABB Technical Manual, Current Edition

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
12	<u>MC Owner:</u> S. McCollum <u>Document SME:</u> Tricia Stanton, Whitney Hawkins	Throughout: Acronyms defined Section 3 – Insertion of PTCT terminology Sections 5 and 8 – inclusion of applicable forms

Signature Manifest

Document Number: PBMT-GEN-051**Revision:** 12**Title:** Infusion of Thawed and Washed Hematopoietic Stem and Progenitor Cells for Allogeneic or Autologous Transplantation**Effective Date:** 10 Jun 2022

All dates and times are in Eastern Time.

PBMT-GEN-051 Infusion of Thawed Washed Stem and Progenitor Cells for Allo or Auto Transplantation

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Name/Signature	Title	Date	Meaning/Reason
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Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		27 May 2022, 07:47:11 AM	Approved