In Depth Training: Forms Journey
Part II

Leigh Ann Laczkowski
Jon Wallace
Peter Wallace

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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

**Survival**

1. Date of actual contact with the recipient to determine medical status for this follow-up report: **2017/11/13**

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: **2017/11/20**

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
   - Recurrent primary disease – 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
   - 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 chimeraism – 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 HSC: □ 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

Survival

1. Date of actual contact with the recipient to determine medical status for this follow-up report: Day +100
   YYYY MM DD

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: 2018 / 01.11
   YYYY MM DD

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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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

Survival
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
3. 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
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

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#### Hematopoietic Cellular Transplant (HCT)

11. Date of this HCT: \[
\begin{array}{ccc}
\text{YYYY} & / & \text{MM} & / & \text{DD}
\end{array}
\]  

\[
\begin{array}{c}
2017 & / & 10 & / & 15
\end{array}
\]

12. Was this the first HCT for this recipient?  
   - [x] 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)  
   - [x] Yes  
   - [ ] No  
   - [x] Autologous  
   - [ ] Allogeneic

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#### Post-HCT Disease Therapy Planned as of Day 0

345. Is this HCT part of a planned multiple (sequential) graft / HCT protocol?  
   - [x] Yes  
   - [ ] No  

346. Is additional post-HCT therapy planned?  
   - [ ] Yes  
   - [ ] 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

1. Date of actual contact with the recipient to determine medical status for this follow-up report: \[2017/12/31\]

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: \[2018/01/01\]

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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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
### Center Forms Due

**Recipient Center Forms Due**

- **Centers:**
  - 9999 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:**
- 

**CPI Period:**
- 

**End Date:**
- YYYY-MM-DD
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

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<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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<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>
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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.
Other Resources

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