HCT Infusion Form (F2006 R5)
Janet Brunner-Grady, PA-C
Program Director- CIBMTR Data Operations
Disclosures

• I have no relevant conflicts of interest to disclose.
Overview of Form

- Pre-collection Therapy
- Product Collection
- Product Transport & Receipt
- Product Processing / Manipulation
- Product Analysis
- Product Infusion
- Donor / Infant Demographic Information
Pre-Collection Therapy (Q1-3)

This question is only enabled for PBSC and bone marrow products from non-NMDP donors.
Product Collection (Q4-7)

- The date of collection should be reported as the first date the stem cell collection was performed.
- If a collection event occurred over multiple days, enter the first date the collection began.
Product Transport & Receipt (Q8-21)

- The product transport & receipt section is completed for products collected off-site and shipped to the transplant center;
- Questions 19-21 apply only to cord blood products.
Product processing and manipulation have been separated into two categories for reporting purposes.
Product Processing / Manipulation

• Why would a product be “processed” prior to infusion?
  – Major ABO incompatibility
    • If the donor’s erythrocytes are incompatible with the recipient’s plasma, they need to be removed prior to infusion.
  – Example: Recipient’s ABO type was “A” and the donor’s ABO type was “B”.
    • Since the recipient’s ABO type is A, their plasma would contain anti-B antibodies, which could hemolyze the donor’s RBCs if not removed before infusion.
    • Since the RBCs were removed, you would report the product was “RBC reduced”.
Product Processing / Manipulation

• Why would a product be “manipulated” prior to infusion?
  – Increase the number of hematopoietic progenitor cells (HPCs) per kg in products for adult recipients (generally associated with CBUs)
    • (e.g., ex-vivo expansion)
  – GVHD prophylaxis
    • (e.g., ex-vivo T-cell depletion, CD34+ selection)
Product Analysis (Q41-93)

- The only timepoint required for all product types is **At Infusion**.
- For CBUs, both **At Infusion** and **At Arrival** timepoints are required.
Product Analysis Date

For the **At Infusion** timepoint, report the date the product was analyzed which may be different than the infusion date (reflective of the cell counts reported for this timepoint).

<table>
<thead>
<tr>
<th>Product Analysis (All Products)</th>
</tr>
</thead>
<tbody>
<tr>
<td>41. Specify the timepoint in the product preparation phase that the product was analyzed</td>
</tr>
<tr>
<td>- Product arrival (cord blood only)</td>
</tr>
<tr>
<td>- At infusion (final quantity infused)</td>
</tr>
<tr>
<td>42. Date of product analysis: _ _ _ _ / _ _ / _ _</td>
</tr>
<tr>
<td>YYYY   MM   DD</td>
</tr>
</tbody>
</table>
Product Analysis

• **Cryopreserved Product:** Report the complete analysis (adjusted for the volume infused) performed upon either at arrival of the product or prior to cryopreservation for the **At Infusion** timepoint.
  - If the cryopreserved product is contained in multiple bags, report the sum of the cell counts for the bags infused.
  - If the cryopreserved product is contained in a single bag, report the cell counts for the volume *infused*.
  - If a complete analysis is performed post-thaw, this analysis should be reported for the **At Infusion** timepoint; however, this is unlikely.
Product Analysis

• **Cryopreserved Product:** What to report for the product analysis at infusion depends on each center’s practice.

**Example 1:** Upon receiving an autologous PBSC product, the TC lab completes a TNC, CD34, and viability analysis prior to the product being cryopreserved on 4/3/2020.

- The product is frozen in 6 bags, each bag containing $1.1 \times 10^6$/kg CD34+ cells.
- The infusion orders indicate a dose of $3.0 \times 10^6$/kg CD34+ cells.
- The only analysis performed prior to infusion was viability.
- Three of the 6 bags were infused for a total dose of $3.3 \times 10^6$/kg CD34+ cells.
Product Analysis

• Cryopreserved Product continued-

Example 1:
• Q41 At Infusion timepoint
• Q42 Date of product analysis (2020/04/03)
• Q57 Total number of CD34+ cells to report is $231 \times 10^6$ CD34+ cells. How was that determined? Three of the 6 bags were infused. Each bag contained $1.1 \times 10^6$/kg CD34+ cells for a total number of CD34+ cells = $3.3 \times 10^6$/kg. Multiply that number by the recipient’s weight (70 kg) = $231 \times 10^6$ CD34+ cells.
Product Analysis

• Cryopreserved Product:

**Example 2:** Upon receiving an autologous PBSC product, the TC lab completed a TNC, CD34, and viability analysis prior to the product being cryopreserved on 4/3/2020.

- The product was frozen in 6 bags, each bag containing $1.1 \times 10^6$/kg CD34+ cells with a volume of 100 mls.
- The infusion orders indicated a dose of $3.0 \times 10^6$/kg CD34+ cells.
- Three of the 6 bags were infused for a total dose of $3.3 \times 10^6$/kg CD34+ cells on 5/4/2020.
- One week (4/27/2020) prior to infusion, a segment from one of the 3 bags chosen was analyzed for TNC, CD34+ & viability.
Product Analysis

• Cryopreserved Product continued-

Example 2:
The analysis from 4/27/2020 revealed a CD34 count of \(7.0 \times 10^5/\text{ml}\).
The volume/bag = 100 mls. Each bag contained 700 \(\times 10^5\) CD34+ cells (or 70 \(\times 10^6\) CD34+ cells).

• Q41 **At Infusion** timepoint
• Q42 Date of product analysis (2020/04/27)
• Q57 Total number of CD34+ cells to report is 210 \(\times 10^6\) CD34+ cells. How was that determined?
  Three of the 6 bags were infused.
  Since each bag contained 70 \(\times 10^6\) CD34/bag & three bags were infused for a total of 210 \(\times 10^6\) CD34 cells.
Product Analysis

• **Processed Product:** Report the last analysis performed prior to infusion for the **At Infusion** timepoint.

**Example:** Upon receiving a PBSC product, the transplant center completes a TNC, CD34, and viability analysis and then the product is RBC reduced. After processing, the CD34 and viability are analyzed again.

The results of the analysis performed after RBC reduction (CD34 and viability) should be reported for the **At Infusion** timepoint.

• In this scenario, the analysis for the TNC performed prior to RBC reduction will **not** be reported.
Product Infusion (Q94-143)

94. Date of this product infusion: ___/___/____

95. Was the entire volume of received product infused?
   □ Yes
   □ No

96. Specify what happened to the reserved portion:
   □ Discarded
   □ Cryopreserved for future use
   □ Other fate

97. Specify other fate: ____________________________

98. Time product infusion initiated (24-hour clock): ___ : ___
   □ standard time
   □ daylight savings time

99. Date infusion stopped: ___/___/____

100. Time product infusion completed (24-hour clock): ___ : ___
    □ standard time
    □ daylight savings time
Example 1: A PBSC product is collected and arrives at the transplant center in four bags. Two of the bags are infused fresh, and the remaining two bags are cryopreserved for future use. Since a portion of the product received was not infused, No should be reported for question 95.
**Example 2:** A marrow product was collected and has a total volume of 1600 mls. The product was buffy coat enriched leaving a volume of 230 mls. The entire buffy coat enriched product was infused. In this case, **Yes** should be reported in question 95.
Adverse Events (CBUs only)

Report all adverse events, regardless of grade or severity, occurring during CBU infusion or fevers within 24 hours of infusion.
Donor/Infant Demographics (Q144-170)

The Donor/Infant Demographics section must be completed for non-NMDP allogeneic donors or CBUs, including cooperative registry donors.
Questions