Audit Updates

February 2, 2021

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CIBMTR, Be The Match

There are no conflicts of interest to disclose
Audit Updates

• FY2020 Audit Program Overview
• Internal Audits
• Quick Fixes
FY2020 Audit Program Overview

Mandi Proue, CCRP, MPH
Manager, Clinical Data Validation
FY2020 Audit Program Overview

• Audit Statistics | FY2017 – FY2020
  – How are transplant centers doing on their audits?
• FY2020 Results
  – October 2019 – September 2020
• Other Updates
  – Remote Audit Program
  – Cellular Therapy Auditing
  – Manual Updates
  – Centralized Data Review
Audit Cycles & Audit Outline

<table>
<thead>
<tr>
<th>Cycle 1</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 2</td>
<td>2002</td>
<td>2003</td>
<td>2004</td>
<td>2005</td>
</tr>
<tr>
<td>Cycle 3</td>
<td>2006</td>
<td>2007</td>
<td>2008</td>
<td>2009</td>
</tr>
<tr>
<td>Cycle 4</td>
<td>2010</td>
<td>2011</td>
<td>2012</td>
<td>2013</td>
</tr>
<tr>
<td>Cycle 5</td>
<td>2014</td>
<td>2015</td>
<td>2016</td>
<td>2017</td>
</tr>
<tr>
<td>Cycle 6</td>
<td>2018</td>
<td>2019</td>
<td>2020</td>
<td>2021*</td>
</tr>
</tbody>
</table>

Transplant Centers are audited every **4 years**, as eligible.

TCs are contacted **in advance** for scheduling.

**16 recipients** are randomly selected from the most recent audit.

**2-3 auditors** come for **3-4 days** for selected case review.

A **summary review** of identified errors.

**Audit report** with **corrective action requirements**, if applicable, is prepared.

*Denotes current or future audit years
CIBMTR Data Audit Passing Criteria

• Critical Field Error Rate ≤ 3%

• A center’s score will be assessed as either:
  – Pass
  – Pass, with required corrective action
  – Fail, with required corrective action

• Corrective Action Requested if:
  – A critical field error rate over 3% (failed audit)
  – Systemic and / or non-systemic reporting errors
  – Consent form issues
  – Outstanding missing documentation issues
Average Error Rates Per Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Critical Field Error Rate</th>
<th>Random Field Error Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2017</td>
<td>2.20%</td>
<td>1.00%</td>
</tr>
<tr>
<td>FY2018</td>
<td>2.50%</td>
<td>1.50%</td>
</tr>
<tr>
<td>FY2019</td>
<td>2.90%</td>
<td>1.40%</td>
</tr>
<tr>
<td>FY2020</td>
<td>3.00%</td>
<td>1.20%</td>
</tr>
</tbody>
</table>
Critical Field Error Rates

74% of all centers audited in the last 4 years have passed their audit

Centers with Passing Score: 147 of 200 (73.5%)
Average Critical Field Error Rate: 2.5%
Centers Audited

200
Total Centers Audited

28
Non-US Centers Audited
Passing Centers

147

of 200 (73.5%) centers passed with a critical field error rate less than or equal to

3%
Passing Centers by Location

73.8%
of U.S. centers passed (127/172)

71.4%
of Non-U.S. centers passed (20/28)
Critical Field Error Rates

- **Average Error Rate**: 2.5%
- **Median Error Rate**: 2.3%
- **Lowest Error Rate**: 0.4%
Top Reporting Areas

• Top reporting areas where errors are commonly found on audits:
  – Method of Disease Assessment (97% of centers)
  – Graft Versus Host Disease (58% of centers)
  – Disease Status (57% of centers)
  – HCT Product and Infusion (57% of centers)
  – Disease Classification and Characteristics (9% of centers)
FY 2020 Annual Audit Comparison Report

- This report will be uploaded to the CIBMTR Portal in March

### Center Specific Audit Summary Report

<table>
<thead>
<tr>
<th>Cycle / Audit Year</th>
<th>Critical</th>
<th>Random</th>
<th>Overall</th>
<th>Pass / Fail</th>
<th>Reporting Areas of Concern</th>
<th>CAP Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 3 / 2008*</td>
<td>5.5%</td>
<td>3.0%</td>
<td>5.3%</td>
<td>Fail</td>
<td>GVHD, Performance Score</td>
<td>Yes</td>
</tr>
<tr>
<td>Cycle 4 / 2012**</td>
<td>3.5%</td>
<td>1.8%</td>
<td>3.3%</td>
<td>Fail</td>
<td>Disease Status, GVHD</td>
<td>Yes</td>
</tr>
<tr>
<td>Cycle 5 / 2016**</td>
<td>2.8%</td>
<td>1.6%</td>
<td>2.6%</td>
<td>Pass</td>
<td>Product Data, Disease Assessment</td>
<td>Yes</td>
</tr>
<tr>
<td>Cycle 6 / 2020**</td>
<td>2.5%</td>
<td>1.6%</td>
<td>2.3%</td>
<td>Pass</td>
<td>Disease Status, Preparative Regimen</td>
<td>No</td>
</tr>
</tbody>
</table>

*Passing Critical Field Error Rate was ≤ 5.0%
**Passing Critical Field Error Rate was ≤ 3.0%
FY2020 Results
October 2019 – September 2020
FY2020 Audit Passing Results

- 0.0 - 0.5%: 1
- 0.6 - 1.0%: 4
- 1.1 - 2.0%: 8
- 2.1 - 3.0%: 7
- > 3.0%: 11
FY2020 Corrective Action Requirements

Corrective action is required when:

- The critical field error rate exceeds 3%;
- Systemic errors are identified during the audit, even if the critical field error rate is ≤ 3.0%;
- Issues are identified with IRB-approved CIBMTR research or repository consent forms; and/or
- Missing documentation identified during the audit are not addressed during the identified follow-up period.

Of 31 (16%) had no corrective action

Of 31 (84%) had required corrective action
The CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW).

Top Performing Centers: FY20
Top Performing Centers in FY2020
(0.6% to 1.0% Critical Field Error Rate)

- CCN 10002 Rady Children’s Hospital
- CCN 10012 Loma Linda University Cancer Center
- CCN 10010 Nationwide Children’s Hospital
- CCN 10052 The Blood and Marrow Transplant Program at Northside Hospital
Top Performing Centers in FY2019
(≤ 0.5% Critical Field Error Rate)

- CCN 10689 Mayo Clinic Arizona and Phoenix Children’s Hospital
Remote Audits
Remote Audit Program

• Remote audit process is identical to the on-site audit process with the exception of auditors accessing the EMR remotely
• All communication, training and meetings conducted via WebEx video calls
• Same number of recipients and data fields reviewed
Remote Audit Requirements

• Remote access to the center’s EMR for each auditor
• If specific source documents are located and saved outside of the EMR they need to be de-identified and emailed securely or uploaded to a secure file sharing service for auditor access
• Daily check-ins with data managers
  – Review reporting questions
  – Discuss each audited case
  – Review audit changes
  – Provide training
Remote Audits: FY20

- 32* total audits performed in FY20
  - 21 on-site
  - 11 remote

*FY20 results include only 31 centers, one center’s results were not finalized at the time of this presentation
Lessons Learned

• Overall, feedback on the remote audit process has been positive.
  – The audit was remote and it didn't actually seem to make a difference if they were here or remote for training purposes.
  – This was our first remote audit. Overall, it was very smooth and organized. I would do another remote audit in the future if it was an option.

• However, on-site auditing remains a preference for some centers surveyed.
  – On-site. The data you have to go through is way easier to go through with someone in person. The level of detail warrants an on-site audit. It's not that this was a bad experience (remote) but enjoyed the on-site far more.
Lessons Learned

• Process changes have been made in real time based on feedback from centers and auditors
  – Daily check-ins
  – Clarifying expectations
  – Safeguarding PHI
FY21 Remote Audits

• Continued travel restrictions will require remote audits
• Once on-site travel resumes, remote auditing will remain as an option using a risk-based approach
  – Prior audit score
  – Data management changes
  – Training needs
Cellular Therapy Auditing
CT Audit Process

Site Selection

• Centers currently scheduled for HCT Audit who have submitted CAR-T infusions

Infusion Selection

• Up to eight CAR-T infusions selected for audit
• All forms in Complete status will be selected for audit
  • CT Forms
  • Disease Inserts
CT Audit Process

• Identical to HCT audit process but focuses on CAR-T infusions
• Performed in tandem with HCT audit
• Separate auditor to review CT records
• Separate audit results and reports
CT Audit Process: Critical Fields

- **Disease status**
  - Pre infusion, best response, current disease status

- **Toxicities**
  - CRS (diagnosis date, therapy, symptoms resolution)
  - Neurotoxicity (date of onset, symptoms, resolution)
  - Hypogammaglobulinemia
  - Tumor lysis syndrome

- **Infections**
CT Audit Process: Critical Fields (cont.)

• Product information
  – Product name
  – Product cell type
  – Product identification
  – Cell counts
Results

- CT Audit results are separate from HCT audit results
  - Centers will receive a separate CT Audit Report
- Error rate (critical, random and overall)
  - Error rate by product type (if applicable)
- Target Accuracy Range
  - Better than Target (CFER ≤3%)
  - Target Range (CFER 3-5%)
  - Higher Than Target (CFER >5%)
Corrective Action and Recommended Areas for Improvement

- **Corrective Action Plan**
  - Requested to address the following concerns
    - Consent Issues requiring correction
    - Outstanding Missing Documentation

- **Recommended Areas for Improvement**
  - When systemic errors are identified that require additional training
    - E.g. systemic errors in lines of therapy reporting
FY 2020: Results

Eight Total Audits Performed

Critical Field Error rates ranged from 2.2% to 5.4%
- 3 better than the target range
- 3 within the target range
- 2 higher than the target range
FY 2020: Common Reporting Errors

• Lines of Therapy
  – Failing to capture all lines of therapy given pre infusion

• Toxicity reporting
  – CRS – incorrectly reporting onset date or date of resolution
  – Neurotoxicity – failing to capture all symptoms of neurotoxicity
  – Hypogammaglobulinemia – failing to capture
FY 2021: Planned CT Audits

- 20-25 audits will be scheduled

Sites will be selected based on:

1. HCT Audit planned
2. Number of CT infusions reported
3. Data Quality indicators

Notification of CT audit will happen 12 weeks prior to scheduled HCT audit
Forms Instruction Manual
FY20 Highlights

- 250 Updates
- 261,507 pages viewed
- 31 Manuals updated and revised including 4 new manuals
- MM Response Criteria
- 12,296 views
Process Improvements

• Data management review of manuals prior to release
  – When a manual is updated (as a result of a revised form), a draft of the revised manuals are now sent with time studies
  – Allows data managers to ask questions, provide feedback, and examples of source documents

• Preview manuals
  – Approximately two weeks prior to the quarterly release, revised manuals are available for review
  – Notification sent via email
Upcoming FormsNet3 Releases

CIBMTR is excited to announce that the next set of revised forms are scheduled for release in FormsNet3 in late January 2021. Approximately two weeks prior to the release, you will find the new forms to preview, along with some of the highlighted changes you can expect to see.

If you have any questions about the forms or upcoming release, please contact CIBMTR-form-feedback@nmdp.org.

Release Highlights
Archived Release Highlights

Forms

Manuals
Weekly Data Operations eBlasts

- Notification of manual updates completed in the past week

CIBMTR Forms Instruction Manual

Audience: International and Domestic Data Managers

Forms Instruction Manual Updates
The following sections of the Forms Instruction Manual have been updated this past week:

- AML Pre-Infusion (2010)
- ALL Pre-Infusion (2011)
- CML Pre-Infusion (2012)
- CLL Pre-Infusion (2013)
- MDS Pre-Infusion (2014)
- JMML Pre-Infusion (2015)
- PCD Pre-Infusion (2016)
- Lymphoma Pre-Infusion (2018)
- WM Pre-Infusion (2019)
- HLH Pre-Infusion (2039)
- MPN Pre-Infusion (2057)
- AML Post-Infusion (2110)
- ALL Post-Infusion (2111)
- MDS Post-Infusion (2114)
- MPN Post-Infusion (2157)
- Disease Classification (2402)
- Appendix H
- Cellular Therapy Essential Data Follow-Up (4100)

For an overview of the updates, review the Manual Updates table at the bottom of the Getting Started page. Please contact the CIBMTR Center Support if there are any questions.
Quarterly Newsletter

• Review of “major” manual updates from the past quarter and why updates were made

CIBMTR Forms Instruction Manual Updates

Several CIBMTR Forms Instruction Manual updates are currently in progress. The primary goal of manual updates is to increase clarification around a reporting instruction, update the instruction to capture necessary data and provide additional reporting examples to assist data management staff in reporting accurate data. In an effort to increase transparency in manual updates, each Data Matters Newsletter moving forward will include a section to review recent updates in the manual. In addition, the Historical Manual Updates section of the Forms Instruction Manual will be undergoing revision to more clearly outline manual updates and reporting instruction changes.

Upcoming Manual Updates – Spring 2020:

Pre-TED (2400) Form
Q80: Number of products infused – Reporting instruction changed from previous version of form and manual

Historically, if a recipient received additional growth factors during the same mobilization cycle (see example below), this would have been considered two products for the purposes of reporting on the CIBMTR forms. However, it is difficult to determine the effect of the first or second mobilizing agent when the collections are part of the same mobilization cycle. Therefore, for the purposes of CIBMTR reporting, when additional growth factors are given during the same mobilization cycle, this should now be considered one product. Only one 2006 form will come due for reporting.

Example: A G-CSF stimulated donor had a PBSC collection, but the cell count was poor. Plerixafor (Mozobil) was added as part of the mobilization and the donor was re-collected the following day. As the change in mobilization occurred during the same mobilization cycle, these collections are considered a single product.
Historical Updates

• Historical manual updates are found in various sections of the Forms Instruction Manual
  – Getting Started page
  – First page of each manual
  – Specific manual sections
Historical Updates

• Getting Started page
  – Lists *all* updates in the calendar year

<table>
<thead>
<tr>
<th>Date</th>
<th>Manual Section</th>
<th>Add/Remove/Modify</th>
<th>Description</th>
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<tbody>
<tr>
<td>12/16/2020</td>
<td>4100: Cellular Therapy Essential Data Follow-Up</td>
<td>Add</td>
<td>Clarified how to report resolution of hypogammaglobulinemia: Hypogammaglobulinemia can be reported as resolved if there are sustained normal levels of IgG in the blood without the need for IVIG infusions for 3 consecutive months.</td>
</tr>
<tr>
<td>12/16/2020</td>
<td>4100: Cellular Therapy Essential Data Follow-Up</td>
<td>Add</td>
<td>Clarified how to report resolution of hypogammaglobulinemia: Hypogammaglobulinemia can be reported as resolved if there are sustained normal levels of IgG in the blood without the need for IVIG infusions for 3 consecutive months.</td>
</tr>
</tbody>
</table>
Historical Updates

• First page of each manual
  – Lists updates since the current version of the manual released
Historical Updates

- Specific manual Updates
  - Lists updates made to each section of the current manual version
  - Provides justification for update, if applicable
  - Categorized by question number versus date of change
Submitting Manual Update Requests

• Submit a ticket through Center Support to request a manual update
  – Select **Forms Instruction Manual Update**
Centralized Data Review
Centralized Data Review Process

Remote review of expected, or common, data issues performed outside of the on-site data audit process

**Pre-Audit Review**
- Data Quality checks are created and then run in the database
- CDR report and queries are developed and sent to center
- Provide training resources, as needed

**Audit**
- CIBMTR staff travel to site
- Source document verification
- Review informed consent
- Conduct training
- Identify systemic issues

**Post-Audit Review**
- Review identified systemic issues and determine which checks to include in surveillance
- Design new checks, if needed

NEW
CDR Goals

• Increased availability of higher quality data
  – More data in Data Back to Centers
  – Fewer study requests
  – Fewer queries
  – Improved audit results
  – Quicker publications

• Additional support to centers through training, education, resources, and more frequent interaction
Centralized Data Review: The Report

- Overview of Query

**Disease Status**

**Disease Status at Transplant Compared to Best Response to Transplant**

This query compares the reported pre-transplant disease status on the Pre – TED Disease Classification (2400 / 2402) Form against the reported *Best Response to HCT* on the Post - TED (2450) Form to ensure reporting consistencies. For each pre-transplant disease status listed under **Query Results**, the reported post-transplant disease status and frequency has been included for each broad disease type. For example, CCR was reported 14 times post-transplant for recipients with ALL who went to transplant in CR1.

**Date range of CDR: 3/11/2016 – 12/9/2019**

Refer to the attached Excel spreadsheet for the query results. Above the query results is a list of each recipient, titled **Investigation**, that should be examined to ensure that the reported data is accurate. See the tab titled **Disease Status at Tx vs. BR**.
Centralized Data Review: The Report

• Reporting Instructions

There are four options for reporting best response to transplant in the Disease Assessment at the Time of Best Response to HCT section of the Post-TED Form:

1) Continued complete remission – for recipients transplanted in CR.
2) Complete remission – for recipients who meet the criteria for CR post-transplant.
3) Not in complete remission – for recipients who do not meet the criteria for CR post-transplant.
4) Not evaluated – for cases where a recipient’s disease status was not evaluated post-transplant and for cases where a recipient never achieved a CR post-transplant and started unplanned therapy given for relapsed, persistent, or progressive disease in a previous reporting period.

See the Disease Assessment at the Time of Best Response to HCT section of the CIBMTR Forms Instruction Manual for more reporting instructions for completing this section of the Post-TED (2450) Form (Revision 4).

The Best Response to HCT is based on the best response to transplant and does NOT include response to therapy given for disease relapse or progression post – transplant.

- If the HCT was planned as part of initial therapy for a recipient with no disease progression or relapse at any time prior to HCT, determine the best response by comparing to the disease assessment at time of original diagnosis.
- If the HCT was performed later in the disease course for a patient who has not received any chemotherapy within 6 months of HCT or has untreated relapse or progression, determine the best response to HCT by comparing the disease status immediately prior to the start of the preparative regimen.
- If the patient had a disease progression or relapse of disease at any time prior to HCT and was treated to reduce the myeloma burden prior to the start of the preparative regimen, determine the best response to HCT by comparing to the disease evaluation at the time of relapse or progression. In other words, the baseline is reset to the time of relapse or progression.
Centralized Data Review: The Report

• A summary of issues identified at your center

After running the CDR checks, there were seven cases that may require further investigation. For example, one recipient was reported to be in CR pre-transplant and Not in complete remission was reported as the best response to HCT. It is recommended to confirm if the recipient was in CR pre-transplant. If confirmed, CCR should be reported as the best response to HCT on all follow-up forms. See the attached spreadsheet tab titled Disease Status at Tx vs BR for a list of all CRIDs and additional details.
Centralized Data Review: The Report

• The Data

<table>
<thead>
<tr>
<th>CRID Number</th>
<th>Infusion Date</th>
<th>Broad Disease</th>
<th>Pre-transplant Disease Status</th>
<th>Post-transplant disease status</th>
<th>Investigation Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>OTH_LEUK</td>
<td>PR</td>
<td>CCR</td>
<td>CCR may only be reported as the best response to transplant for recipients who go to transplant in CR. This recipient was reported to be in Partial remission at the time of transplant. Verify the pre-transplant and post-transplant disease statuses and update accordingly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MDS</td>
<td>CR</td>
<td>NCR</td>
<td>If a recipient is transplanted in CR, their best response to transplant for all follow-up reporting periods should be CCR. Verify the pre-transplant and post-transplant disease statuses and update accordingly.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grand Total</th>
<th>4</th>
<th>1</th>
<th>1</th>
<th>1</th>
</tr>
</thead>
</table>

Table: CIBMTR

Query Results:
Looking Back

1/15/2020!

CDR suite created
First CDR completed
Survey centers
CDR applied to all centers

FY19
Process documents created
CDR remaining pilot centers
Process refinement and add new checks

FY20
Pilot Process

- 11 centers included in pilot process
- Surveys sent to all pilot centers
  - Feedback received from four centers
<table>
<thead>
<tr>
<th>Question</th>
<th>Answers</th>
</tr>
</thead>
</table>
| How much time did your center spend reviewing the report and investigating queries | 2 centers: 0 – 5 hours  
2 centers: 6- 10 hours                                                   |
| Does your center believe that the CDR process will be beneficial to improving data reporting? | All said yes  
Comments:  
*I believe this is a great process being implemented by the CIBMTR, that will give us the opportunity to investigate and correct potential discrepancies. The education on reporting instructions is a plus!*  
*The inconsistencies in data found by the CDR was helpful as a broad check on the data integrity* |
| What was the biggest challenge when using the CDR report?               | *It was pretty straight forward, no big challenges*  
*Scheduling staff time to investigate the report*  
*It was not challenging, just helpful.*  
*Having the time to look back at each individual case.* |
Next Steps

- **FY19**
  - Process documents created

- **1/15/2020!**
  - First CDR completed

- **FY20**
  - CDR remaining pilot centers
  - Survey centers

- **FY2021**
  - Process refinement and add new checks
  - CDR applied to all centers
Centralized Data Review Suite

- Consent Response
- Pre-HCT Disease Status vs Best Response
- ANC Recovery
- GVHD Response
- Disease Assessment
- Comorbidities
- Method of Manipulation
- Current Disease Status Indicator for CRF Forms
- Platelet Recovery
- TBI Doses
- Method of Disease Assessment
Next Steps

FY19
- Process documents created

CDR suite created
- First CDR completed
- Survey centers
- Process refinement and add new checks
- CDR applied to all centers

FY20
Looking Ahead: FY21

- **Pilot Phase 1**
  - Completed

- **Send CDR reports to all centers who failed their prior audit**

- **Feedback received and reviewed**

- **Create additional CDR checks and reports**

- **Continue surveying centers**

- **Continue process refinement and determine which centers to target for Phase 3**

- **CDR checks applied to FY22 centers identified for Phase 3**

**FY21**
Thank You
Internal Audits
Site Strategies for Ensuring Data Accuracy
February 2, 2021

Mandi Proue, MPH CCRP
Manager, Clinical Data Validation
Internal Audits

- Overview
- Best Practices
- Center Examples
Internal Audits Overview
Why are we talking about internal audits again?

- Quality Assurance Best Practice
- FACT Requirement
- Learning Opportunity
- CIBMTR Audit CAP Requirement (sometimes)
Best Practices: Create a Plan

• **Forms:** Which forms will be included?
  – All forms, CRFs only, specific diseases, forms completed by new staff

• **Fields:** Exactly which data fields will be included?
  – All data fields, critical fields only, disease status (define specific fields)

• **Auditors:** Who will be conducting the internal audit?
  – Manager, peers, QA staff

• **Frequency:** When will audits be conducted?
  – Annually, bi-annually, quarterly. Set an audit schedule.

• **Define Success:** What is an acceptable result?
  – Recommend <2% critical field error rate
Selecting Forms and Fields

**Frequency of Errors by Reporting Area**

<table>
<thead>
<tr>
<th>Reporting Area</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytogenetics</td>
<td></td>
</tr>
<tr>
<td>Molecular</td>
<td></td>
</tr>
<tr>
<td>Clinical / Hematobi</td>
<td></td>
</tr>
</tbody>
</table>

**Frequency of Errors by Form and Field Type**

<table>
<thead>
<tr>
<th>Form</th>
<th>Critical Data Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Errors</td>
</tr>
<tr>
<td>Comprehensive Report Forms (CRF) -- Follow-up</td>
<td></td>
</tr>
<tr>
<td>Recipient Baseline Data</td>
<td>3</td>
</tr>
<tr>
<td>100 Day Post-H</td>
<td></td>
</tr>
<tr>
<td>Six Month to An</td>
<td></td>
</tr>
<tr>
<td>Recipient Death</td>
<td></td>
</tr>
</tbody>
</table>

**Appendix D. Corrective Action Requirements**

Review the [Corrective Action](#) section (Appendix C) of this report for additional direction. Print this section of the report, address each item listed, and send a signed copy of this page and supporting materials to your auditor.

**GVHD Training**

*Develop a GVHD training plan for data managers to ensure accurate GVHD reporting.*
Selecting Forms and Fields

• Include variety

Diseases

Product Types

TED

CRF

Data Management Staff

Difficult Scenarios
**Milestone Reports**

**Trainings and Milestone Reports**

- **CIBMTR / FACT Training**
  - Click here to enter.
- **Medical Director Contact:**
  - Click here to enter.
- **Data Manager Contact:**
  - Click here to enter.
- **Milestone Report Number:**
  - Click or tap here.
- **Milestone Report Due Date:**
  - Click or tap here.

**In 2017, FACT and CIBMTR entered into collaborative efforts regarding data audits, enhancing accredited programs. As part of this collaboration, CIBMTR conducted an audit of a CIBMTR corrective action plan.**

**Site Staffing Changes**

Document any staffing changes that affect medical directors, clinical staff, etc. Please indicate who the new staff member is and that the CIBMTR responsibility matrix is updated in the Network Partner Portal so that all data providers can expect to see these changes.

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**Internal Audits**

Review Appendix D of the CIBMTR Audit Results and complete the table below to provide an overview of the findings from the internal audit. If more than one internal audit was performed, copy and paste the table below. To ensure accuracy of the provided milestone report and supporting documentation, if applicable, the center’s internal audit reports must be available upon request. It is recommended to submit all Internal audit reports at the time of milestone report submission to reduce the need for documentation requests.

<table>
<thead>
<tr>
<th>Internal Audit Date</th>
<th>Click or tap to enter a date.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Auditor</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Audit Report</td>
<td>Identify who the audit report was reviewed/approved by and the corresponding date.</td>
</tr>
<tr>
<td>Top Reporting Issues (e.g., Disease status, GVHD, etc.)</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Audit Results Presented</td>
<td>Identify with whom the audit results were shared internally (e.g., GM Committee) along with corresponding date.</td>
</tr>
<tr>
<td>Date Range of HCTs Audited</td>
<td>Click here to enter a date. – Click here to enter a date.</td>
</tr>
<tr>
<td>Number of Recipients Audited</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Number of Critical Fields Audited</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Number of Critical Field Errors</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Critical Field Error Rate (%)</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Key Area Reviewed*</td>
<td>Form(s) Reviewed</td>
</tr>
</tbody>
</table>

**Corrective actions and Due Dates**

- Document action items identified as a result of assessing the underlying causes of errors (if applicable). Include a tentative completion date of action items. Indicate (Y/N) if complete.

1. Document action items identified as a result of assessing the underlying causes of errors (if applicable). Include a tentative completion date of action items. Indicate (Y/N) if complete.
Best Practices: Critical Fields

- Critical fields for CIBMTR Audit:
  - Important for accurate completion of outcomes analyses
  - Audited for every recipient
  - Questions are dependent on type of transplant and disease type
  - Errors in these fields determine the critical field error rate which determines if a center passes or fails their CIBMTR audit
<table>
<thead>
<tr>
<th>QuestionNumber</th>
<th>QuestionText</th>
<th>AuditStatus</th>
<th>Total # of Critical Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence Number:</td>
<td></td>
<td>Show</td>
<td></td>
</tr>
<tr>
<td>Date Received:</td>
<td></td>
<td>Show</td>
<td></td>
</tr>
<tr>
<td>CIBMTR Center Number:</td>
<td></td>
<td>Show</td>
<td></td>
</tr>
<tr>
<td>CIBMTR Research ID:</td>
<td></td>
<td>Show</td>
<td></td>
</tr>
<tr>
<td>Event date:</td>
<td>Is this the report of a second or subsequent transplant or cellular therapy for the same disease?</td>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Is the disease (AML) therapy related?</td>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Specify prior disease</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Specify other prior disease:</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Date of diagnosis of prior disease</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Date of diagnosis of prior disease:</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Cytotoxic therapy</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Radiation</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Other therapy</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Specify other therapy:</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Did the recipient have a documented antecedent hematologic disorder?</td>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>What was the date of diagnosis of antecedent hematologic disorder?</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>What was the classification of the antecedent hematologic disorder at diagnosis?</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Specify other antecedent hematologic disorder:</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>WBC</td>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>WBC value</td>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Date sample collected:</td>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Blasts in blood</td>
<td>Random</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Source of blasts in blood:</td>
<td>Random</td>
<td></td>
</tr>
</tbody>
</table>
Best Practices: Review Errors

• Reviewing errors identified on internal audits is one of the most important tools for improvement

What is the error?
What category of reporting area does it fall into?

What was the reason for the error?
Is this a systemic issue?
How can we correct this moving forward?
Best Practices: Review Errors

• Look for trends in error categories
  – Can help target training

• Identify any systemic reporting issues
  – May require additional analysis to get at the root cause of the error
  – 5 Whys
Best Practices: Audit Report

Audit Plan  | Auditors  | Goals
---|---|---
Audit Scope and Details  | Audit Dates
Findings / Recommendations and Summary of Findings

Follow-up (Corrective and Preventative Action)
Results Reviewed Documentation
Deviation Documentation, if applicable
Center Examples
## The Blood and Marrow Transplant Program at Northside Hospital, CCN 10052

<table>
<thead>
<tr>
<th>Transplant Population(s)</th>
<th>Reporting Level</th>
<th>Number of Full Time Positions*</th>
<th>Transplant Volume (per year)</th>
<th>Frequency of Internal Audits</th>
<th>Specified Staff to conduct internal audits?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>CRF</td>
<td>4</td>
<td>250</td>
<td>Weekly</td>
<td>Data Supervisor</td>
</tr>
</tbody>
</table>

*Number of full-time positions dedicated to completing CIBMTR forms

### When and how is training implemented after an internal audit?

“Audit sheets are completed for each patient / form that is audited, which lists all errors identified during the review. Data managers are expected to review and correct all errors and to follow-up with the data supervisor, as needed, regarding questions / clarification needed. If the data supervisor notices a trend in errors made by the data manager(s), an individual or group training will be scheduled, as needed. Additionally, a designated data manager visits the CIBMTR website on a weekly basis to check for Manual updates and sends a summary of changes to the data department every week to ensure we stay on top of any updates made to the form completion guidelines.”
The Blood and Marrow Transplant Program at Northside Hospital, CCN 10052

• Internal Audit Details:
  – All forms are audited prior to submitting in FN3 (all forms for all recipients)
  – All data fields are reviewed for each form

• Suggestions:
  – Ensure the designated auditor is familiar with both internal practices as well as the CIBMTR data reporting requirements
  – It is essential to review the Forms Instruction Manual on a regular basis
The Blood and Marrow Transplant Program at Northside Hospital, CCN 10052 – Continued

---

**Blood and Marrow Transplant Program at Northside Hospital**

**CIBMTR Form Audit Worksheet**

<table>
<thead>
<tr>
<th>Form</th>
<th>Completed By (Initials/Date)</th>
<th>Analyzed By (Initials/Date)</th>
<th># Errors</th>
<th># Critical Errors</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-TED / 2400</td>
<td>JT 01/09/20</td>
<td>JC 01/10/20</td>
<td>2</td>
<td>2</td>
<td># 85 = 70% (see MD dictation); #96 include Obese (BMI = 36.1)</td>
</tr>
<tr>
<td>Pre-CTED / 1000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease Classification / 2402</td>
<td>JT 01/07/20</td>
<td>JC 01/10/20</td>
<td>0</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

**Which form track was patient assigned to? TED or Research**

<table>
<thead>
<tr>
<th>Form</th>
<th>Completed By (Initials/Date)</th>
<th>Analyzed By (Initials/Date)</th>
<th>Date of Contract (if applicable)</th>
<th># Errors</th>
<th># Critical Errors</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2406 Day 100</td>
<td>JT 09/22/20</td>
<td>KC 09/25/20</td>
<td>06/12/20</td>
<td>3</td>
<td>2</td>
<td>#15 = 06/12/20; #43 = N/A (involves dose &lt;Dangerous); #168 = N/A</td>
</tr>
<tr>
<td>2406 8 Months</td>
<td>JT 07/30/20</td>
<td>KC 07/31/20</td>
<td>06/30/20</td>
<td>1</td>
<td>1</td>
<td>#4-Contract date of contact to 06/30/20 (date labs were performed)</td>
</tr>
</tbody>
</table>

---
### The Center for Bone Marrow Transplantation at Geisinger, CCN 10936

<table>
<thead>
<tr>
<th>Transplant Population(s)</th>
<th>Reporting Level</th>
<th>Number of Full-Time Positions*</th>
<th>Transplant Volume (per year)</th>
<th>Frequency of Internal Audits</th>
<th>Specified Staff to Conduct Internal Audits?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>TED</td>
<td>1</td>
<td>50</td>
<td>Bi-weekly</td>
<td>BMT Manager &amp; Clinical Data Coordinator</td>
</tr>
</tbody>
</table>

*Number of full-time positions dedicated to completing CIBMTR forms

---

Do you have any helpful suggestions or tips for other sites who are developing or refining internal audit processes?

“We have an audit worksheet that we are consistently updating and improving. Another thing that has helped increase awareness of the data was having our BMT coordinators fill out the Form 2400 and Form 2402 on their patients; it helped them understand the importance of ensuring all the information was in the electronic medical record for our data coordinator.”
The Center for Bone Marrow Transplantation at Geisinger, CCN 10936

• Internal Audit Details
  – All forms, fields and recipients are reviewed

• Suggestions
  – Data manager is present during audits and is involved in identifying errors and has immediate information on type of errors and reasons why errors occurred.
The Center for Bone Marrow Transplantation at Geisinger, CCN 10936
When and how is training implemented after an internal audit?

“Immediately following an audit, the findings are provided to the data manager who completed the form. Internal audit findings are reported at the quarterly Quality Meetings. Training is focused on reviewing instructions in the CIBMTR manual, getting a refresher through the CIBMTR e-Learning modules, discussing any concerns or issues at the data managers meeting and communicating with CIBMTR to assist in providing clarification with questions we come across that we don’t quite understand. We also have regular meetings with our transplant physicians to present questions regarding disease status, classification and GVHD to ensure we submit the correct data based on CIBMTR criteria and our physicians’ professional judgement.”

*Number of full-time staff dedicated to completing CIBMTR forms
• Internal Audit Details
  – All 2400 and 2402 forms are audited as well as a selection of 2450 and 2006 forms
  – All data fields are reviewed
  – All allogeneic transplants are audited and one randomly selected autologous transplant

• Suggestions
  – Overall internal audits are a very difficult, taxing and time-consuming process
Utah Blood and Marrow Transplant Program at Huntsman Cancer Institute – Adults, CCN 10192

<table>
<thead>
<tr>
<th>Transplant Population(s)</th>
<th>Reporting Level</th>
<th>Number of Full-Time Positions*</th>
<th>Transplant Volume (per year)</th>
<th>Frequency of Internal Audits</th>
<th>Specified Staff to conduct internal audits?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>CRF</td>
<td>3</td>
<td>200</td>
<td>Monthly</td>
<td>Data Team Supervisor</td>
</tr>
</tbody>
</table>

*Number of full-time positions dedicated to completing CIBMTR forms

How are recipients selected for internal audits?

“They are selected at random from the list of forms completed in the previous month. Two of our data coordinators do the bulk of CIBMTR reporting while the other manages internal lists and database, physician requests, etc. Forms are picked proportionally by the number that each of the data coordinators complete. This is done by filtering in FN3 by user, completion date, and allo vs auto, etc. Forms may also be included if they are newly completed follow-up forms from a previously audited patient.”
Utah Blood and Marrow Transplant Program at Huntsman Cancer Institute - Adults, CCN 10192

• Internal Audit Details:
  – Review includes a range of 3-10 recipients per month which equals about 10-15 total forms per month
  – Audit focuses on critical and random fields
  – The data team meets 1-2 times a week to review questions and discuss the findings for every audit. Every error is reviewed including the explanation of why the error happened and strategies to avoid repeating the error in the future.
Utah Blood and Marrow Transplant Program at Huntsman Cancer Institute - Adults, CCN 10192

- Suggestions:
  - Include forms completed recently in each audit and review the results quickly after the audit is completed
    - This helps identify the reason for the error and correct the error before it happens again
  - Use the critical fields spreadsheets to determine training opportunities and priorities
When, and how, is training implemented after an internal audit?

- Audit findings are shared with data manager in real time. Auditors share their findings and discuss with the data manager the thought processes behind any data entry found to have errors – this assists in correcting errors by means of hands-on learning.
- Training is planned to happen as close to the audit closure as possible. Key clinical and quality team members (as applicable based on expertise) are involved in training and education.
- On-going follow-ups and meetings with the data manager to stay focused on continued efforts to submit accurate and quality data and to identify additional training needs.
Internal Audit Details
- Random selection of 1/3 of all recipients who have completed their transplant
- All critical and random fields for the 2400, 2450, 2004 and 2005 forms

Suggestions
- Communicate the primary purpose of the audit to be quality assurance (reliability and validity of the data) and not punitive
- Share audit findings with the medical director, data manager and core quality team members. This helps ensure a team approach towards implementing appropriate education/training
## Advocate Bone Marrow Transplant and Cellular Therapy Program

### CIBMTR Data Quality Audit - INTERNAL AUDIT

<table>
<thead>
<tr>
<th>CIBMTR FORM #</th>
<th>Data Field</th>
<th>Data Accurately Reported as Applicable (if no, please describe in comments)</th>
<th>Source Documentation Present</th>
<th>Auditor’s Initials/Comments</th>
<th>Audit Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2400 (Pre-TED)</td>
<td>Demographics ©</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date Of Birth</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Race/Ethnicity</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2400 (Pre-TED)</td>
<td>Consents ©</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRB # 3383</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRB # 6336 (ALLO only)</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2400 (Pre-TED)</td>
<td>HCT and CT Info ©</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Previous Transplant if yes, # of prior HCTs</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2400 (Pre-TED)</td>
<td>Clinical Status of Patient ©</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>KPS Score</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2400 (Pre-TED)</td>
<td>CMV Status</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre-HCT Prep Regimen and Lines Of Therapy ©</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prep Regimen Prescribed</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date Prep Regimen Began</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prep Regimen drugs</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irradiation performed</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post HCT Disease Therapy</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subsequent transplant/cellular therapy</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2400 (Pre-TED)</td>
<td>GVHD (ALLO only) ©</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Put N/A for AUTO in comment</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Select GVHD prophylaxis drugs</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2400 (Pre-TED)</td>
<td>Comorbid Conditions (R)</td>
<td>YES □ NO □ YES □ NO □</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
How are recipients selected for internal audit review?

- **Data Manager Audit**
  - Every form is audited for every recipient. This helps catch errors that create a trickle-down affect. It also creates learning experiences for both the data and quality manager

- **Quality Manager Audit**
  - Recipients are selected at random. Audited recipients continue to be audited as new forms are completed
Billings Clinic Cancer Center, CCN 11013

• Internal Audit Details
  – Data manager completes the ongoing audits and the quality manager completes the quality audits every 6 months
  – As audits are completed, the data manager and quality manager review the findings. Any disagreements in findings are reviewed by the team and the medical director for their input. Once findings are agreed upon, training and education on the topics is completed.
***Any questions not listed were found to be in agreement***

<table>
<thead>
<tr>
<th>Question #</th>
<th>Reported Value</th>
<th>Audited Value</th>
<th>Reason for difference in values</th>
</tr>
</thead>
</table>

- **Type of Data**
  - Vitalis
  - Height & Weight

- **Assessments**
  - Physician Notes, Karnofsky Status & review of patient for cycle completed

- **Scans**
  - Any Radiology Reports per cycle

- **Laboratory Data**
  - SFERS, UPERs, FCs, Immune & tumor markers, urine, SBP, Flow Cytometry, PFTs, ECHOs

- **Cycle Treatment**
  - Chemotherapy, radiation, maintenance, etc.

- **Additional Information**
<table>
<thead>
<tr>
<th>Transplant Population(s)</th>
<th>Reporting Level</th>
<th>Number of Full-Time Positions*</th>
<th>Transplant Volume (per year)</th>
<th>Frequency of Internal Audits</th>
<th>Specified Staff to Conduct Internal Audits?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>TED</td>
<td>3</td>
<td>180</td>
<td>Every 6 months</td>
<td>Quality Management Coordinator / Clinical Nurse Educator</td>
</tr>
</tbody>
</table>

*Number of full-time positions dedicated to completing CIBMTR forms

**Do you have any helpful suggestions or tips for other sites who are in the process of developing or refining their internal audit processes?**

- Have a clear standardized tool (SOP for internal auditing, corrective and preventative action plan, audit summary reports).
- Internal auditor to become familiar with the CIBMTR manual and ongoing changes to the manual instructions and form versions.
- Provide internal auditor with FormsNet3 access so they are able to see all the drop-down options, rather than supplying a printed version of the forms.
- Data managers to keep clear documentation of correspondences from CIBMTR to provide to internal auditor, helpful if instructions in the CIBMTR manual are unclear.
• Internal Audit Details
  – Review includes a minimum of 3 autologous and 3 allogeneic transplants
    • Appropriate sample size is calculated by taking the square root number of the total transplants per FY divided by the audit period (bi-annual = 2 per year)
  – Forms reviewed include 2400, 2450 and 2402
  – All critical fields and four random fields are audited per form.
Transplant Essential Data (TED) Audit Tool

Unique Patient Identifier:

Instructions: fields denoted with * are mandatory and to be audited for all charts. Randomly select and audit 4 other applicable charts in Pre and Post TED.

Pre-TED
(Refer to CIBMTR Form 240)

Recipient Data
*Recipient date of birth
*Recipient gender

Hematopoietic Cellular Transplant (HCT):
*Date of HCT
*If history of prior HCT information

Donor Information for this HCT
Donor information: donor type, ID, match, age, sex, ABO (Allo only)

Consent
*Date recipient signed consent for release of data to CIBMTR

Clinical Status of Recipient Prior to Preparative Regimen (Conditioning):
 Karnofsky/Lansky score at transplant
Recipient CMV-antibodies (IgG or Total) and ABO

Conditioned Conditions
Comorbid conditions or malignancies

Pre-HCT Preparation Regimens (Conditioning)
Pre-HCT prep (TBI, date and radiation, if applicable)

Correct agents and total cumulative dose

GvHD Prophylaxis (Allo only)
GvHD prophylaxis (yes/no) and regimen

Disease Classification
(Refer to CIBMTR Form 2412)

Correct Incorrect Deficiencies/Comments

Audit Summary: Transplant Essential Data Form
Required Submission Months: January, July

Instructions:
- Complete this summary based on the ABMTP TED Audit Tool.
- Submit to the Program Quality Management Coordinator no later than the last day of the required submission month.

Patient Population
- Pediatric
- Adult

Description of Trends (strengths and deficiencies describing incorrect fields)

Actions:
- No Action Required
- Action Required – Forward to quality designate

Submitter (Print Name): __________________ Date Submitted: ________

ABMTP TED Audit Tool
BMTF-0336 Rev 2.1
2000/Sept/23

Page 1 of 2
Acknowledgements

• Thank you to each center who provided information for this presentation in addition to all centers who complete milestone reports.
Quick Fixes: Reporting Instruction Clarifications and Updates
February 2, 2021

Ariana Hendrickson
Senior Clinical Research Associate, Clinical Data Validation
Quick Fixes

• Key Field – Subsequent Infusion
• Lines of Therapy for Subsequent Infusions
• Indicator Question
• Lymphoma Reporting on Disease Classification (2402)
• Cellular Therapy Essential Data Follow-Up (4100)
  – Hypogammaglobulinemia
  – Lab Values
Key Field – Subsequent Infusion
Key Field – Subsequent Infusion

- First question found on each pre-infusion disease specific form
- The intent of this question is to prevent duplicate reporting of diagnostic assessments
Key Field – Subsequent Infusion

• Report no and continue with the next question in any of the following scenarios:
  – This is the first infusion reported to the CIBMTR
  – This is a subsequent infusion for a different disease
  – This is a subsequent infusion for the same disease, but the baseline pre-infusion disease specific form was not previously completed (i.e., the prior infusion was on the TED track)

• Report yes and skip the diagnostic assessment questions if the form is completed for the same disease and the baseline pre-infusion disease specific form was completed previously
Key Field – Subsequent Infusion

- HCT 1 on 2/14/2014
- HCT 2 on 1/10/2017
- CT on 2/7/2018
Lines of Therapy for Subsequent Infusions
Lines of Therapy for Subsequent Infusions

• When there is a subsequent infusion and a prior pre-infusion disease specific form is completed, only therapy administered after the prior infusion until the start of the preparative regimen for the current infusion are required to be reported.

• However, if a prior pre-infusion disease specific form has not been completed, all therapy from diagnosis until the start of the preparative regimen for the current infusion should be reported.
Example A

- Recipient diagnosed with DLBCL in July 2017
  - Six cycles of R-CHOP administered – CR achieved
- The recipient relapses in April 2018
  - Receives three cycles of GDP
  - In addition, radiation is given – achieved PR
- Autologous HCT in August 2018
  - Receives consolidation radiation – CR achieved
- Relapses in November 2018
  - One cycle of DHAP given – progression
  - One cycle of Cytoxan administered – no response
- Cellular Therapy in February 2019
Indicator Question
Indicator Question

- Disease Assessment at the Time Best Response to HCT or Cellular Therapy
- Disease Status at the Time of Evaluation for This Reporting Period

104. Does the current disease status reflect the disease detected in this reporting period section (as captured in questions 51-89), without subsequent therapy?

- Yes - Go to questions 144
- No - Go to question 105
- Not applicable (disease not assessed in the reporting period) - Go to First Name

Specify the method(s) used to assess the disease status at the time of evaluation for this reporting period:

105. Were tests for molecular markers performed (e.g. PCR, NGS)?

- Most recent disease assessments
- Current disease status
Indicator Question

Disease Status at the Time of Evaluation for This Reporting Period

104. Does the current disease status reflect the disease detected in this reporting period section (as captured in questions 51-89), without subsequent therapy?
   □ Yes - Go to questions 144
   □ No - Go to question 105
   □ Not applicable (disease not assessed in the reporting period) - Go to First Name

• This question is found on the AML, ALL, MDS, and MPN post-infusion disease specific forms
• This section is intended to capture the most recent disease assessments
Indicator Question

- Report **yes** in *any* of the following scenarios:
  - Disease was detected by any method in the reporting period (reported in the Disease Detection Since the Date of Last Report section of the form) and no therapy was given to treat disease between the date(s) of assessments reported in the Disease Detection Since the Date of Last Report and contact date
  - Disease was detected by any method in the reporting period (reported in the Disease Detection Since the Date of Last Report section of the form), therapy was given, but no assessments performed after the start of therapy
Indicator Question

• Report **no** and continue with the most recent disease assessment questions in the reporting period in any of the following scenarios:
  – Disease was not detected by any method of assessment during the reporting period
  – Disease was detected in the reporting period (reported in the Disease Detection Since the Date of Last Report), therapy was given, and additional assessment(s) were performed after therapy

• Report **not applicable** if no assessments were performed during the current reporting period, including a physician’s exam
Indicator Question

Q104: Does the current disease status reflect the disease detected in this reporting period (questions 51-89), without subsequent therapy?

Was disease detected during the reporting period? (i.e., were any assessments in questions 51-89 reported as Yes)?

- **YES**
  - After the assessments that detected disease (reported in questions 51-89 as Yes) were performed, was subsequent therapy administered and were additional assessment(s) performed after therapy?
    - **NO**
      - Report Yes for Q104 and skip Q105-143.
    - **YES**
      - Report No for Q104 and report the latest disease assessments after the initiation of therapy in Q105-143.

- **NO**
  - Report No for Q104 and report the latest disease assessments in Q105-143.
### Example B

<table>
<thead>
<tr>
<th>Date</th>
<th>BMBX</th>
<th>Molecular</th>
<th>Flow Cytometry (BM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/10/2015</td>
<td>AML, 85% blasts</td>
<td>FLT3-ITD positive</td>
<td>72% blasts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FLT3-TKD negative</td>
<td></td>
</tr>
<tr>
<td>11/1/2015</td>
<td>NED, 2% blasts</td>
<td>FLT3-ITD negative</td>
<td>NED</td>
</tr>
<tr>
<td>12/16/2015 – HCT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/15/2016</td>
<td>NED</td>
<td>FLT3-ITD negative</td>
<td>NED</td>
</tr>
<tr>
<td>3/20/2016</td>
<td>NED</td>
<td>Not performed</td>
<td>NED</td>
</tr>
<tr>
<td>3/25/2016 – D100</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Diagnosis date: 3/10/2015
- HCT date: 12/16/2015
- Day 100 contact date: 3/25/2016
Example B
### Example B

**Disease Status at the Time of Evaluation for This Reporting Period**

104. Does the current disease status reflect the disease detected in this reporting period section (as captured in questions 51-89), without subsequent therapy?

<table>
<thead>
<tr>
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<th>BMBX</th>
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<td>FLT3-ITD negative</td>
<td>NED</td>
</tr>
<tr>
<td>12/16/2015</td>
<td><strong>- HCT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/15/2016</td>
<td>NED</td>
<td>FLT3-ITD negative</td>
<td>NED</td>
</tr>
<tr>
<td>3/20/2016</td>
<td>NED</td>
<td>Not performed</td>
<td>NED</td>
</tr>
<tr>
<td>3/25/2016</td>
<td><strong>- D100 Contact Date</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**CIBMTR**

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

CRP/DM CONFERENCE 2021 | 117
Example B

105. Were tests for molecular markers performed (e.g. PCR, NGS)?
- Yes
- No
- Unknown

116. Was the disease status assessed via flow cytometry?
- Yes
- No

Specify tissue and results at the time of evaluation for this reporting period:

117. Blood
- Yes
- No

118. Date sample collected: ___ / ___ / ___

121. Bone marrow
- Yes
- No

122. Date sample collected: 2016 / 3 / 20

123. Was disease detected?
- Yes
- No

124. Specify percent disease detected: ___ • ___ • ___ %
Example B

125. Were cytogenetics tested (karyotyping or FISH)?
- Yes
- No
- Unknown

126. Were cytogenetics tested via FISH?
- Yes
- No

127. Results of tests:
- Abnormalities identified
- No abnormalities

137. Was the disease status assessed by clinical / hematologic assessment?
- Yes
- No

138. Date assessed: __2016__/__3__/__20__

139. Was disease detected?
- Yes
- No

140. Was the disease status assessed by other assessment?
- Yes
- No

141. Date assessed: __YYYY__/__MM__/__DD__

142. Specify other assessment: ____________________________

143. Was disease detected?
- Yes
- No
### Example C

<table>
<thead>
<tr>
<th>Date</th>
<th>CBC</th>
<th>BMBX</th>
<th>Molecular</th>
<th>Flow Cytometry (BM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/10/2015</td>
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<td>11/1/2015</td>
<td>NED, 2% blasts</td>
<td></td>
<td>FLT3-ITD negative</td>
<td>NED</td>
</tr>
<tr>
<td><strong>12/16/2016 - HCT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/15/2016</td>
<td>10% blasts</td>
<td></td>
<td>FLT3-ITD positive</td>
<td></td>
</tr>
<tr>
<td>3/20/2016</td>
<td>Persistent AML, 55% blasts</td>
<td></td>
<td>Not performed</td>
<td>65% blasts</td>
</tr>
<tr>
<td><strong>3/25/2016 – D100 Contact Date</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Diagnosis date:</strong> 3/10/2015</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>HCT date:</strong> 12/16/2016</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Day 100 contact date:</strong> 3/25/2016</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Therapy was not administered in the Day 100 reporting period</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example C

Disease Detection Since the Date of Last Report

Indicate if disease was detected since the date of last report - including relapsed disease, persistent disease, and minimal residual disease.

51. Were tests for molecular markers performed (and positive for disease) (e.g. PCR, NGS)?

- Yes
- No
- Unknown

52. Date sample collected: 2016 / 03 / 15

55. FLT3 – TKD (point mutations in D835 or deletions of codon 1836)
- Positive
- Negative
- Not done

56. FLT3 – ITD mutation
- Positive
- Negative
- Not done

57. IDH1
- Positive
- Negative
- Not done

58. IDH2
- Positive
- Negative
- Not done

59. KIT
- Positive
- Negative
- Not done

60. NPM1
- Positive
- Negative
- Not done

61. Other molecular marker
- Positive
- Negative
- Not done

62. Specify other molecular marker: _____________________
Example C
Example C

80. Was disease detected by clinical/hematologic assessment?
- Yes
- No

81. Date assessed: 2016 / 3 / 15

82. Central nervous system
- Yes
- No

83. Skin
- Yes
- No

84. Soft tissue
- Yes
- No

85. Other site(s)
- Yes
- No

86. Specify other site(s): Blood

87. Was disease detected by other assessment?
- Yes
- No

88. Date assessed: YYYY / MM / DD

89. Specify other assessment:

90. Was intervention given for relapsed disease, persistent disease, or minimal residual disease? (since the date of the last report)
- Yes
- No

91. Specify reason for which intervention was given
### Example C

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<tr>
<th>Date</th>
<th>CBC</th>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/15/2016</td>
<td>10% blasts</td>
<td>AML relapse, 66% blasts</td>
<td>FLT3-ITD positive</td>
<td></td>
</tr>
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<td>3/20/2016</td>
<td></td>
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### Example D

<table>
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<tr>
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</tr>
<tr>
<td>12/16/2015</td>
<td>HCT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/16/2016</td>
<td>AML relapse, 66% blasts</td>
<td>FLT3-ITD positive</td>
<td>70% blasts</td>
</tr>
<tr>
<td>2/1/2016</td>
<td>Re-induction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/20/2016</td>
<td>Persistent AML, 55% blasts</td>
<td>Not performed</td>
<td>65% blasts</td>
</tr>
</tbody>
</table>

### 3/25/2016 – D100 Contact Date

- Diagnosis date: 3/10/2015
- HCT date: 12/16/2015
- Day 100 contact date: 3/25/2016
Example D

**Disease Detection Since the Date of Last Report**

Indicate if disease was detected since the date of last report - including relapsed disease, persistent disease, and minimal residual disease.

51. Were tests for molecular markers performed (and positive for disease) (e.g. PCR, NGS)?
   - Yes
   - No
   - Unknown

52. Date sample collected: 2016 / 1 / 16

55. FLT3 – TKD (point mutations in D835 or deletions of codon 1836)
   - Positive
   - Negative
   - Not done

56. FLT3 – ITD mutation
   - Positive
   - Negative
   - Not done

57. IDH1
   - Positive
   - Negative
   - Not done

58. IDH2
   - Positive
   - Negative
   - Not done

59. KIT
   - Positive
   - Negative
   - Not done

60. NPM1
   - Positive
   - Negative
   - Not done

61. Other molecular marker
   - Positive
   - Negative
   - Not done

62. Specify other molecular marker: ____________________
Example D

63. Was disease detected via flow cytometry?
   - Yes
   - No

   Specify tissue and results:
   64. Blood
      - Yes
      - No

   65. Date sample collected: \( \text{YYYY} / \text{MM} / \text{DD} \)

   66. Specify percent disease detected: \( \_\_\_\_ \_\_\_\_\_\% \)

   67. Bone marrow
      - Yes
      - No

   68. Date sample collected: \( \text{2016} / 1 / 16 \)

   69. Specify percent disease detected: \( \_70 \cdot 0 \_\_\_\% \)

70. Was disease detected via cytogenic testing (karyotyping or FISH)?
   - Yes
   - No
   - Unknown

   71. Were cytogenetic abnormalities identified via FISH?
      - Yes
      - No

   72. Date sample collected: \( \text{YYYY} / \text{MM} / \text{DD} \)
Example D

80. Was disease detected by clinical / hematologic assessment?

Yes
No

81. Date assessed: \( \frac{2016}{1} \frac{1}{16} \)

Specify site(s) of disease:

82. Central nervous system
83. Skin
84. Soft tissue
85. Other site(s)

Yes
No

86. Specify other site(s): Bone marrow

87. Was disease detected by other assessment?

Yes
No

88. Date assessed: \( \frac{YYY}{MM} \frac{DD}{DD} \)

89. Specify other assessment:

90. Was intervention given for relapsed disease, persistent disease, or minimal residual disease? (since the date of the last report)

Yes
No

91. Specify reason for which intervention was given:

Minimal residual disease
Persistent disease
Relapsed disease
**Example D**

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<td><strong>3/25/2016 – D100 Contact Date</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example D

105. Were tests for molecular markers performed (e.g. PCR, NGS)?
- Yes
- No
- Unknown

116. Was the disease status assessed via flow cytometry?
- Yes
- No

Specify tissue and results at the time of evaluation for this reporting period:

117. Blood
- Yes
- No

118. Date sample collected: YYYY / MM / DD

121. Bone marrow
- Yes
- No

122. Date sample collected: 2016 / 3 / 20

123. Was disease detected?
- Yes
- No

124. Specify percent disease detected: 65.0 %
Example D

125. Were cytogenetics tested (karyotyping or FISH)?
   - [x] No
   - □ Yes
   - □ Unknown

126. Were cytogenetics tested via FISH?
   - [x] No
   - □ Yes

127. Results of tests:
   - □ Abnormalities identified
   - □ No abnormalities

137. Was the disease status assessed by clinical / hematologic assessment?
   - [x] Yes
   - □ No

138. Date assessed: 2016 / 3 / 20

139. Was disease detected?
   - [x] Yes
   - □ No

140. Was the disease status assessed by other assessment?
   - [x] No
   - □ Yes

141. Date assessed: YYYY / MM / DD

142. Specify other assessment:

143. Was disease detected?
   - □ Yes
   - □ No
Lymphoma Reporting on Disease Classification (2402)
Pre-Infusion Disease Status

• When determining the pre-infusion disease status, compare the restaging assessments immediately prior to the preparative regimen to the assessments at baseline
  – “Baseline” is defined as the disease at diagnosis or at relapse / progression

• When a transformation has occurred, count the response number (CR1, REL2, etc.) beginning with the transformed lymphoma
  – Do not include the responses to the lymphoma sub-type prior to the transformation
### Example E

<table>
<thead>
<tr>
<th>Date</th>
<th>Lymph Node Biopsy</th>
<th>PET / CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/15/2018</td>
<td></td>
<td>Cervical mass identified</td>
</tr>
<tr>
<td>5/16/2018</td>
<td>Cervical node: Follicular lymphoma</td>
<td></td>
</tr>
<tr>
<td><strong>5/20/2018</strong> – Induction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/1/2018</td>
<td></td>
<td>Complete response to therapy</td>
</tr>
<tr>
<td>9/30/2018</td>
<td></td>
<td>New cervical lymphadenopathy</td>
</tr>
<tr>
<td>10/2/2018</td>
<td>Cervical node: Consistent with transformed DLBCL</td>
<td></td>
</tr>
<tr>
<td><strong>10/10/2018</strong> – Re-induction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11/20/2018</td>
<td></td>
<td>Complete response to therapy</td>
</tr>
<tr>
<td><strong>12/15/2018</strong> – HCT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**394. What was the disease status?**

- CR1 - 1st complete remission: no bone marrow or extramedullary relapse prior to transplant – **Go to question 395**
- CR2 - 2nd complete remission – **Go to question 395**
- CR3+ - 3rd or subsequent complete remission – **Go to question 395**
Total Number of Lines of Therapy

- Found on the Disease Classification (2402) form
- Intended to capture the total number of lines of therapy administered since the original lymphoma diagnosis up until the start of the preparative regimen / infusion, regardless of if the recipient received a prior infusion
Example F

A recipient received a line of induction, achieved CR, and then went to HCT. Post-HCT, the recipient transformed, received a line of re-induction followed by a line of consolidation and achieved another CR prior to the second HCT.
Cellular Therapy Essential Data Follow-Up (4100)
Cellular Therapy Essential Data Follow-Up

• The Cellular Therapy Essential Data Follow-Up (4100) form focuses on key follow-up information including the following
  – Development and severity of toxicities
    • Cytokine release syndrome
    • Neurotoxicities
    • Hypogammaglobulinemia
    • Tumor lysis syndrome
  – Various lab values
Hypogammaglobulinemia

- Hypogammaglobulinemia refers to low levels of circulating immunoglobulins, in the blood
  - Determined by quantitative levels of immunoglobulins G (IgG), A (IgA) and M (IgM)
  - Levels lower than 600 mg/dL of circulating IgG are considered to be hypogammaglobulinemia
    - Children ages 4 to 10, levels lower than 500mg/dL are considered hypogammaglobulinemia
Hypogammaglobulinemia

- **Report yes** if IgG dropped below 600 mg/dL (or 500 mg/dL for children ages 4 – 10) in the reporting period
  - Regardless if the IgG was below 600 mg/dL prior to the cell therapy infusion, or
  - If the IgG was below 600 mg/dL prior to the cell therapy infusion and persisted into the current reporting period
- **Report no** if the IgG did not drop below 600 mg/dL in the reporting period
- **Report unknown** if IgG was not assessed
Hypogammaglobulinemia

- Report hypogammaglobulinemia resolved when there are sustained normal levels of IgG in the blood (≥ 600 mg/dL) without the need for IVIG infusions for 3 consecutive months.
## Example G

<table>
<thead>
<tr>
<th>Date</th>
<th>IgG (mg/dL)</th>
<th>IVIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/1/2018</td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>2/5/2018 – CT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/20/2018</td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>4/30/2018</td>
<td>405</td>
<td>1 dose administered</td>
</tr>
<tr>
<td>5/16/2018 – D100 Contact Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5/17/2018</td>
<td>555</td>
<td>1 dose administered</td>
</tr>
<tr>
<td>7/15/2018</td>
<td>700</td>
<td></td>
</tr>
<tr>
<td>8/20/2018 – 6M Contact Date</td>
<td>695</td>
<td></td>
</tr>
</tbody>
</table>
Example G

132. Hypogammaglobulinemia
   - Yes - Go to question 133
   - No - Go to question 139
   - Unknown - Go to question 139

133. Was the date of onset previously reported?
   - Yes – Go to question 135
   - No – Go to question 134

134. Date of onset: __2018__ - __4__ - __20__
    YYYY MM DD

135. Did hypogammaglobulinemia resolve?
   - Yes – Go to question 136
   - No – Go to question 137

136. Date resolved: ________ ____ ________ - ________ - ________
    YYYY MM DD

Day 100
Example G

132. Hypogammaglobulinemia
   - Yes - Go to question 133
   - No - Go to question 139
   - Unknown - Go to question 139

133. Was the date of onset previously reported?
   - Yes - Go to question 135
   - No - Go to question 134

134. Date of onset: ___ ___ ___ - ___ ___ - ___
     YYYY    MM    DD

135. Did hypogammaglobulinemia resolve?
   - Yes - Go to question 136
   - No - Go to question 137

136. Date resolved: ___ ___ 2018 - ___ 8 - 2020
     YYYY    MM    DD
Lab Values

- The following lab values are collected on the Cellular Therapy Essential Data Follow-Up form:
  - Interleukin-6
  - Interferon-gamma
  - Soluble interleukin-2 receptor α
  - Total serum ferritin
  - C-reactive protein

- Report the **maximum** value and date in the reporting period
  - If there are the same maximum value on multiple days, report the earliest date
Best Practices

- Disease Trackers
- Review of CIBMTR forms
- Frequent Review of CIBMTR Forms Instruction Manual
- Regular Meetings with Physicians and Data Managers
Questions