PRO: Infusion of Products for Cellular Therapy
December 17, 2009

National Institutes of Health
Clinical Center
Nursing and Patient Care Services

PROCEDURE: INFUSION OF PRODUCTS FOR CELLULAR THERAPY

Approved by:

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Chief, Nursing and Patient Care Services

Formulated: 3/00
Implemented: 3/00
Reviewed: 3/08
**Procedure:** Infusion of Products for Cellular Therapy

**Equipment:**
- Pre-stamped progress notes (2)
- Primary IV tubing (2)
- Universal Secondary Tubing
- Three-way Stopcock (optional)
- Sodium Chloride 0.9% 250 mL (2 bags)
- Infusion pump for emergency NS line only
- Hard candies/ Room deodorizer/ Orange slices (order from Dietary)
- Box of gloves

**Emergency Spill Equipment to have at bedside:**
- Sterile gloves (2 pairs)
- Sterilized straight 5-1/2” hemostats (4)
- Alcohol swabs

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<tr>
<th>STEPS</th>
<th>KEY POINTS</th>
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| **PRE-INFUSION** | 1. Cell infusions are scheduled with the CPS Service Coordinator by the research team, and then assigned to a CPS technologist. The component order in approved electronic medical record will reflect how many bags/aliquots are to be given. Donor lymphocyte infusions may occasionally be ordered and/or cancelled on short notice due to individual patient situation. Coordination of the product infusion:

Cryopreserved (frozen) products are thawed when the unit RN notifies cell processing (CPS) to prepare the product. If multiple infusions (bags/aliquots) are required, a time limitation around the availability of supportive services exists, therefore starting as soon as CPS is ready is critical.

Fresh infusions (collected within past 24 hours) need to be infused as soon as CPS verbalizes that the product is ready. Due to the deteriorating viability of the product, timely infusion of the product is critical. Unless otherwise stated by an Attending MD, the infusion takes priority over all medical testing and patient requests (i.e. ADL’s).

2. Pre-medication will only be given to patients receiving cryopreserved cells due to the DMSO preservative used. |
| 1. Call the Cell Processing Section (CPS) technologist assigned to the patient at 301-435-4801 or -4810 the day before or the day of the cell infusion to confirm the number of bags/syringes, type of product to be administered, fresh or cryopreserved (frozen) product, and start time of the infusion. |
| 2. Check the licensed independent practitioner’s (LIP) component order and infusion order to determine:
  a. component type and product number to be administered
  b. number of units/aliquots to be administered
  c. date to be administered
  d. special processing
  e. duration of infusion
  f. pre-medication orders, if indicated |
3. Verify blood product consent has been obtained and signed in the past 12 months, except for emergency transfusions, by visualizing the signed consent document in the medical record.

4. Ensure emergency equipment is available in patient’s room:
   a. Oxygen
   b. Suction machine
   c. Vital signs monitor
   d. 0.9% sodium chloride solution and administration set
   e. Emergency spill equipment

5. Verify that emergency medications are readily available in the area where patients will receive treatment.

6. Prepare room with deodorizers for patients receiving cryopreserved cells.

7. Measure and record vital signs (temperature, heart rate, respiratory rate, blood pressure, and oxygen saturation, as clinically indicated), pulmonary assessment, and circulatory assessment.

8. Provide patient education, including infusion process, potential complications, and associated symptoms to report.

9. Review renal function tests and CBC with treatment team.

10. Verify patency of IV access.

11. Start an IV infusion of 250 mL 0.9% sodium chloride at KVO to function as emergency/hydration line. Use primary infusion pump tubing and connect it hub to hub to the VAD lumen directly or via three-way stopcock.

12. Administer pre-medication as ordered.

13. The RN will notify the patient’s LIP when cells are to be infused. The LIP will be immediately available on the patient care unit (PCU).

14. Notify CPS technologist when the patient is ready to receive the first unit/ aliquot of cells. Verbally confirm the patient’s name, date of birth, medical record number, component number ordered in the

9. Based upon laboratory parameters, the LIP may choose to implement certain orders, e.g. aggressive hydration because DMSO may affect renal function, as can the hemolysis of RBC’s in the product.

10. It is recommended to use a CVC for infusion of cellular products, but peripheral access is acceptable.

11. This emergency line can also be used for administration of IV pre-medication.

12. Allow 30-60 minutes for oral medications and 10-30 minutes for IV medications to become effective.

13. RN can not begin infusion until LIP is available on the patient care unit (PCU).

14. Verification of the component order in the CRIS component order validates the active order and ensures thawing of the correct component.
CRIS component order, nurses name, and patient care unit.

15. When the CPS technologist delivers the thawed product to floor, the RN and technologist will confirm product number, patient's name, medical record number, date of birth, and bag # against the electronic component order in CRIS.

15. This check process will be documented by the CPS technologist in the laboratory computer system upon return to CPS. See Attachment A for an example of how the product will look.

16. Two competent individuals will compare:
   a. Cellular product received on the PCU to cellular product requested in the medical order.
   b. The cellular product number on the product container with the product number on the cellular product tag.
   c. Compare the expiration date and time on the cellular product container label to the current date and time.

16. Competent individuals are defined as RN’s who have completed the Blood Administration competency and successfully administered cellular products.

   Cellular product information must be compared to the information in the CRIS component order. The product numbers listed under the CRIS results tab only indicates what was released from CPS.

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<td><strong>INFUSION</strong></td>
<td><strong>1.</strong> Patients on Continuous Veno-Venous Hemofiltration (CVVH) on the day of cellular product infusion: CVVH will be discontinued at the start of the cellular product infusion and for 4 hours following the infusion.</td>
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<td><strong>2.</strong> Connect a second primary line of NS to the patient. This can be done either via a three-way stopcock or directly to a lumen separate from the emergency line. Cellular therapy products are to run via gravity, an infusion pump should NEVER be used to administer these products.</td>
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<td><strong>3.</strong> At the bedside, 2 competent individuals will perform identification procedure with cellular product immediately prior to spiking bag or connecting syringe. Verify the patient’s name and medical record number on the cellular product unit with the information on the recipient’s identification bracelet. Alternatively, if the patient does not have a hospital identification band, ask the patient or parent/guardian to state the patient’s full name and</td>
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<td>date of birth, according to MAS 03-1: Patient Identification.</td>
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<td>4. Observe each product for unusual color, appearance, temperature, or change in integrity of the container. Call CPS with any questions or concerns regarding the component.</td>
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<td>5. <strong>Syringe infusion:</strong> Infuse a free-flowing NS flush solution during administration of cellular products. Administer the cellular product through the designated primary IV tubing at the most proximal port to the patient. When completed, backflush the syringe with NS and infuse the dilute solution. Repeat until all syringes containing product have been infused.</td>
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<td>6. <strong>Bag infusion:</strong> Connect the secondary tubing to the primary normal saline line designated for cellular therapy and use backflush technique to prime the secondary tubing with normal saline. Spike the cellular product bag with secondary tubing (do not prime the tubing with cellular product). Infuse the cellular product via gravity, as tolerated by patient. When bag is empty, backflush secondary tubing with enough NS to rinse bag and infuse the dilute solution.</td>
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<td>7. Measure and record temperature, heart rate, respiratory rate, and blood pressure (oxygen saturation, if clinically indicated) before and after each bag/syringe has been infused.</td>
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<td>8. After each bag/syringe has infused, remove the adhesive backed &quot;Cell therapy product&quot; tag from the bag/syringe and place on progress note in patient's medical record.</td>
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<td>9. If more than one bag/syringe is to be infused, contact CPS at 301-435-4801 at the completion of each unit. CPS will then prepare and deliver the next unit of cells.</td>
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| 7. If bag infusion takes longer than 15 minutes, measure and record vital signs at 15 minute intervals.  
   a. Expect facial flushing at the start of each bag. Slow infusion; flushing will resolve within several minutes and does not usually require additional medication. |  
| 8. Placing the adhesive product tag in the patient’s record is in addition to, and does not replace, documentation in approved electronic medical record.  
   a. CPS will have completed left-hand side of label prior to delivery of product. At completion of infusion, RN will complete right-hand side of label with start time, end time, and initials of infusionist. |  
| 9. Once a cryopreserved product is thawed, survival time of cells is very short. Cell infusion must be initiated immediately after thawing. Do not request next unit of cells until previous unit is complete. |
### POST INFUSION

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<td>1. Check temperature, heart rate, respiratory rate, and blood pressure (oxygen saturation, if clinically indicated) after all units of cells have been infused and document in approved electronic medical record using blood product administration screens.</td>
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<td>2. Outpatients may be released thirty minutes to one hour after completion of infusion if vital signs are stable.</td>
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<td>3. Reinforce discharge instructions, in particular, when to notify health care team, and document discharge instructions in approved electronic medical record.</td>
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### TRANSFUSION REACTION

If at anytime during infusion the patient exhibits signs/symptoms of transfusion reaction, the following actions should be taken:

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<td>1. STOP the infusion of cells. DO NOT disconnect or discard the cellular product.</td>
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<td>2. Keep the emergency line open at KVO.</td>
<td>2. Emergency medications can be administered through this line if required.</td>
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<td>3. Notify the LIP and DTM fellow immediately</td>
<td>3. The DTM fellow will notify CPS.</td>
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<td>4. Administer emergency medications as ordered by LIP.</td>
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| 5. Follow CCND Blood Product Administration Procedure for transfusion reaction. Exception: DO NOT return the bag or syringe of cellular product to DTM. Leave the product connected to the cellular product line. | 5. CPS will send a technologist to the patient care unit to:  
   a. Secure the product  
   b. Return product to CPS for processing, if needed. |

### DOCUMENTATION

1. Completed “Cell therapy product” tag, peel off, and apply to a medical progress note.
2. Record pre and post transfusion documentation including vital signs, product volumes, product number, and summary note of patient's response in approved electronic medical record.
3. Record pre-medication in approved electronic medical record.
TECHNICAL COMPLICATIONS

In the event of a bag leakage or puncture:

1. When a bag has been punctured in the process of inserting a spike, do not attempt to remove the spike from the bag.
2. Close off tubing to the bag using integral clamp or hemostat.
3. Use 2 hemostats to isolate the area of the puncture. Keep the bag upright with the punctured area at the top. Do not squeeze the bag!
4. Telephone the CPS technologist responsible for the product at ext. 301 435-4801. Explain that the bag has been damaged and that someone is needed immediately to retrieve the cells.
5. Put on a new pair of sterile gloves and wipe the outside of the bag with alcohol.
6. When the technologist arrives, he/she will transport the product to the CPS for evaluation and, if possible, for transfer to another container.

REFERENCES

1. Areman, E. Salvage of Cell Therapy Product from Punctured Bag, Bethesda, MD. 2000
5. Georgetown University Hospital Bone Marrow, Peripheral Blood Stem Cells, Peripheral Blood Leukocytes and Granulocytes for Infusion Procedure
FIGURE I
PROCEDURE: INFUSION OF PRODUCTS FOR CELLULAR THERAPY

- NORMAL SALINE 250 mL
- PUMP (OPTIONAL)
- Emergency/Pre-med line

- Cell Line

- Secondary Tubing

- No Pump - To Gravity

- Cellular Product in Syringe

- To Patient

- See detail

- VAD Lumen

- Emergency/Pre-med line

- Separate VAD lumens

- Cell Line
ATTACHMENT A: Infusion of Products for Cellular Therapy