In Depth Training: Forms Journey
Part I

Leigh Ann Laczkowski
Jon Wallace
Peter Wallace

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There are no conflicts of interest to disclose.
Consent Overview

- All recipients should be approached to sign the CIBMTR Research consent form
- CIBMTR requires documentation of annual IRB renewal with approved consent forms each year. CIBMTR consent forms are available on the CIBMTR website
- CIBMTR requires follow-up on allogeneic transplants in accordance with the 2005 Stem Cell Act
Consent Overview

• Pre-TED information may be submitted to CIBMTR without consent of recipient since CIBMTR meets the definition of a Public Health Authority
  – CIBMTR requires 2400 and 2402 forms to be completed for autologous transplants for database integrity

• CIBMTR has separate allogeneic and autologous consent forms due to the differences in the law

• If a recipient gets a transplant at another hospital then a new consent form must be signed at that time (consent does not follow patient)
Consent Overview

• Centers must consent recipients twice if they receive both allogeneic and autologous transplants
  – Some centers have a combined allogeneic and autologous consent form, in this case, CIBMTR does not require re-consenting
  – A center’s IRB may require a second database consent form to be signed, and centers should refer to the higher standard set by their IRB
Consent Overview

- Update the consent status on the Pre-TED (F2400) to reflect any changes over time (e.g., recipient rescinds consent)
- CIBMTR reports on transplant volumes each year to the government and this is on the HRSA website
- CIBMTR allows centers to voluntarily report cellular therapy infusions except for DCIs which are required
- Cellular therapy is now part of the consent form so multiple consents only occur if the donor type changes
Consent Reporting Example 1

• What should you do first when a recipient at your center has had a previous transplant at another facility?
  A. Get the recipient to sign a new CIBMTR research database consent form
  B. Register a new CIBMTR Recipient ID for the recipient’s subsequent transplant
  C. Do not consent the recipient, but reach out to the previous center to get a transfer form completed
  D. Do not report any information to CIBMTR because the recipient signed a consent form at the other center
Consent Reporting Example 1

• What should you do first when a recipient at your center has had a previous transplant at another facility?
  
  A. Get the recipient to sign a new CIBMTR research database consent form
  
  B. Register a new CIBMTR Recipient ID for the recipient’s subsequent transplant
  
  C. Do not consent the recipient, but reach out to the previous center to get a transfer form completed
  
  D. Do not report any information to CIBMTR because the recipient signed a consent form at the other center
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.
CRID Assignment Form (2804)

• Assigned when recipient receives a transplant/therapy
• Collects crucial information
  – Prevents duplicate CRID
  – Missing fields = increased risk of duplicate reporting
• Each question is the origin for autopopulation
  – “Source of truth” for recipient
• One CRID Assignment Form per recipient
Data Checks

• Queries to update F2804 fields will be placed on F2400 and F2000
  – Incorrect DOB, sex, missing RID
• When form is erroneous it affects entirety of recipient 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 (F2814)

• Gathers information to begin CIBMTR reporting
• Completed for each indication requiring a recipient to register for a CRID
• Each question is the origin for autopopulation
  – Also “source of truth” for future forms
    • Infusion type and date
Choosing Indication

- Initial vs subsequent:
  - HCT
  - Cellular Therapy (non-HCT)
  - Marrow toxic injury therapy
  - Non-cellular therapy (e.g. immunotherapy)

- A new F2814 should be completed if a marrow toxic injury or non-cellular therapy recipient goes on to have an HCT or CT

- 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 F2814 and F2400
  - Review and reprocess follow-up forms
TED vs. CRF

• Which is which?
  – TED – Transplant Essential Data
    • F2400, F2402, F2450
  – CRF – Comprehensive Report Forms
    • F2000 & F20xx, F2100 & F21xx, (F2200, F2300 – retired), F2900
  – Overlap? - No
  – What to look for?
    – Track change, disease inserts, primary disease change
Comorbidities Overview

• Dr. Sorror has published a paper reviewing how he assesses comorbidities and CIBMTR has similar guidelines in Appendix J
• CIBMTR guidelines summarize Dr. Sorror’s paper and give examples of what not to report
• CIBMTR does not need the entire medical history of the recipient reported in the other specify field
  – Conditions reported here are not used to calculate the Co-morbidity Index score
• Only report conditions with significant potential impact to recipient’s transplant outcome or overall survival
Comorbidities Overview

• Dr. Sorror’s original paper is from 2005 and CIBMTR has validated the comorbidity index
• Centers need documentation for each comorbidity such as tests that prove the existence of each one
• CIBMTR asks about timeframes for each comorbidity differently and this is documented in the manual
• Do centers have any tips or good processes for determining all of the comorbidities for a recipient?
• DLCO and FEV1 for the pulmonary comorbidities are corrected for hemoglobin, scoring system
Comorbidity Reporting Example 1

• Which of the following comorbidities should be reported in the comorbidities section?

A. An infection that has resolved prior to day 0 of the recipient’s transplant with no current therapy
B. A pulmonary embolism that occurred 10 years prior to the recipient’s transplant with no current therapy
C. A pulmonary comorbidity due to an abnormal FEV1 test despite the DLCO test being normal
D. Splenomegaly that is associated with the recipient’s disease that resulted in a splenectomy
Comorbidity Reporting Example 1

- Which of the following comorbidities should be reported in the comorbidities section?
  
  A. An infection that has resolved prior to day 0 of the recipient’s transplant with no current therapy
  
  B. A pulmonary embolism that occurred 10 years prior to the recipient’s transplant with no current therapy
  
  C. A pulmonary comorbidity due to an abnormal FEV1 test despite the DLCO test being normal
  
  D. Splenomegaly that is associated with the recipient’s disease that resulted in a splenectomy
Comorbidity Reporting Example 2

- Which comorbidities can be reported if the recipient’s history shows multiple syncopal episodes due to aortic stenosis and ventricular tachycardia as well as diabetes that has been controlled through diet alone?
Comorbidity Reporting Example 2

- Centers should not report a cardiac comorbidity in this example because only a history of coronary artery disease, a myocardial infarction, congestive heart failure, or LVEF $\leq 50\%$ are valid reasons.

- Diabetes that is controlled through diet alone with no insulin injections does not need to be reported.
Comorbidity Reporting Example 3

• How should a center document a prior solid tumor that does not have a check box?

• CIBMTR would want the solid tumor comorbidity checked yes, but all of the specific options should be marked no.

• In this scenario the center should use the Unable to Answer override code to bypass the errors that will appear for each question.
Post HCT Follow-Up Forms

- Reporting disease status
  - Best response to HCT
  - Current disease response

- Reporting disease treatment
  - Maintenance therapy
  - Therapy for relapsed, persistent, or progressive disease
Assessing Disease Status

• Although there are many interpretations of disease response criteria, when reporting data to the CIBMTR, use the guidelines in the Forms Instruction Manual to determine disease status
Where to Find the Disease Criteria

- Forms Instruction Manual

Comprehensive Disease Specific Manuals

- 2010/2110: Acute Myelogenous Leukemia (AML)
  - AML Response Criteria
  - 2010: AML Pre-HCT
  - 2110: AML Post-HCT

- 2011/2111: Acute Lymphoblastic Leukemia (ALL)
  - ALL Response Criteria
  - 2011: ALL Pre-HCT
  - 2111: ALL Post-Infusion Data

- 2012/2112: Chronic Myeloid Leukemia (CML)
  - CML Response Criteria
  - 2012: CML Pre-Infusion Data
  - 2112: CML Post-Infusion Data
How to Track Disease

• Appendix G has a sample disease tracker specifically for multiple myeloma

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<tr>
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<th>IgA</th>
<th>IgD</th>
<th>IgE</th>
<th>IgG</th>
<th>IgM</th>
<th>Light Chain:</th>
<th>Kappa(κ)</th>
<th>Lambda(λ)</th>
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# How to Track Disease

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<th>Date</th>
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<td>Day+100</td>
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<tr>
<td>6 month Date of Contact</td>
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</table>
Why Track Disease Parameters

• Assessing disease response can get complicated
• Creating a disease tracking spreadsheet makes it easier to compare disease parameters across reporting periods
• When in doubt, communicate with the transplant physician
  – Beneficial when reconciling the clinic notes
Disease Assessments Post-HCT

• TED track
  – Disease Assessment at the Time of Best Response to HCT
  – Current Disease Status
• Disease status options are limited to “Complete Remission” or “Not in Complete Remission”
• Captured on F2450 R4 for all malignant diseases
Disease Assessments Post-HCT

- CRF track
  - Disease Assessment at the Time of Best Response to HCT
  - Current Disease Status
- All disease status options are available (i.e. CR, PIF, PR, NR/SD)
- Captured on F21XX for all malignant diseases
Best Response to HCT (TED Forms)

• Intended to capture best response the malignant disease had to HCT
  – Includes post-HCT treatment given for maintenance or consolidation
  – Once post-HCT treatment is given for relapsed or progressive disease, the clock stops on this question (no longer tracking the effect of transplant)
Best Response to HCT (TED Forms)

Disease Assessment at the Time of Best Response to HCT

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) - Go to question 98
- Complete remission (CR) - Go to question 77
- Not in complete remission - Go to question 76
- Not evaluated - Go to question 98

- Even though the question states “since the date of last report”, the best response may have occurred during a previous reporting period
Best Response to HCT (TED Forms)

- **In CR at time of HCT**
  - Day 100: Continued Complete Remission
  - 6 Month: Complete Remission (best response previously reported)

- **Not in CR at time of HCT**
  - Never In Complete Remission
  - No therapy given for relapsed, persistent, OR progressive disease
  - Once therapy begins for relapsed, persistent, OR progressive disease, use "Not Evaluated" on subsequent forms
Best Response to HCT (TED forms)

• Once a Complete Remission has been achieved post-HCT (without therapy being given for progressive disease), the best response will always be reported as “Complete Remission”

• If a recipient does not achieve a Complete Remission, reporting can be complicated
## Best Response Scenario (TED)

### Multiple Myeloma Disease Status Tracking

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<th>IgD</th>
<th>IgE</th>
<th>IgG</th>
<th>IgM</th>
<th>Light Chain:</th>
<th>Kappa(κ)</th>
<th>Lambda(λ)</th>
<th>Values</th>
<th>Yes/No</th>
<th>% Plasma Cells in BM</th>
<th>Plasma-cytomas?</th>
<th>Lytic Lesions?</th>
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<td>IgG Kappa</td>
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</table>
Best Response Scenario (TED)

- Recipient with multiple myeloma achieves a VGPR prior to HCT
- At Day+100, recipient continues to be in VGPR
- During 6 Month period, recipient has evidence of progression and begins therapy
- At 1 year, recipient remains on therapy
- How does this get reported on F2450 in each reporting period?
Best Response Scenario (TED)

- On Day+100 form, Q75 would be “Not in Complete Remission”
Best Response Scenario (TED)

76. Specify disease status if not in complete remission:
   - Disease detected - Go to question 79
   - No disease detected but incomplete evaluation to establish CR - Go to question 79

77. Was the date of best response previously reported?
   - Yes - Go to question 98
   - No

78. Date assessed: ___/___/____

Specify the method(s) used to assess the disease status at the time of best response:

*For Q79-97, report the latest disease assessment performed during the reporting period for each method listed

95. Was the disease status assessed by clinical/hematologic assessment?
   - Yes
   - No
   - Not applicable

96. Date assessed: 2016/08/09

97. Was disease detected?
   - Yes
   - No
Best Response Scenario (TED)

• On 6 Month form, Q75 would be “Not in Complete Remission”
Best Response Scenario (TED)

76. Specify disease status if not in complete remission:
   - Disease detected - Go to question 79
   - No disease detected but incomplete evaluation to establish CR - Go to question 79

77. Was the date of best response previously reported?
   - Yes - Go to question 98
   - No

   78. Date assessed: __ __ __/ __/ __

   Specify the method(s) used to assess the disease status at the time of best response:

   *For Q79-97, report the last disease assessment performed prior to the initiation of therapy for relapsed/persistent/progressive disease for each method listed*

95. Was the disease status assessed by clinical / hematologic assessment?
   - Yes
   - No
   - Not applicable

96. Date assessed: 2016 / 10 / 22

97. Was disease detected?
   - Yes
   - No
Best Response Scenario (TED)

- On 1 Year form, and all subsequent forms, Q75 would be “Not evaluated”

Recipient received therapy for progression
- No longer evaluating response to HCT
  - Now the recipient is responding to the treatment
Best Response to HCT (CRF track)

• Intended to capture best response the malignant disease had to HCT
  – Includes post-HCT treatment given for maintenance or consolidation
  – Date response first established is the date that is reported
  • Once the recipient’s best response category is captured, “previously reported” option can be used
## Best Response Scenario (CRF)

<table>
<thead>
<tr>
<th>Date</th>
<th>Monoclonal Protein</th>
<th>Immunofixation (Serum)</th>
<th>Immunofixation (Urine)</th>
<th>SPEP</th>
<th>UPEP</th>
<th>24-Hour Urine</th>
<th>k/λ ratio</th>
<th>% Plasma Cells in BM</th>
<th>Plasma-cytomas?</th>
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<td>IgG Kappa</td>
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<td>&lt;200</td>
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<tr>
<td>11/1/16 (6M)</td>
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<td></td>
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<td>0.25</td>
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<tr>
<td>2/15/17</td>
<td>IgG Kappa</td>
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<td></td>
<td>0.20</td>
<td></td>
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<td></td>
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<td>IgG Kappa</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>
Best Response Scenario (CRF)

- Recipient with multiple myeloma achieves a VGPR prior to HCT
- At Day+100, recipient continues to be in VGPR
- At 6 Months and 1 Year, recipient remains in VGPR
- How does this get reported on F2116?
Best Response Scenario (CRF)

- On Day+100 form

3. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease.)

Very good partial remission (VGPR) - serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.

4. Was the date of best response previously reported?

☐ yes
☒ no

5. Date assessed: ___________ 2016 ___________ 07 ___________ 15 ___________
Best Response Scenario (CRF)

- On 6 Month form

3. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease.)

- Very good partial remission (VGPR) - serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.

4. Was the date of best response previously reported?
   - yes
   - no

5. Date assessed: __________ YYYY __ MM __ DD
Current Disease Status (TED & CRF)

- Captures last disease assessment performed during the reporting period
- Includes any treatment given for relapsed, persistent, or progressive disease
- TED track
  - “Complete Remission” or “Not in Complete Remission” (or “Not evaluated”)
- CRF track
  - All disease specific options available
Disease Assessments Post-HCT

- Best response to HCT and current disease status do not always match
- Best response to HCT could be “Never in CR”
  - If recipient receives therapy for progression and then achieves a complete remission, current disease response can be reported as “CR”
Reporting Therapy Post-HCT

• F2450 R4 now collects all therapy a recipient receives for primary disease
  – Therapy is categorized as either maintenance (including consolidation and treatment for minimal residual disease) or as treatment for relapse, persistent, or progressive disease
  – No longer categorized as planned vs unplanned

• The intent can change throughout the course of therapy
Therapy Reporting Scenario

• Recipient with Ph+ ALL s/p related allo HCT in CR1
• Started on maintenance imatinib mesylate during the Day +100 reporting period
• During 6 month reporting period, recipient relapsed and imatinib mesylate was increased and dasatinib added
• During 1 year reporting period, recipient achieved CR and continued dasatinib
Therapy Reporting Scenario

• How does this get reported?
  – Initially, imatinib mesylate would be reported as maintenance therapy
  – Once a relapse is documented, imatinib mesylate would be considered therapy for relapsed disease (along with dasatinib)
  – Once a CR is re-established, dasatinib would no longer be reported as therapy for relapsed disease and would be considered maintenance therapy
Therapy Reporting F2450 (D100)

Post-HCT Therapy

Report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

98. Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy.)

- Yes
- No

99. Systemic therapy

- Yes
- No

110. Tyrosine kinase inhibitors (TKI)

- Yes
- No

111. Bosutinib
- Yes
- No

112. Dasatinib (Sprycel)
- Yes
- No

113. Imatinib mesylate (Gleevec)
- Yes
- No

114. Nilotinib (AMN107, Tasignal)
- Yes
- No
Therapy Reporting F2450 (6M)

Post-HCT Therapy

Report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

98. Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy.)

- Yes
- No

99. Systemic therapy

- Yes
- No

*If at least one dose given in reporting period prior to relapse
Therapy Reporting F2450 (6M)

Intervention for relapsed disease, persistent disease, progressive disease, or decreased/loss of chimerism

164. Was intervention given for relapsed, persistent or progressive disease, or decreased/loss of chimerism since the date of last report?
   - Yes
   - No

Specify intervention(s):
173. Systemic therapy
   - Yes
   - No

184. Tyrosine kinase inhibitors (TKI)
   - Yes
   - No

185. Bosutinib
   - Yes
   - No

186. Dasatinib (Sprycel)
   - Yes
   - No

187. Imatinib mesylate (Gleevec)
   - Yes
   - No

188. Nilotinib (AMN107, Tasignal)
   - Yes
   - No
Therapy Reporting F2450 (1Y)

Post-HCT Therapy

Report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

98. Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy.)
   - Yes
   - No

99. Systemic therapy
   - Yes
   - No

100. Tyrosine kinase inhibitors (TKI)
   - Yes
   - No

111. Bosutinib
   - Yes
   - No

112. Dasatinib (Sprycel)
   - Yes
   - No

113. Imatinib mesylate (Gleevec)
   - Yes
   - No

114. Nilotinib (AMN107, Tasigna)
   - Yes
   - No

[Diagram showing flowchart with options and selections indicated by blue checkmarks and arrows.]
Therapy Reporting F2450 (1Y)

*If at least one dose given in reporting period prior to CR*
In Depth Training: Forms Journey Part II

Leigh Ann Laczkowski
Jon Wallace
Peter Wallace

Thursday, February 22\textsuperscript{nd}, 2018

There are no conflicts of interest to disclose.
Subsequent HCTs

- A HCT is an infusion of a product that contains CD34+ cells with the intent to restore hematopoiesis
- Often preceded by a preparative regimen, but not always
- The clinical definition at a center may differ from CIBMTR’s definition (i.e. “stem cell boost”, “auto boost”)
Subsequent HCTs Continued

- In general, subsequent HCTs require that the reporting forms start over
  - Auto rescue is the exception, forms do not start over
- The last date of contact for initial HCT should be the day prior to the preparative regimen for the subsequent HCT
- If no preparative regimen given, use day prior to subsequent HCT
Subsequent HCT Reporting Scenario 1

- Recipient with NHL, DLBCL in CR1, s/p auto HCT on 6/15/2016
- Returned to clinic for routine follow-up and was found to have relapsed disease July 2017 and began treatment
- Received a matched related allo HCT on 11/20/2017 with preparative regimen starting 11/14/2017
Points to Consider

- Is this subsequent infusion a rescue or a subsequent HCT?
- How should this infusion be reported on F2450 R4?
- Is another Pre-TED required?
Subsequent HCT Reporting Scenario

1 Answer

- This would be considered a subsequent HCT
- The recipient relapsed following an auto HCT and went on to receive an allo HCT
- A new Pre-TED would be required for the 11/20/2017 infusion
How To Report This Scenario

<table>
<thead>
<tr>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of actual contact with the recipient to determine medical status for this follow-up report: <strong>2017/11/13</strong></td>
</tr>
<tr>
<td>2. Specify the recipient’s survival status at the date of last contact</td>
</tr>
<tr>
<td>- Alive – Answers to subsequent questions should reflect clinical status since the date of last report. - Go to question 7</td>
</tr>
<tr>
<td>- Dead – Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. - Go to question 3</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Subsequent Transplant</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Did the recipient receive a subsequent HCT since the date of last report?</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>8. Date of subsequent HCT: <strong>2017/11/20</strong></td>
</tr>
<tr>
<td>9. What was the indication for subsequent HCT?</td>
</tr>
<tr>
<td>- Graft failure / insufficient hematopoietic recovery – Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
</tr>
<tr>
<td>- Persistent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
</tr>
<tr>
<td>- Recurrent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
</tr>
<tr>
<td>- Planned second HCT, per protocol – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
</tr>
<tr>
<td>- New malignancy (including PTLD and EBV lymphoma) – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
</tr>
<tr>
<td>- Insufficient chimerism – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
</tr>
<tr>
<td>- Other – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 10</td>
</tr>
</tbody>
</table>

10. Specify other indication: _________________________

11. Source of HSCs:  |
|   - Allogeneic, related  |
|   - Allogeneic, unrelated  |
|   - Autologous  |
Subsequent HCT Reporting Scenario 2

- Recipient with HD s/p auto HCT 12/15/2017
- ANC initially recovers on Day +12
- Shortly after, ANC declines and recipient is given an auto “boost” using stored cells on 1/11/2018
Points to Consider

• Is this subsequent infusion an auto rescue or a subsequent HCT?
• How should this infusion be reported on F2450 R4?
• Is another Pre-TED required?
Subsequent HCT Reporting Scenario 2

Answer

• This would be considered an auto rescue
• The cells are being given because the peripheral counts indefinitely declined after the initial hematopoietic recovery
• A new Pre-TED would not be required for the 1/11/2018 infusion
• Although this meets the definition of HCT, to reduce the reporting burden, CIBMTR does not require new forms
How To Report This Scenario

<table>
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<tr>
<th>Survival</th>
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<tbody>
<tr>
<td>1. Date of actual contact with the recipient to determine medical status for this follow-up report:  <strong>Day +100</strong></td>
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<tr>
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</tr>
<tr>
<td>2. Specify the recipient's survival status at the date of last contact</td>
</tr>
<tr>
<td><img src="checkmark" alt="Alive" /> – Answers to subsequent questions should reflect clinical status since the date of last report. - Go to question 7</td>
</tr>
<tr>
<td><img src="x" alt="Dead" /> – Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. - Go to question 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subsequent Transplant</th>
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<tbody>
<tr>
<td>7. Did the recipient receive a subsequent HCT since the date of last report?</td>
</tr>
<tr>
<td><img src="checkmark" alt="Yes" /></td>
</tr>
<tr>
<td><img src="x" alt="No" /></td>
</tr>
<tr>
<td>8. Date of subsequent HCT: <strong>2018 / 01.11</strong></td>
</tr>
<tr>
<td>9. What was the indication for subsequent HCT?</td>
</tr>
<tr>
<td><img src="checkmark" alt="Graft failure / insufficient hematopoietic recovery" /> – Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td><img src="x" alt="Persistent primary disease" /> – Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td><img src="x" alt="Recurrent primary disease" /> – Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td><img src="x" alt="Planned second HCT, per protocol" /> – Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td><img src="x" alt="New malignancy (including PTLD and EBV lymphoma)" /> – Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td><img src="x" alt="Insufficient chimerism" /> – Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td><img src="x" alt="Other" /> – Complete a Pre-TED Form 2400 for the subsequent HCT. - Go to question 11</td>
</tr>
<tr>
<td>10. Specify other indication: ___________________</td>
</tr>
<tr>
<td>11. Source of HSCT</td>
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<td><img src="x" alt="Allogeneic, related" /></td>
</tr>
<tr>
<td><img src="x" alt="Allogeneic, unrelated" /></td>
</tr>
<tr>
<td><img src="checkmark" alt="Autologous" /></td>
</tr>
</tbody>
</table>
Subsequent HCT Reporting Scenario 3

- Recipient with testicular ca s/p auto HCT 10/15/2017
- Earliest completion date for 100 day F2450 is 1/23/2018
- Recipient received second planned tandem auto HCT 12/15/2017 with preparative regimen starting 12/10/2017
Points to Consider

• Is this subsequent infusion an auto rescue or a subsequent HCT?
• How should this infusion be reported on F2450 R4?
• Is another Pre-TED required?
Subsequent HCT Reporting Scenario 3

Answer

• This infusion would be considered a subsequent HCT
• In the case of tandem HCTs, the plan is to perform multiple HCTs regardless of disease status or assessments
• A new Pre-TED would be required for the 12/15/2017 HCT
How To Report This Scenario

1. Date of actual contact with the recipient to determine medical status for this follow-up report: **2017/12/09**

2. Specify the recipient’s survival status at the date of last contact:
   - Alive – Answers to subsequent questions should reflect clinical status since the date of last report. - Go to question 7
   - Dead – Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. - Go to question 3

Subsequent Transplant

7. Did the recipient receive a subsequent HCT since the date of last report?  
   - Yes
   - No

8. Date of subsequent HCT: **2017/12/15**

9. What was the indication for subsequent HCT?
   - Graft failure / insufficient hematopoietic recovery – Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11
   - Persistent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11
   - Recurrent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11
   - Planned second HCT, per protocol – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11
   - New malignancy (including PTLD and EBV lymphoma) – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11
   - Insufficient chimerism – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11
   - Other – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 10

10. Specify other indication: __________________________

11. Source of HSCs:
   - Allogeneic, related
   - Allogeneic, unrelated
   - Autologous

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TRAINING & DEVELOPMENT | 71
Bonus Round

Does a planned tandem HCT need to be reported on any other form?
Bonus Round

Tandem HCTs are initially captured on F2400 R5

Hematopoietic Cellular Transplant (HCT)

11. Date of this HCT: \( \frac{2017}{YYYY} \), \( \frac{10}{MM} \), \( \frac{15}{DD} \)

12. Was this the first HCT for this recipient?
   - Yes

13. Is a subsequent HCT planned as part of the overall treatment protocol (not as a reaction to post-HCT disease assessment)? (For autologous HCTs only)
   - Yes → 14. Specify subsequent HCT planned:
     - No
     - \( \times \) Autologous
     - \( \square \) Allogeneic

Post-HCT Disease Therapy Planned as of Day 0

345. Is this HCT part of a planned multiple (sequential) graft / HCT protocol? \( \times \) Yes \( \square \) No

346. Is additional post-HCT therapy planned?
   - \( \square \) Yes
   - \( \square \) No
Subsequent HCT Reporting Scenario 4

- Recipient with MM s/p auto HCT 5/15/2014
- Achieved VGPR and began lenalidomide maintenance post-HCT
- Presented with progressive disease December 2017 and began carfilzomib
- Recipient with pancytopenia due to carfilzomib, therapy held
- 1/1/2018, received auto boost to restore peripheral counts so carfilzomib could restart
- Earliest complete date for 4 year form is 5/15/2018
- Recipient expired on 1/15/2018
Points to Consider

• Is this subsequent infusion a rescue or a subsequent HCT?
• How should this infusion be reported on F2450 R4?
• What would be the actual contact date on the 4 year form?
• Is another Pre-TED required?
Subsequent HCT Reporting Scenario 4 Answer

- This infusion would be considered a subsequent HCT
- The progress notes may say the cells are being given for hematopoietic recovery, but the low counts are due to the treatment for progressive disease, not the initial HCT
- The date of contact would be the day prior to the subsequent HCT
- A new Pre-TED would be required for the 1/1/2018 auto HCT
- The date of death would be captured on the 100 day form for the 1/1/2018 HCT
  – Date of death and subsequent HCT can never be reported on the same follow-up form
How To Report This Scenario

<table>
<thead>
<tr>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of actual contact with the recipient to determine medical status for this follow-up report: <strong>2017/12/31</strong></td>
</tr>
<tr>
<td>2. Specify the recipient’s survival status at the date of last contact:</td>
</tr>
<tr>
<td>- Alive – Answers to subsequent questions should reflect clinical status since the date of last report. - Go to question 7</td>
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<tr>
<td>7. Did the recipient receive a subsequent HCT since the date of last report?</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>8. Date of subsequent HCT: <strong>2018/01/01</strong></td>
</tr>
<tr>
<td>9. What was the indication for subsequent HCT?</td>
</tr>
<tr>
<td>- Graft failure / insufficient hematopoietic recovery – Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11</td>
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<td>- Other – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 10</td>
</tr>
<tr>
<td>10. Specify other indication: __________________________</td>
</tr>
<tr>
<td>11. Source of HSC:</td>
</tr>
<tr>
<td>- Allogeneic, related</td>
</tr>
<tr>
<td>- Allogeneic, unrelated</td>
</tr>
<tr>
<td>- Autologous</td>
</tr>
</tbody>
</table>

CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

TRAINING & DEVELOPMENT | 77
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
Center Forms Due

- Can run a real-time Forms Due Report at any time
- “Center Forms Due” option under the Recipient or Donor Tabs
- Can be customized by: status code, form type, date type, CPI period, start date, end date, or infusion type
- Auto HCTs prior to 12/3/07 are not included in CPI, but will appear on the Center Forms Due list

TRAINERING & DEVELOPMENT | 79
Center Forms Due

Recipient Center Forms Due

Centers:
- 99999 FORMSNET TEST RESEARCH CENTER

Status Codes:
- DUE Form has not started
- ERR Form has errors
- SVD Form was saved
- MOD Form was modified

Forms:
- 2000 Recipient Baseline Data
- 2004 Infectious Disease Markers
- 2005 Confirmation of HLA Typing
- 2006 Hematopoietic Cellular Transplant (HCT) Infusion

Date Type:
- Earliest Completion Date

Start Date: YYYY-MM-DD

Infusion Type:
- 

Search

CIBMTR
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TRAINING & DEVELOPMENT | 80
Query Management

• Queries reduce emails and turnaround time for data clean-up
• Forms that have queries on them will be in QRY status
• After interacting with a query, the form will change to pending (PND) until a CRC can review the response
• Can find forms in QRY status using the Center Forms Due feature
Query Status Codes

• QRY: the form is in query status and needs to be addressed by the center

• PND: the form is in pending status and needs to be reviewed by the CRC
Two-Steps to Query Resolution

1. Update the answer
2. Interact with the query
Before You Submit…

• Ensure there are no new potential errors prior to re-submitting the form
  – New validations
  – Parent/child questions
  – Other sections being enabled/disabled

• Good data practice: Check for queries every week to aim for a two-week resolution timeline
Scenario 1: Query Management

• A data manager reviews the center’s queries using the Center Forms Due feature. They locate the form in QRY status and update their answer. They are disappointed to see that the form is still in QRY status. What went wrong?
Scenario 1: Query Management

- Answer: Resolving queries is a two-step process. Updating the answer is only half of that. The data manager also needs to interact with the query and re-submit in order to have the form switch to PND status.
Test Your Knowledge: Query Management

• A data manager successfully responded to the query, but the pending response was rejected by the CRC. What are some potential reasons why this could happen?
Test Your Knowledge: Query Management

• Answer: There are many answers to this question, but some of the most common ones include the answer was not updated, documentation was not submitted, a value is still out of range/discrepant, etc. When in doubt, contact your CRC for further explanation.
Error Corrections

How to complete an Error Correction (EC):

1. Provide sequence number of original form (located in the Forms Grid of FormsNet3)
2. Provide CRID, Infusion Date, and CCN
3. Today’s date is the date you are completing the EC
4. Provide your initials in Initials box to indicate you are approving the change
Test Your Knowledge: Error Corrections

• Question: I only have one question to correct. Do I need to complete the entire form?
Test Your Knowledge: Error Corrections

• Answer: No, you only need to correct and submit the relevant pages for data you are changing.
Test Your Knowledge: Error Corrections

• Question: Can I edit information on forms that are in audit (AUD) status?
Test Your Knowledge: Error Corrections

- Answer: No, you need to follow the standard EC process to make adjustments to data in AUD status forms. These error corrections will then be reviewed by the auditors.
Error Corrections

- Only complete the fields where data are changing, but be aware a change to one question may result in other questions needing to be answered or deleted
- Only page(s) with data changes need to be sent
- Verify the version of the EC form matches the form version in FormsNet3
- Completed form is sent to CIBMTR Recipient Forms CIBMTRRecipientForms@NMDP.ORG
- CRC reviews correction and changes are updated in FN3 or sent back to data manager for further review
Verifying the Form Version

Form 2400 R3.0: Pre-Transplant Essential Data

Retired CIBMTR Forms

<table>
<thead>
<tr>
<th>Number</th>
<th>Abbr</th>
<th>Name</th>
<th>Rev</th>
<th>Effective</th>
<th>Retired</th>
<th>Related Materials</th>
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</thead>
<tbody>
<tr>
<td>2400</td>
<td>Pre-TED</td>
<td>Pre-Transplant Essential Data</td>
<td>3.0</td>
<td>December 2012</td>
<td>October 2013</td>
<td>Error Correction (PDF)</td>
</tr>
</tbody>
</table>
Transfers

- In the event of a recipient transferring care to another transplant center for either subsequent HCT or follow-up care, the Request for Recipient Transfer (Form 2801) should be completed and submitted to the CIBMTR.
- Transfer will be complete after both centers have signed and returned the form to the CIBMTR.
- A CRC can provide contact info for another center to arrange a transfer.
Completing the Request for Recipient Transfer Form 2801

- Either center can initiate the form, but the transferring center’s information should be completed in the key fields.
- The form cannot be accepted until the information is correct, so be sure to correspond with the other center to ensure information is accurately and legibly recorded.
- We encourage consent to be signed at the receiving center before the transfer occurs, but a recipient may decline.
Scenario 1: Recipient Transfer

• A recipient’s care transferred to referring or another physician outside of the transplant center. Who is responsible for follow-up forms?
Scenario 1: Recipient Transfer

• Answer: If a recipient is transferred back to their referring physician, or another physician outside of the transplant center, it is the continued responsibility of the transplant center to obtain source documentation of post-HCT evaluations.
Scenario 2: Recipient Transfer

• Center A initiated a transfer with Center B. Center B did not respond, so the transfer was never completed. Who is responsible for the follow-up forms?
Scenario 2: Recipient Transfer

- Answer: If the form was never completed and keyed, the transfer effectively did not happen, so Center A would still be responsible for the follow-up on that recipient. Center B can refuse the transfer, although we encourage the two data managers to work things out so that the transfer can be completed.
Scenario 3: Recipient Transfer

• Center A transfers a CRF recipient to Center B, which is a TED-only center. A subsequent transplant is performed. Center B is only willing to complete TED level data on this recipient. If…

1. This recipient is on a BMT CTN clinical trial, can Center B refuse to submit the CRF data?
2. This recipient is not on a BMT CTN clinical trial or other study, can Center B refuse to submit the CRF data?
Scenario 3: Recipient Transfer

- Center A transfers a CRF recipient to Center B, which is a TED-only center. A subsequent transplant is performed. Center B is only willing to complete TED level data on this recipient. If...

1) Answer: Center B would be responsible for the CRF forms for follow-up because the recipient is on a BMT CTN clinical trial.

2) Answer: Yes. In this instance, Center B might get permission from upper CIBMTR management to submit only TED level data on this recipient. A data manager should contact their CRC for situations like this. Center B is a designated TED center, but they would get reimbursement for follow-up forms on this recipient because the recipient had already started down the CRF track if they agreed to complete the forms.
Test Your Knowledge: Recipient Transfer

• True or False: The form must be completed on paper and scanned or faxed to the CIBMTR to be keyed by Data Entry staff.
Test Your Knowledge: Recipient Transfer

• True or False: The form must be completed on paper and scanned or faxed to the CIBMTR to be keyed by Data Entry staff.

• Answer: True! Because this form will have signatures of both data managers, it must be received on paper by the CIBMTR and keyed into FormsNet3 by Data Entry staff. If you fax a Form 2801 and see it has not been keyed by the CIBMTR within a few business days, follow-up with your CRC to see if there is an issue causing delay.
Test Your Knowledge: Recipient Transfer

• True or False: The transferring center must always be the one to initiate the Form 2801.
Test Your Knowledge: Recipient Transfer

• True or False: The transferring center must always be the one to initiate the Form 2801.

• Answer: False! The Form 2801 can be initiated by either the transferring center or the receiving center by contacting the other center to discuss. The key field portion of the Form 2801 must contain the transferring center’s information.
Lost to Follow-up

• When a center has been unsuccessful in reaching a recipient, the Lost to Follow-up (LTF) feature can be used.

• The LTF icon only displays for forms in DUE status.

• Located in the first column of the forms grid and looks like 🌍.
Test Your Knowledge: Lost to Follow-up

• If a recipient is on CRF track, does the report form and disease insert need to be made Lost to Follow-up separately?
Test Your Knowledge: Lost to Follow-up

• If a recipient is on CRF track, does the report form and disease insert need to be made Lost to Follow-up separately?

• Answer: Yes, each form will need to be made Lost to Follow-Up separately by using the Lost to Follow-up icon in the first column of the forms grid because they are separate forms.
Test Your Knowledge: Lost to Follow-up

• How can the form be completed later if information on the recipient comes available?
Test Your Knowledge: Lost to Follow-up

• How can the form be completed later if information on the recipient comes available?

• Answer: You can contact your CRC to request that the status of the form be changed back to DUE.
Lost to Follow-Up

- Recipient can only be declared Lost to Follow-up after the transplant center has tried to make contact and is unsuccessful at reaching them
- Must select a reason code

<table>
<thead>
<tr>
<th>Reason for Lost to Follow-up (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Called home and/or work phone numbers - all phone numbers no longer current</td>
</tr>
<tr>
<td>Sent Letter - returned forwarding expired or non-deliverable for some reason</td>
</tr>
<tr>
<td>International recipient – have lost contact</td>
</tr>
<tr>
<td>Treating physician has not seen recipient or has not had any contact in the past year</td>
</tr>
<tr>
<td>Contacted hospital billing department</td>
</tr>
</tbody>
</table>
Other Resources

- **Forms Instruction Manual** and **Retired Forms Manuals**
- **Data Management Guide**
- **FormsNet3 Training**
- **CRP/DM Conference Materials**
- **Additional Online Training**
Questions