In Depth Training: Form Journey

Andréa Benoit
Kavita Bhavsar
Leigh Ann Laczkowski
Sue Logan

Elliott Mitchem
Alisha Mussetter
Tina Thole

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There are no conflicts of interest to disclose.
Get to Know Your Neighbors!

- Where are you from?
- How long have you been working as a Data Manager/with CIBMTR?
- Is this your first tandem?
- Any sightseeing plans?
Test Your Knowledge

• Handout
Completed Form? Think again

Error Review
Form 2400 R4.0: Pre-Transplant Essential Data
CRID: 0008900435  Visit: Pre-TED

3 Error(s)

Errors:

Error Message: (Question #43) Instance #1(1) "Q43 - Age" must be answered when (Question #41) Instance #1(1) "Q41 - Date of birth (Unknown)" equal "Unknown".

(Question #43)Instance #1(1) - Blank
(Question #41)Instance #1(1) - Unknown

Comments

Error Message: (Question #90) "Q90 - What scale was used to determine the recipient’s functional status?" Incorrect scale used for the Kamofsky/Lansky scale. Patients 16 years of age and over should use the Kamofsky scale.

(Question #90) - L
(Question #11) - 2015-10-01
UA Unable to Answer

Comments

Error Message: If the recipient is greater than 10 years old and height is reported in inches, it must be between 39 - 84.

(Question #155) - 15
(Question # ) - inches
VC Verified Correct

Comments

Continue With Submission
A Patient Has A Story

EVENT

Birth  HCT  CT  Death

Pre-TX Therapy  Prep Regimen  GVHD Prophylaxis  Engraftment  ...

CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH
Validations Along the Way

CIBMTR System Information Flow

- Form Validation Rules
- Data Quality Checks
- CIBMTR System Information Flow
- Manual data cleanups or DQT requests fed into PERL Script
- Automated Perl Script (Mon 8pm) detects processed or deleted forms from prior week
- Validation Rules
- New, Changed or Deleted Forms Data (PL/SQL Files)
- ETL (monthly)
- Value Mapping
- Column Mapping
- Perl Retrieval
- RDB
- NMDP
HRSA Deliverables

Source of truth (Center Database) → Consecutive Transplant Reporting → Accurate CIBMTR Data → CIBMTR Studies

Cord Blood Reports

TCSA ↔ CVDR
Getting Started

• CRID Assignment Form (2804)
  – What and How to update
    • Queries and data checks
• Indication Form (2814)
  – Do’s and Don’ts
• TED vs CRF Track
  – What to look for?
    • Track changes, disease inserts, etc.
• Knowledge Check
CRID Assignment Form (2804)

- Assigned when patient receives a transplant/therapy
- Collects crucial information
  - Prevents duplicate CRID
- Key fields
  - “Source of truth” for patient
  - Missing fields = increased risk of duplicate reporting
Data Checks

• Queries to update F2804 fields
  – Incorrect DOB, sex, missing RID
• When form is erroneous, effects the entirety of patient forms
• Auto-population
• Luckily, when the F2804 fields are updated, you’re all done, right?

NOT QUITE
How to Update

• Update F2804 and reprocess remaining follow-up forms

Do same for TED/CRF forms in grid
Indication for CRID Assignment (2814)

- Gathers information to begin CIBMTR reporting
- Completed for each indication requiring a patient to register for a CRID
- Key fields
  - Also “source of truth” for future forms
    - Infusion type and date
Choosing Indication

• Initial vs subsequent:
  – HCT
  – Non-HCT Cellular Therapy (CT)
  – Marrow toxic injury therapy
  – Non-cellular therapy

• If different than previous indication, additional F2814 should be completed

• HCT indication vs. CT indication
  – Different forms required
Things to Keep in Mind (F2814)

- Subsequent HCT or subsequent Cellular Therapy ≠ new F2814
- Event date defaults as “today’s date” on forms grid

Before completion-
(CRID created 2/9)

After completion-

- Event date changed = forms will update automatically
- HCT type changes = review and edit F2400
  - Review and reprocess follow-up forms
TED vs. CRF

• Which is which?
  – TED – Transplant Essential Data
    • 2450, 2451 (retired)
  – CRF – Comprehensive Report Forms
    • 2000 & 20xx, 2100 & 21xx, (2200, 2300 – retired), 2900
    • 2004, 2005, 2006 – both TED/CRF

• Overlap? - No

• What to look for?
  – Track change, disease inserts, primary disease change
Knowledge Check

• Please analyze the scenario illustrated in your packet to determine what mistakes were made and what updates need to be done in order to ensure the accuracy and completeness of this patient’s forms
Scenario Review

• What went right? What went wrong?
• F2804 and F2814 importance
  – Revise, review, then refresh
• TED and CRF differences
  – One or the other
  – Unsure? – contact CRC
• Complete and accurate from the beginning results in reducing burden in the long run!
In Depth Training: Form Journey Con’t.

Thursday, February 23, 2017
Product and Donors, their forms, and why they’re important

- Determine correct number of products and donors
- Determine what forms are required for the product/donor reported
- Determine how many of each form is required and for which donor/product
Determine Number of Products and Donors

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

- Appendix O: How to Distinguish Infusion Types
- Appendix P: Definition of a Product
Determine what Forms are expected to be complete

- The Pre-TED F2400 is the source of which forms come due
  - Based on Donor type, Product type, Consent and TED or CRF track chosen
  - Infectious Disease Markers Form 2004
  - HLA Typing Form 2005
  - Infusion Form 2006
  - Additional Forms
    - Follow up forms, Disease inserts, other infection forms, study forms
Specify donor on Pre-TED F2400

- Enables/disables ID fields
- NMDP vs non-NMDP
- Donor vs. cord
  - Validation different downstream
- F2400 captures all donors
    - May or May Not be needed for each donor
    - When required, ID’s should match across the forms
- Infusion F2006 Q15: Was the product derived from an NMDP donor or CBU or a non-NMDP CBU?
  - Should be consistent with Q1: Specify Donor
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
Uniform ID’s everywhere

Recipient Information Grid

IDM Form 2004

Pre-TED Form 2400

HLA Form 2005

Infusion Form 2006
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 autologous PBSC/marrow may or may not have an ID
  - Then use DOB and Sex
- Should be consistent with Registry Code
  - Ex: St. Louis on one form and SLCBB on another is not consistent
Reporting ‘NMDP’ Products

• NMDP and CBU ID always numbers
  – Format is 1234-5678-9
• If NMDP donor or CBU selected, NMDP Recipient ID (RID) must be displayed in Recipient Information grid
  – Including subsequent transplants
  – Add or Edit via Search/Edit CRID (on CRID Assignment F2804)
  – Monthly clean-up
Scenario

- A patient is transferred to my center for their 2\textsuperscript{nd} transplant, an NMDP cord blood unit. Am I allowed to update the CRID assignment form and add the NMDP RID, even though the CRID was not created at my center?
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></td>
<td></td>
<td></td>
<td>Form 2004 (Donor) Form 2005 (Recipient)</td>
</tr>
<tr>
<td></td>
<td>Non-NMDP Unrelated Donor</td>
<td>Consent for sample repository?</td>
<td>Form 2006 (Recipient) Form 2005 (Donor)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Form 2005 (Recipient) Form 2005 (Donor)</td>
</tr>
</tbody>
</table>

#### Pre-TED 2400 Completed

- **Yes**: Form 2006 (for each product)
- **No**: Form 2005 (Recipient)

### 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></td>
<td>NMDP Unrelated Donor</td>
<td>Form 2004 (Donor) Form 2005 (Recipient)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Form 2006 (for each product) Form 2005 (Donor)</td>
</tr>
</tbody>
</table>

#### Pre-TED 2400 Completed

- **Form 2004** (Donor)
- **Form 2005** (Recipient)
- **Form 2006** (for each product)
- **Form 2005** (Donor)
Determining # of F2004/5/6s expected

- Pre-TED F2400 used to make forms due
- IDM F2004 and HLA F2005 are donor specific
- Infusion F2006 is product specific
- Example:

```
31. Specify donor:
   - Autologous - Go to question 46
   - Autologous cord blood unit - Go to question 35
   - NMDP unrelated cord blood unit - Go to question 32
   - NMDP unrelated donor - Go to question 33
   - Related donor - Go to question 40
   - Related cord blood unit - Go to question 35
   - Non-NMDP unrelated donor - Go to question 34
   - Non-NMDP unrelated cord blood unit - Go to question 35
```
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
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 this form is not required

Related donor:
- PBSC

Unrelated non-NMDP donor:
- BM

Timeline:
- **Unrelated non-NMDP donor**: BM
  - 2004
  - 2005
  - 2006

- **Related donor**: PBSC
  - 2004
  - 2005
  - 2006
Scenario

- My recipient had a related transplant that included a marrow and a cord unit from the same donor. What forms are due? How many donor instances are completed on the Pre-TED F2400?
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: 2004, 2006
- CBU: 2004, 2006

(2) Donor instances completed on Pre-TED F2400
Attachment of Lab Reports

- Most common areas we request reports:
  - HLA data
  - Infusion details
  - Any ‘weird’ data (ex: out of normal range cell counts)
- As a public health authority, CIBMTR is authorized to view these records
  - Reduces queries
- Be sure to de-identify and add CRID to each page before uploading!
  - Detailed instructions in manual
Donor/Product Review

- 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 affected forms.
- Providing accurate donor information will impact what forms come due.
Scenario 1: Engraftment

• Is this reported correctly?
• What would you do to fix it?
• What are the processes at your center?
Scenario 2: GVHD and Death

• What forms have to be corrected?
  – Is aGVHD reported correctly?
  – Is cGVHD reported correctly?
• What is the cause of death?
• What should be the date of last contact reported on the 1 year F2100?
Scenario 3: Best Response to Transplant

• Note: Patient was in CR at time of transplant and relapsed 10/10/2015. Patient received treatment and achieved CR again.

• What was the patient’s response to transplant?

• Does best response to transplant have to match current disease status?
Scenario 4: Form Track Change

• What track is this patient on?
  – Can this happen?

• What is the correct way to answer the subsequent transplant question(s) on F2018?
Test Your Knowledge

• Review Handout
How are we trying to Reduce the Burden for You?

• Form validations are reviewed and added periodically
• **Query Functionality** in FormsNet
  – Making older forms FormsNet-editable
  – New Data Quality Checks
• Attachment Feature