

**STANDARDIZED PROCEDURE**  
**ALLOGENEIC /AUTOLOGOUS HEMATOPOIETIC STEM CELL**  
**INFUSION (Adult, Peds)**

**I. Definition:**

The infusion of allogeneic /autologous hematopoietic progenitor cells as a part of hematopoietic stem cell transplant or donor lymphocyte infusion.

**II. Background Information**

**A. Setting:**

The setting (inpatient vs outpatient) and population (adults vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

**B. Supervision:** The necessity of this protocol will be determined by the Advanced Health Practitioner in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Advanced Health Practitioner.

Direct supervision will not be necessary once competency is determined, as provided for in the protocol. The Advanced Health Practitioner will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

**C. Indications**

Patients with a hematology /oncology diagnosis undergoing hematopoietic progenitor cells transplant as part of clinical trial, institutional trial or standard of care protocol.

**D. Contraindications:** Massive GI bleeding, septic shock or other overwhelming medical condition.

**III. Materials**

- a. Normal Saline bag.
- b. Manifold tubing
- c. Alaris IV pump tubing
- d. 2 four-way stopcocks
- e. 2 sets Alaris 20 inch tubing

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**IV. Stem cell infusion procedure**

**A. Pretreatment Evaluation**

1. History of malignancy undergoing HPCT; history of previous HPCT.
2. Patient evaluation, general appearance, vital signs; check stem cell orders and patient identification carefully.

**B. Set up**

- a. RN to confirm time with Hematopoietic progenitor cell transplant (HPCT) laboratory.
- b. RN to prepare infusion equipment
- c. RN to administer premeds.

**C. Patient Preparation**

1. The Attending MD/AHP will explain the side effects of the procedure, including cough, nausea, vomiting, diarrhea, intestinal cramps, abnormal taste, facial flushing, chest tightness, shortness of breath, hypertension, bradycardia, and conduction block. A time out will be performed prior to the start of the procedure.
2. An open vial of peppermint oil at the bedside is recommended to cut the smell of the preservative DMSO. It is recommended that patient's suck on hard candy to cut the taste of DMSO. An emesis basin should be placed near the patient.
3. The Attending MD/AHP will confirm the connection of the infusion line to the IV set-up. The hematopoietic cells in aliquot bags will be individually thawed by the HPCT medical laboratory technologist.
4. The RN will prime the IV filter tubing with normal saline, and attach it to the four-way stopcock, proximal to the patient. Once thawed each hematopoietic stem cell bag will be spiked, and attached to the filter tubing. The Attending MD/AHP may attach a 30 cc syringe to the second four-way stop- cock proximal to the patient.
5. The AHP/MD will re-confirm that the hematopoietic cell product to be infused is the appropriate product for the intended recipient. This will mean confirmation that the product is autologous (same donor and recipient) or allogeneic family member or unrelated. This will be done by comparing the hematopoietic cell product label to the product infusion sheet and the recipient's armband.

**D. Procedure: Stem Cell Infusion**

1. The Attending MD/AHP will infuse each cryopreserved hematopoietic cell product bag individually. Cells can be infused by gravity, or per AHP/MD judgment, may be pushed at no greater than 60ml per minute via a syringe. Do not run normal saline concurrently with the cells.

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2. Renal failure prophylaxis. If cryopreserved bone marrow is infused, or ABO incompatible cryopreserved hematopoietic cells are infused, renal failure prophylaxis will include mannitol 25 g IV prior to infusion and mannitol 12.5 g IV six hours later.
3. The Attending MD or AHP will document the start time of the stem cell infusion on the transfusion administration sheet.
4. The Attending MD/AHP will order antiemetics as needed for nausea and vomiting. A slowed infusion rate may also alleviate nausea and vomiting.
5. The RN and Attending MD/AHP will monitor the patient for signs of chest pain, chest tightness, nausea, vomiting, diarrhea, fluid overload, facial flushing, bradycardia.
  - f. For chest pain it is recommended to stop the hematopoietic stem cell infusion and run saline. A physical examination should be performed along with vital signs, oxygen supplementation, and EKG if appropriate. Resume the hematopoietic cell infusion once the patient is stabilized.
  - g. For nausea and vomiting it is recommended to slow the hematopoietic stem cell infusion and administer anti-emetics as appropriate.
  - h. For symptoms of fluid overload it is recommended to stop the infusion --- administer diuretics as appropriate.
  - i. For diarrhea it is recommended to stop the infusion. A commode can be placed at the bedside. The infusion can be re-initiated once the diarrhea has been controlled.
  - j. Just prior to the end of the final stem cell infusion, the Attending MD/AHP will obtain a 1-2 ml sample of stem cells in the 30 ml syringe attached to the four way stop cock.
  - k. The sample is removed by the Attending MD/AHP and given to the HPCT medical technologist.
1. At the end of the stem cell infusion, the Attending MD/AHP will notify the RN that the transplant is completed. The RN will re-attach the line to the IV pump.

**E. Post-Procedure**

1. Assess patient for possible side effects.
2. The Attending MD/AHP will complete appropriate forms, including signature, and document the completion time of the stem cell infusion.
3. The Attending MD/AHP will write a procedure note, including any complications, and the CD34 ( $6 \times 10^6/\text{kg}$ ) and/or CD3 ( $1 \times 10^7\text{CD3}/\text{kg}$ ) cell dosed infused.

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**V. Documentation**

**A. Documentation is in the electronic medical record**

1. Documentation of the consent, pretreatment evaluation and any abnormal physical findings.
2. Record the time out, indication for the procedure, blood product administration confirmation / laboratory, procedure, start and stop times of stem cell infusion, amount infused, the outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions.

**B. All abnormal events** are reviewed with supervising physician.

**VI. Competency Assessment**

**A. Initial Competence**

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
2. The Advanced Health Practitioner will demonstrate knowledge of the following:
  - a. Medical indication and contraindications of stem cell infusion.
  - b. Risks and benefits of the procedure
  - c. Related anatomy and physiology
  - d. Consent process (if applicable)
  - e. Steps in performing the procedure
  - f. Documentation of the procedure
  - g. Ability to interpret results and implications in management.
3. The AHP will observe the procedure at least once in its entirety. Under the direct supervision of the attending physician, the AHP will perform the Hematopoietic Stem Cell Infusion procedure successfully **three** times and will be evaluated for competence and technical skill..
4. Supervising physician will document Advanced Health Practitioner's competency prior to performing procedure without direct supervision.
5. The Advanced Health Practitioner will ensure the completion of competency sign-off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

**B. Continued proficiency**

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.

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2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least **three** times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

**VII. RESPONSIBILITY**

Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

**VIII. HISTORY OF PROCEDURE**

Revised Sept 2012 by Subcommittee of the Committee for Interdisciplinary Practice

Reviewed Sept 2012 by the Committee on Interdisciplinary Practice

Prior revision Nov 2008

Approved Sept 2012 by the Executive Medical Board and the Governance Advisory Council.

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