Part 1- Donor and Transplant Number Alignment

Alisha Mussetter – Clinical Research Coordinator II
Tiffany Hunt, MS, CCRP – Clinical Research Coordinator II
Wednesday February 17th, 2016
How to participate in a live poll via the mobile app

- Ensure your phone is connected to WiFi or cellular network.
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- Enter your response, based on options presented by the speaker and TAP Submit. (Wait for speaker’s instructions before you respond to questions)
Objectives

• Understand what alignment is and why it is important
• How to determine chronological transplant number
• Provide accurate donor number
Alignment of fields reported in multiple places

• Making efforts to eliminate duplicate fields
  – Still required in some places
  – Donor ID and transplant number are important to align the forms

• Think very carefully before using an override!
Chronological number

• Why is it important
  – Gives overview of HCT history (big picture)
  – SCTOD requirement (CVDR, TCSA)
    • Inclusion/exclusion criteria
  – Study related
    • Outcomes of 1\textsuperscript{st} vs 2\textsuperscript{nd} HCT
      • Inclusion/exclusion criteria
    – Maintain data quality/completeness
How Chronological number is determined

• CIBMTR considers HCT an infusion
  – That contains CD34+ cells
  – With intention to restore hematopoiesis

• Auto Rescues – do not count for chronological number
  – Meets the definition of transplant
  – Form follow up tracking does not reset
Not included in Chronological number determination

• Other types of infusions
  – DCI
  – Cellular Therapy
  – MIBG therapy (back to back HCTs)
Transfer patient

• CRID is a lifetime number in our database
  – We look at whole picture
  – Need entire transplant history
• Transplants that occurred at other centers should be counted in chronological number
Recipient Information Grid

- Shows the infusions that CIBMTR knows about
- Chronological number should align with grid
- If HCT missing
  - Verify proper reporting on applicable forms
  - Please report issues to your CRC
- AlloR/AlloU/Auto or Product missing
  - Verify proper reporting on applicable forms
  - Please report issues to your CRC
Recipient Information Grid

- Additional unexpected infusion date present
  - Verify dates reported match across all forms, including follow up and Pre-TED
  - Contact your CRC
  - Again, chronological number should align with the grid
According to the CIBMTR definition of transplant, if a recipient receives a transplant followed by an autologous rescue, how many transplants did the recipient have?

Option 1: 1 transplant  
Option 2: 2 transplants  
Option 3: no transplants

RESULTS:  
Form 2400: Pre-TED

- CIBMTR’s primary data source
- Changed how chronological number is asked
  - Version 1-3 asks for chronological number of *this* HCT
  - Version 4 ask for number of *prior* HCT
- Report prior autos in transplant history
  - If >1 prior transplant, contact CRC for assistance
Form 2450: Post-TED

• Still asks for chronological number of this HCT
  – Version 1-2 will match F2400 v1-3
  – Version 3 will be +1 of what is reported on F2400
    Version 4

• It is important to make sure the chronological number is consistent across the forms
Reporting tips

• Updating HCT date
  – First transplant: Indication Form 2814
  – ANY subsequent transplant: Last Follow Up form for prior HCT
    • Don’t update F2814 with subsequent HCT date!!

• Date of prior HCT on F2400 and Baseline Form 2000 must match the Follow Up form
  – Will add another date into the recipient grid

• Autopopulated field updates
  – Resubmit completed forms
A patient receives an autologous transplant at Candy Land Hospital. The patient transfers care and later receives an allogeneic transplant at your hospital. What is the correct chronological number to report?

- **Option 1:** Chronological # is 1
- **Option 2:** Chronological # is 2
- **Option 3:** Chronological # does not matter

• **RESULTS:**
Number of Donors

- F2400 allows up to 5 donors/products to be reported

- Reference Appendix O: How to Distinguish Infusion Types
Multiple products vs multiple donors

• Multiple donors
• Single donor, multiple products
  – If a multiple products are infused, then multiple (i.e. two or more) F2400 donor instances
    • Q’s 31 through 62
On Form 2400, how many donor instances (Q31-62) need to be completed when a single related donor provides PBSC and Marrow for infusion?

- Option 1: One Donor, One Donor Instance
- Option 2: Two Products = Two Donor Instances
- Option 3: One Donor Instance, Both Products

RESULTS:
Registry or UCB Bank ID

• This ID is shorthand for the collection center or bank where the product came from
• Why?
Registry or UCB Bank ID (F2400/F2006)

- Included to supplement BMDW:
  - St Louis Cord Blood Bank (SLCBB)
  - Viacord (VIAC)
  - Cord Blood Registry (CB)
  - New York Blood Center (NYCB)

- **TIP:** Search BMDW or [Infusion Form 2006 (PDF-RF)](http://example.com)
  - Note many large registries still have 2 codes

- The registry reported must match between F2400 and F2006
Specify Other Registry or UCB Bank (F2400/F2006)

- Other, specify option added - USE SPARINGLY
- Check BMDW or PDF-RF for country first
  - Spain, France, Italy, Australia all have codes
  - For related and autologous cord blood products, these questions should still be answered. The banks that stored these units are still expecting outcomes information
  - Donor ID, NMDP Co-op, and “Unknown” should not be reported here
    - If you need help determining the source, the transplant coordinator that requested the product should be able to tell you where it came from.
Specify Other Registry or UCB Bank (F2400/F2006)

- OK to use specify for Directed Infusions
  - i.e., collected for a specific recipient and stored locally
- Report collection/storage facility
  - Not lab where manipulation is performed
Quiz

St. Louis Cord Blood Bank has a registry code on the Form 2400?

Option 1: True!
Option 2: False!

• RESULTS:
Quiz

The registry code is the same as the donor ID.

Option 1: True!
Option 2: False!

• RESULTS:
Your allogeneic product came from an NMDP Co-op in Canada. How should this product be reported?

<table>
<thead>
<tr>
<th>Option 1: Registry code CND or HEM should be chosen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Option 2:</strong> Report as an NMDP product, no registry code provided</td>
</tr>
<tr>
<td><strong>Option 3:</strong> Report in Other, specify field as 'Canada via NMDP'</td>
</tr>
</tbody>
</table>

**RESULTS:**
Summary

• CIBMTR has to ask questions in multiple places and these must match across all forms

• Chronological transplant number is vital in patient transplant history and needs to be reported accurately

• Reporting the correct number of donors and completing correct number of donor ‘sections’ is important to form generation and data distribution
Questions?

Thank You

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Objectives

- How to report identification of recipient, donor, and cord unit
- Provide consistent and accurate ID’s across forms
- Ensure forms come due appropriately
Identification numbers

• Most common area with mistakes
• Why?
  – No universal system
  – More than one ID for the same donor/CBU
  – Format of ID is not enough
Identification numbers

• NMDP Recipient ID assigned by Case Management when a Preliminary Search is initiated. Needed in FN3 to map the two databases together.

<table>
<thead>
<tr>
<th>Who assigns it?</th>
<th>NMDP Case Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it assigned</td>
<td>when a preliminary search is initiated</td>
</tr>
<tr>
<td>Where is it used</td>
<td>NMDP, FN3</td>
</tr>
<tr>
<td>Format</td>
<td>XXX-XXX-X</td>
</tr>
<tr>
<td>How is it used</td>
<td>To link NMDP and CIBMTR systems</td>
</tr>
<tr>
<td>What happens if it’s wrong/missing</td>
<td>Link broken</td>
</tr>
</tbody>
</table>

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32
Identification numbers

- CIBMTR Research ID (CRID) assigned to the recipient by the transplant center using Form 2804. All CIBMTR reporting happens under this number

<table>
<thead>
<tr>
<th>Who assigns it?</th>
<th>Transplant Center*</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it assigned</td>
<td>When a recipient is registered using F2804</td>
</tr>
<tr>
<td>Where is it used</td>
<td>FN3</td>
</tr>
<tr>
<td>Format</td>
<td>Numeric, up to 10 digits</td>
</tr>
<tr>
<td>How is it used</td>
<td>CIBMTR reporting</td>
</tr>
<tr>
<td>What happens if it’s wrong/missing</td>
<td>Reporting incorrect data, or recipient is missing from FN3</td>
</tr>
</tbody>
</table>
Identification numbers

- NMDP Cord Blood Unit (CBU) ID or Donor ID assigned by NMDP to all units and products existing within NMDP member banks and collection centers. Needed on 2000 and 2006 to map to NMDP donor records

<table>
<thead>
<tr>
<th>Who assigns it?</th>
<th>NMDP member banks/collection centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it assigned</td>
<td>When donor registers</td>
</tr>
<tr>
<td>Where is it used</td>
<td>NMDP, FN3</td>
</tr>
<tr>
<td>Format</td>
<td>XXXX-XXXXX-X</td>
</tr>
<tr>
<td>How is it used</td>
<td>To link NMDP donor data to FN3</td>
</tr>
<tr>
<td>What happens if it’s wrong/missing</td>
<td>Link broken</td>
</tr>
</tbody>
</table>
Identification numbers

- ICCBBA ISBT128 Donation Identification Number (DIN)
  Globally unique number composed of a Facility Identification Number (5 characters), Collection Year (2 digits), and Serial Number (6 digits).

<table>
<thead>
<tr>
<th>Who assigns it?</th>
<th>ICCBBA participating collection centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it assigned</td>
<td>Upon product collection</td>
</tr>
<tr>
<td>Where is it used</td>
<td>FN3 forms</td>
</tr>
<tr>
<td>Format</td>
<td>See next slide</td>
</tr>
<tr>
<td>How is it used</td>
<td>Additional verification for correct ID and source</td>
</tr>
<tr>
<td>What happens if it’s wrong/missing</td>
<td>Linking/distribution of data to the wrong product/cord blood bank</td>
</tr>
</tbody>
</table>
ISBT DIN

- Should be found on shipment paperwork or product labeling
Identification numbers

- Cord Blood Bank ID number. Each CBB will also have an identifier for their units. Often, these follow a specific pattern for each bank, which also helps to identify the source.

<table>
<thead>
<tr>
<th>Who assigns it?</th>
<th>Cord blood bank</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it assigned</td>
<td>At collection</td>
</tr>
<tr>
<td>Where is it used</td>
<td>FN3 forms</td>
</tr>
<tr>
<td>Format</td>
<td>Varies by bank</td>
</tr>
<tr>
<td>How is it used</td>
<td>Identifies individual unit</td>
</tr>
<tr>
<td>What happens if it’s wrong/missing</td>
<td>Distribution of data back to incorrect bank; cord bank unnecessary work/redundancy</td>
</tr>
</tbody>
</table>
Identification numbers

- Transplant Center Identification Number. Some transplant centers also assign IDs to products that come into their center for transplantation. This does not get reported on CIBMTR forms.

<table>
<thead>
<tr>
<th>Who assigns it?</th>
<th>Transplant center</th>
</tr>
</thead>
<tbody>
<tr>
<td>When is it assigned</td>
<td>Varies by transplant center</td>
</tr>
<tr>
<td>Where is it used</td>
<td>Internal records</td>
</tr>
<tr>
<td>Format</td>
<td>Varies</td>
</tr>
<tr>
<td>How is it used</td>
<td>Identifies patient</td>
</tr>
<tr>
<td>What happens if it’s wrong/missing</td>
<td>CIBMTR does not collect; associating with wrong CRID could lead to data inconsistency</td>
</tr>
</tbody>
</table>
Identification number summary

- Cords and NMDP products ALWAYS need ID
- Related and Autologous cord units also ALWAYS need ID
  - If a product was frozen and stored, ID exists
- Only related PBSC, marrow and autos may or may not have an ID
  - Then use DOB and Sex
Quiz

Match the ID with the Source: G00012345678

Option 1: non-NMDP ID
Option 2: ICCBBA ISBT 128 DIN
Option 3: NMDP Donor/CBU ID

RESULTS:
Quiz

Match the ID with the Source: A12345Z

Option 1: non-NMDP ID
Option 2: ICCBBA ISBT128 DIN
Option 3: NMDP Donor/CBU ID

RESULTS:

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Quiz

Match the ID with the Source: 9123-4567-8

Option 1: non-NMDP ID
Option 2: ICCBBA ISBT128 DIN
Option 3: NMDP Donor/CBU ID

RESULTS:
A recipient who is infused with an NMDP product will always need an NMDP RID added to FormsNet3.

**Option 1: True!**

**Option 2: False!**

RESULTS:
A recipient requires a RID to be added for subsequent transplants using NMDP products when the first transplant did not

Option 1: True!
Option 2: False!

RESULTS:
Uniform ID’s everywhere

Recipient Information Grid

Form 2004

Form 2005

Form 2006

Form 2400

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Key Fields

• Purposes: Enable, Map, Distribute, Connect
  – Enables FormsNet to store the data in the correct place (HCT date, CRID, CCN, chronological #)
    • Ensures we are moving things correctly internally
  – Allows CIBMTR to map data correctly to other data sources (Donor and CBU IDs)
    • Allows CIBMTR to map data from different forms (2004/2005/2006/chimerism together)
Specify donor on F2400

- Enables/disables ID fields
- NMDP vs non-NMDP
- Donor vs. cord
  - Validation different downstream
- F2400 captures all donors
  - May or may not need F2004/2005/2006
- Validation improved
  - Check with your CRC if you get an error
- F2006 Q15: Was the product derived from an NMDP donor or CBU or a non-NMDP CBU?
  - Should be consistent with Q1: Specify Donor
Reporting ‘NMDP’ Products

- NMDP and CBU ID always numbers
  - Format is 1234-5678-9
- If NMDP donor or CBU selected, Recipient ID (RID) must be displayed in Recipient Information grid.
  - Including subsequent unrelated transplant
  - Add or Edit via Search/Edit CRID
  - Monthly clean-up
- Should be consistent with Registry Code
Determining # of F2004/5/6s expected

- F2400 used to make forms due
- F2004 and F2005 are donor specific
- F2006 is product specific
- Example:
Multiple resources available

### Non-NMDP Unrelated Donor – TED Track

<table>
<thead>
<tr>
<th>Pre-TED</th>
<th>Donor Type Reported</th>
<th>Consent for Research Sample Repository</th>
<th>Forms Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-TED 2400 Completed</td>
<td>Non-NMDP Unrelated Donor</td>
<td>Yes</td>
<td>Form 2004 (Donor) Form 2005 (Recipient)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NO</td>
<td>Form 2006 (for each product) Form 2005 (Donor) Form 2005 (Recipient)</td>
</tr>
</tbody>
</table>

### Non-NMDP Unrelated Donor – CRF Track

<table>
<thead>
<tr>
<th>Pre-TED</th>
<th>Donor Type</th>
<th>Forms Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-TED 2400 Completed</td>
<td>NMDP Unrelated Donor</td>
<td>Form 2004 (Donor) Form 2005 (Recipient) Form 2006 (for each product) Form 2005 (Donor)</td>
</tr>
</tbody>
</table>
Scenario

• My recipient has HLA reports available for both the cord unit and the maternal donor. What forms are due in FN3?
Form expectations

• Meeting CPI vs meeting reporting requirements
  – For Cord Units, the 2005 is required
    • The Maternal Cord 2005 is considered supplemental – it does not meet the reporting requirements of the cord/donor 2005
F2005 tips

• Q12- ‘Was the person for whom this typing is being done used as the donor?’
  – Reporting typing done on family members not selected as donors is optional, but may be beneficial for additional HLA studies.
• Change made on when we ask this question – only for biological relative
Scenario

- My recipient had a marrow infusion from an unrelated non-NMDP donor and a PBSC infusion from a related donor. What forms are due?
Form expectations

- Each donor must have their own F2004/2005
  - Required for all non-NMDP donors and recipients
- Each product must have its own F2006
  - Very few cases where it’s not required

<table>
<thead>
<tr>
<th>Unrelated non-NMDP</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>donor: BM</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Related donor:</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBSC</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Scenario

• My recipient had a related transplant that included a marrow and a cord unit from the same donor. What forms are due?
Form expectations

- Each donor must have their own F2004/2005
  - Required for all non-NMDP donors and recipients
- Each product must have its own F2006
  - Very few cases where it’s not required

Related donor: BM, CBU

- 2004, 2006
- 2005
Summary

• There are multiple identification numbers for each donor and recipient, and providing the correct ID in the correct field is important, causing significant errors if done incorrectly.

• Once an ID is provided, this ID must be consistently reported on all effected forms.

• Providing accurate donor information will impact what forms come due.
Tip- Clearly define Center Processes

- Have SOPs on hand for data processing activities (i.e. completing, reviewing, entering forms)
- Create tools (i.e. where to look if the info isn’t in the cell processing report)
- Training – eLearnings
- Expectations of timing
- Designated time for working on forms
Helpful Links

• **Tip sheet**: Locating the source of Cord Blood Unit


• **Appendix O**: How to Distinguish Infusion Types

• **Online training**: eLearning courses on HLA, pre-TED and Infusion Data
Questions?