Peak Performance: Improving Data Quality

CRP/DM Conference
February 21, 2018

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Mandi Proue, Senior Clinical Research Associate
Presentations

• Cycle 5 Overview - Deb

• Corrective Action Plans - Ashley

• Best Practices - Mandi
Cycle 5 Review (FY2014 – FY2017)

• Cycle 5 Statistics
  – How did transplant centers do on their audits?

• CIBMTR Emphasis on Improved Data Quality:
  – Forms Instruction Manual
  – eLearning Opportunities
  – Collaboration with FACT
  – Website access (Portal, Audit, etc.)
Audit Cycles & Audit Outline

Transplant Centers are audited every 4 years, as eligible.

TCs are contacted in advance for scheduling.

16 recipients are randomly selected since 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 active requirements prepared.
Audit Cycles


- NMDP began audit program
- NMDP & IBMTR combined audit programs
- Passing critical field error rate drops from 5% to 3%

- Manula - FIM
- Audit Consequences

FACT / CIBMTR Collaboration
Audit Passing Criteria

- Critical Field Error Rate ≤ 3%

- A center’s score will be assessed as:
  1. Pass,
  2. Pass, with required corrective action, or
  3. Fail, with required corrective action.

- Corrective Action Requested If:
  1. A critical field error rate over 3%,
  2. Systemic and/or non-systemic errors,
  3. Consent form issues,
  4. Outstanding missing documentation issues.
Cycle 5 Overview
Average Error Rates Per Cycle

![Average Error Rates Per Cycle](image_url)
Centers with Passing Score in Cycle 5: 174 of 217 (80%)
Average Critical Field Error Rate for Cycle 5: 2.3%
Cycles 1-5 Pass / Fail

Pass / Fail - Domestic & International

Cycle 1: Domestic - 56% Pass, 43% Fail
Cycle 2: Domestic - 84% Pass, 16% Fail
Cycle 3: Domestic - 92% Pass, 8% Fail
Cycle 4: Domestic - 78% Pass, 22% Fail
Cycle 5: Domestic - 79% Pass, 21% Fail

International - 100% Pass

CIBMTR

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH
Cycle 5 – Centers Audited

217
Total Centers Audited

34
Non-US Centers Audited
Cycle 5 - Passing Centers

174 of 217 (80%) centers passed with a critical field error rate less than or equal to 3%
Cycle 5 - Passing Centers by Location

145

of 183 (79%) of U.S. centers passed

29

of 34 (85%) of Non-U.S. centers passed
Cycle 5 Critical Field Error Rates

- **Average Error Rate**: 2.3%
- **Median Error Rate**: 2.0%
- **Lowest Error Rate**: 0.3%
## Cycle 5 - Reporting Areas of Concern

<table>
<thead>
<tr>
<th>Reporting Area</th>
<th># Centers</th>
<th>% Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of Disease Assessment</td>
<td>122</td>
<td>56%</td>
</tr>
<tr>
<td>Disease Status</td>
<td>110</td>
<td>51%</td>
</tr>
<tr>
<td>Product &amp; Infusion</td>
<td>92</td>
<td>42%</td>
</tr>
<tr>
<td>GVHD</td>
<td>61</td>
<td>28%</td>
</tr>
<tr>
<td>Disease Classification &amp; Characteristics</td>
<td>38</td>
<td>18%</td>
</tr>
</tbody>
</table>
Cycle 5 – Top Performing Centers
(1.0% to 0.6% Critical Field Error Rate)

- **CCN 10007** – Avera McKennan Transplant Institute
- **CCN 10010** – Nationwide Children's Hospital
- **CCN 10016** – Nemours / Wolfson Children's Clinic & Hospital
- **CCN 10020** – University of North Carolina Hospitals
- **CCN 10052** – The Blood and Marrow Transplant Program at Northside Hospital
Cycle 5 – Top Performing Centers (1.0% to 0.6% Critical Field Error Rate, cont.)

- **CCN 10114** – Scripps Blood & Marrow Transplant Program
- **CCN 10132** – Indiana University Hospital / Riley Hospital for Children
- **CCN 10143** – City of Hope National Medical Center
- **CCN 10208** – University of Kansas
- **CCN 10737** – University of Calgary — Tom Baker Cancer Centre
Cycle 5 – Top Performing Centers
(1.0% to 0.6% Critical Field Error Rate, cont.)

• **CCN 10738** – Sydney Children's Hospital
• **CCN 10788** – The Children’s Hospital at Westmead
• **CCN 10830** – Starship Children's Hospital, University of Auckland
• **CCN 10869** – St. Luke’s Mountain State Tumor Institute
• **CCN 10872** – Princess Margaret Hospital, University of Toronto, Autologous Program (now CCN 11211)
Cycle 5 – Top Performing Centers
(1.0% to 0.6% Critical Field Error Rate, cont.)

• **CCN 10946** – Oklahoma Oncology Inc., St. Francis Hospital

• **CCN 11042** – Doernbecher Children’s Hospital, OHSU
Cycle 5 – Top Performing Centers
(≤0.5% Critical Field Error Rate)

- **CCN 10689** – Mayo Clinic Arizona & Phoenix Children's Hospital
- **CCN 11025** – Imperial College London, St. Mary's Hospital
Cycle 5 – Data Quality Initiatives

• Manula / Forms Instructions Manual Launched – 2015
• Audit Consequences – 2015
• FACT-CIBMTR Collaboration – 2017
• Audit Portal – 2017
• Audit Website – 2017
• eLearning Modules
• Improved CAP Process
Manula / Forms Instruction Manual

• Launched March 31, 2015
• Moved >800 pages of materials into new system
• Improved usability (navigation, searching, printing)
• Allows for internal analysis of manual usage by external users
• Allows for more timely updates and targeted changes based on user feedback
Manula / Forms Instruction Manual

- To date 1,389 pages of instruction
- New / Revised Manual Sections - 29
- In FY2018 – 9 New / Revised Sections
- Manual Updates – noted in each section of the manual AND Monthly e-Blast to sites
- Manual Releases coincide with the Forms Revision Process
Audit Consequences

• Implemented June 2015
  – For centers that have particularly high error rates or consistently fail to meet data quality standards
  – Only applies to audits after June 2015; audit consequences cannot be retroactively applied; however, past audits will be used to determine the number of consecutive passed/failed audits
Audit Consequences, cont.

• Audit Consequences will be applied when:
  – There is a critical field error rate of $\geq 8\%$ on any single audit
  – Two consecutive audits with a critical field error rate $\geq 5\%$
  – Three consecutive audits with a critical field error rate $\geq 3\%$
Audit Consequences, cont.

- Specific consequences can be found on the Audit Website
- Very few centers will have audit consequences applied
- Sites will be notified at the beginning of each fiscal year if their site is at risk of audit consequences. Also, addressed in audit reports.
FACT / CIBMTR Data Audit Collaboration

• Designed to:
  – Reduce duplicative data audit efforts
  – Enhance quality improvement efforts
  – Provide support to accredited programs
Audit Portal

- Online access to previous audit documents
  - Includes Audit Reports, Audit Completion Certificates, and CAP items, among other relevant audit documents

- Found in CIBMTR Portal, at [https://portal.cibmtr.org](https://portal.cibmtr.org)
  - Same Portal used to access Data Back to Centers (DBtC), Center Performance Analytics (CPA), etc.

- **IT/access issues?** Contact CIBMTR Portal Help at [cibmtr-portalhelp@mcw.edu](mailto:cibmtr-portalhelp@mcw.edu)

- **Questions about folder content?** Contact Jenna Umar, Clinical Trials Assistant, at [jhullerm@nmdp.org](mailto:jhullerm@nmdp.org)
CIBMTR Website
CIBMTR Audit Program Website

- General overview of the CIBMTR Audit Program
  - High level information for medical directors and center staff
  - **CIBMTR Audit Guide** goes into more detail
- **URL:** [https://www.cibmtr.org/DataManagement/AuditProgram/Pages/index.aspx](https://www.cibmtr.org/DataManagement/AuditProgram/Pages/index.aspx)

- Answers general questions such as:
  - Why do we audit?
  - What do we audit?
  - Who gets audited?
  - How often do we audit?
  - What happens after an audit?
  - What is a CAP?
  - ...And more!
E-Learnings Available at CIBMTR.org

Data Reporting focused – 6 E-Learnings Available

- Multiple Myeloma 101 – Part 1
- Multiple Myeloma 101 – Part 2
- VOD / SOS Reporting (Form 2553)
- MDS and MPN Reporting
E-Learnings Available at CIBMTR.org

Data Reporting focused – 6 E-Learnings Available

- Infusion Data (Form 2006) Reporting Overview
- Reporting Preparative Regimen on the Pre-TED and Baseline
Improved Corrective Action Plan Process

• Previous CAP items are reviewed at the time of the next audit

• Auditor review/evaluation:
  – Has the percentage of errors decreased in the reporting area?
  – Are the tools implemented as part of the prior CAP being used?

• Overall evaluation of each prior item is completed along with recommendations for continuation or additional action, if needed
Center Specific Summaries
Center Specific Summaries

• Summaries Include:
  – Center Specific Statistics
    • Historical Audit Information (Error rates, Reporting Areas of Concern, etc.) for all audits
    • Error Rate Bar Graph (all cycles)
  – Cycle 5 Critical Field Error Rates for all centers
  – How your center compares to others in the cycle
## Center Specific Summaries

### Center Specific Audit Summary Report

<table>
<thead>
<tr>
<th>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>2000*</td>
<td>2.0%</td>
<td>1.5%</td>
<td>1.6%</td>
<td>Pass</td>
<td>Kamofsky/Lansky, Diagnosis Date, GVHD</td>
<td>No</td>
</tr>
<tr>
<td>2004*</td>
<td>2.6%</td>
<td>2.6%</td>
<td>2.6%</td>
<td>Pass</td>
<td>Kamofsky/Lansky, ANC, GVHD</td>
<td>No</td>
</tr>
<tr>
<td>2008*</td>
<td>0.8%</td>
<td>1.3%</td>
<td>1.1%</td>
<td>Pass</td>
<td>Consents, Date of Contact, ANC</td>
<td>Yes</td>
</tr>
<tr>
<td>2012**</td>
<td>3.3%</td>
<td>1.6%</td>
<td>3.0%</td>
<td>Fail</td>
<td>Disease status, GVHD, Method of latest disease assessment</td>
<td>Yes</td>
</tr>
<tr>
<td>2016**</td>
<td>2.7%</td>
<td>1.9%</td>
<td>2.8%</td>
<td>Pass</td>
<td>Disease Status, Latest Disease Assessment, HCT Product and Infusion, Pre-HCT Therapy</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Error Rate Summary

![Error Rate Summary](image)
Audit Team Fun Facts

• In 2017 alone, roughly 403,000 fields were audited.
• During cycle 5, over 1.4 million fields were audited.
• Since the audit program’s inception in 1999, about 4.5 million data fields have been audited.
• The audit team has traveled to 18 countries.
Corrective Action Plans
Ashley Birch
Senior Clinical Research Associate
Outline

• CAP process
• Cycle 5 CAP overview
• CAP response examples
CAP Process
When is a CAP required?

- **Pass**: Pass with required corrective action
- **Fail**: Fail with required corrective action
Why is a CAP required?

• Critical field error rate > 3.0%
• Systemic errors (even if CFER ≤ 3.0%)
• Issues with CIBMTR Research Database or Research Sample Repository consent forms
• Outstanding missing documentation
CAP Requirements

Appendix C. Corrective Action
• How to complete the CAP process

Appendix D. Corrective Action Requirements
• Corrective action items
• Signature lines for data management and medical director
• Due date
CAP Response Review

Review & evaluate CAP response

If response unsatisfactory: request additional information from the center

Send audit completion certificate to center
FACT inspectors will evaluate successful implementation of CIBMTR corrective action requirements.

The effectiveness of any corrective actions will be evaluated during the next audit.
Cycle 5
CAP Overview
Cycle 5 Corrective Action Items

162 centers had to complete

370 corrective action requirements
Cycle 5 Corrective Action Items

118

of 162 (72.8%) centers passed with a critical field error rate less than or equal to

3%
Cycle 5 Corrective Action Items

% of Transplant Centers with Corrective Action Items

- Consent: 36%
- Disease Status and Assessment: 16%
- Product and Infusion: 10%
- Missing Documentation: 7%
- Graft Versus Host Disease: 6%
- Data Management Training: 3%
- Combined Total of Remaining Corrective Action Items: 22%

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CAP Response Examples
Corrective Action - Consent

• 127 of 162 (78.4%) corrective action plans assigned in Cycle 5 had at least one consent issue

• Historically, consent issues have been a top corrective action plan item
  – For more information about how to assess individual consent forms for completeness – see the Tandem 2016 presentation and accompanying handout.
## Corrective Action – Systemic Consent Issue

<table>
<thead>
<tr>
<th>Corrective Action Item</th>
<th>Corrective Action Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 of 16 (75%) recipients audited had at least one consent form issue relating to blank fields. Create a process to ensure completeness of consents.</td>
<td>A tool was created to track pre-HCT screening tests and appropriate tests. As part of the tool, MD and data managers were required to review the consents for completeness. Internal audits were conducted to review the completeness of consents.</td>
</tr>
</tbody>
</table>
## Corrective Action – Systemic Consent Issue

<table>
<thead>
<tr>
<th>Corrective Action Item</th>
<th>Corrective Action Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work with the IRB to establish a protocol that ensures all consents are correctly completed.</td>
<td>SOP created to ensure all consents meet the IRB requirements. Quality coordinator will review the completed consent forms.</td>
</tr>
</tbody>
</table>
Corrective Action – Systemic Consent

Issue

PURPOSE
To ensure all the consents meet the IRB requirements.

RESPONSIBILITIES
Investigators conduct consent process and obtain signed consents from participants.

PROCEDURES
- BMT coordinator to ensure the Participant Information Sheet and Consent Form (PICF) are updated and approved by the IRB
- Investigators provide the correct version of the PICF to the participant
- Investigator explain the PICF and answer participant’s questions
- Investigator obtain the signatures, names and dates required on the PICF
- Investigator provide a copy of the signed PICF to the participant
- Data manager ensure the PICF is completed correctly
- Data manager scan all pages of signed PICF into the BMT Document in MOSAIQ (electronic medical record)
- BMT quality coordinator finally checks and approves the MOSAIQ document.
Corrective Action – Disease Status and Assessments

• 79 of 162 (48.7%) corrective action plans assigned in Cycle 5 involved systemic issues reporting disease status and/or assessments data fields

**Example Corrective Action Item**

Establish a resource or training process to ensure accurate interpretation of lab reports, path reports, and radiology reports used in determining disease assessment for varying diseases. This resource or process should also include a system for verifying that all required fields have been completed.
Corrective Action – Disease Status and Assessments

<table>
<thead>
<tr>
<th>Corrective Action Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data managers will review the CIBMTR data management manual</td>
</tr>
<tr>
<td>Physicians conduct a verification review of disease status prior to HCT</td>
</tr>
<tr>
<td>Data manager will meet with physician prior to data entry if discrepancies are identified</td>
</tr>
<tr>
<td>Internal audit form will be revised to include CIBMTR critical fields</td>
</tr>
<tr>
<td>Internal audits conducted every month, 6 months, or annually</td>
</tr>
<tr>
<td>Educational presentation to be developed and maintained for future training needs</td>
</tr>
<tr>
<td>Dedicated physician for each disease will provide training to the data managers on disease assessment methods and results</td>
</tr>
</tbody>
</table>
Corrective Action – Disease Status and Assessments

Disease Status and Assessment

- Dedicated Physician for each disease site will provide training to both the data managers on disease assessment methods and results. The dedicated physicians to be determined by the Medical Director.
- Autologous transplant clearance checklist has been put in place to capture disease status and assessment pre-transplant. See attached.
- Post-transplant follow up checklist will be put into process flow to capture disease status and assessment. Alternative ways to capture this information to be discussed with the team.
Corrective Action – Disease Status and Assessments

**Disease Status and Disease Assessment:**

An information/inservice session was held among all staff completing case report forms to review the specific disease status criteria as defined in the CIBMTR Data Management Manual. This ensures that all staff has a solid understanding of disease assessment methods and accurate interpretation of the findings. Disease status of recipients will be reviewed and updated based on these guidelines. It was established the chimerism results are not a molecular diagnostic tool to be used to establish CR, even in the absence of a bone marrow biopsy. Those patients who do not have a bone marrow assessment completed in order to establish a CR post-transplant, (i.e. Leukemias) will be reported as No, never in CR from HCST and the latest assessment date will be noted. This establishes that the patient has been seen post-transplant but did not have the required assessments as defined in the guidelines to establish a CR.

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Corrective Action – Product and Infusion

• 37 of 162 (22.8%) corrective action plans assigned in Cycle 5 required improvement in reporting HCT product and infusion data fields

Example Corrective Action Item

Develop a plan to ensure accurate completion of the product and infusion data with source documentation available.
Corrective Action – Product and Infusion

<table>
<thead>
<tr>
<th>Corrective Action Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 2006 will be filled out by stem cell lab and will be verified by data manager with original source documents</td>
</tr>
<tr>
<td>Obtain copies of all stem cell processing for each recipient and keep in research chart</td>
</tr>
<tr>
<td>Revised internal stem cell processing forms to capture thaw completion times for cryopreserved products and adverse events</td>
</tr>
<tr>
<td>Complete Form 2006 eLearning module</td>
</tr>
</tbody>
</table>
Corrective Action - GVHD

• 21 of 162 (12.9%) corrective action plans assigned in the Cycle 5 involved systemic issues reporting GVHD data fields

Example Corrective Action Item

Submit a detailed plan describing how your center will improve the reporting of acute and chronic GVHD on CIBMTR forms.
## Corrective Action - GVHD

### Corrective Action Responses

Developed a GVHD assessment tool based on reporting guidelines for physicians to complete. The documentation is reviewed at the weekly BMT meeting and the data managers clarify any discrepancies with the clinical staff.

Quality manager will review the GVHD source documentation for five recipients and measure GVHD documentation compliance and submit results to the medical director. Additionally, the data manager will add GVHD documentation compliance score to the annual audit report to the quality committee.
Corrective Action - GVHD

### aGVHD Assessment - ADULT in Past 7 Days

- No Acute GVHD to Date
- History of Acute GVHD with no current Flare
- Acute GVHD progressed to Chronic
- Active Acute GVHD (complete Clinical GVHD Assessment below)

### Clinical GVHD Assessment - Highest Stage in Past 7 Days

Karnofsky Score: ____________

<table>
<thead>
<tr>
<th>ORGAN: CLINICAL STAGE: (circle GVHD involved organ)</th>
<th>BIOPSY: (if done in past 7 days)</th>
<th>Differential Diagnosis: (MUST complete if other organ etiology occurring)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td></td>
<td>Drug  Infect  TPN  VOD  Other</td>
</tr>
<tr>
<td>0</td>
<td></td>
<td>(&lt;25%)  (25-50)  (&gt;50%)  (bullous/Desquamation)</td>
</tr>
</tbody>
</table>

### Differential Diagnosis:

- Drug
- Infect
- TPN
- VOD
- Other

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Corrective Action – Data Management Training

- HCT related training for data managers
- Internal audits
- Request interim CIBMTR Data Audit
- Milestone reporting to the CIBMTR bi-annually
Data Management Training:

A policy and procedure defining the training process was developed and a vacant position was updated to a senior level data coordinator who will be responsible with training staff to provide an additional resource for ensuring ongoing staff competency.

Training is provided on a monthly basis and will cover issues identified during the audit. Additional training will be developed based on errors identified during internal audit.

Data managers are required to attend BMT rounds, Liquid Tumor conferences, as well as Grand Round to relate the data collected. In addition, data managers will attend the Tandem meetings.
Corrective Action – Data Management Training

Data Management Training:

The site developed a mandatory training plan for reporting disease status and assessment, acute and chronic GVHD, and HCT product and infusion for all data management staff. The training plan consisted of:

- Training data management staff on where to obtain source documents in the EMR.
- Review of the CIBMTR Manual
  - Data managers encouraged to discuss any ambiguity with site’s CRC and designated clinician (medical director)
- Review all available eLearning modules
- Onsite training session by CIBMTR staff member
- Attend the BMT Tandem meetings
- Staff supervision by the medical director
  - Real-time communication with MD for any ambiguity related to reporting CIBMTR data
  - Weekly meetings with MD to resolve questions and discuss ongoing challenges
Corrective Action – Data Management Training

Data Quality Assurance:

An auditing policy and procedure was developed. Internal audits are conducted by an experienced internal auditor who does not report on the CIBMTR forms. The internal audit will consist of:

- Random forms selected for audit
- Departmental training and random audits
- Formal documentation of outcomes and follow-up on issues identified

CIBMTR forms are reviewed monthly with initial focus on correcting critical fields and GVHD issues. There is 100% manager review on training session data forms and 10% random manager review of the monthly forms submitted to CIBMTR.

Audit findings shared with data managers and reported to BMT leadership to implement preventative and corrective action plans.
Corrective Action – Data Management Training

Physician Training:

Physician and mid-level practitioners will participate in a training plan which consists of:

- Provided with links to the CIBMTR Manual – specifically disease status criteria
- Monthly education sessions which will involve discussing disease assessments and disease status to ensure all members are in agreement with CIBMTR
- A simplified manual for acute and chronic GVHD was created and is reviewed by physicians and mid-level practitioners with each periodic GVHD assessment
- A chronic GVHD template was created and is to be used in clinical notes
Sharing CAP Responses

• If your center is interested in connecting with centers that have successfully implemented CAPs, contact abirch@nmdp.org

• I will reach out to the site to see confirm if they are willing to share tools/resources developed for CAP response
Best Practices in Reporting Data to the CIBMTR
Mandi Proue, Senior Clinical Research Associate
CIBMTR Best Practices in Data Reporting Survey

• Goals of survey:
  – Select high performing centers
    • Centers with a critical field error rate of ≤1.5% on their last audit (Cycle 5)
  – Seek input from high performing centers on
    • Data management practices
    • Training programs
    • Internal audit processes
    • Use of resources
Survey Outline

- Who?
- Data Manager Training
- Internal Audits
- Tools and Resources
- What’s Next?
Who: High Performing Centers

- 68 centers selected
  - Survey link sent to primary data contact (forwarded as needed)
  - 45 responses (66% response rate)
    - 36 complete surveys
    - 9 partial surveys
Who: How many transplants?

Over half (55%) perform at least 100 transplants annually
– 37% perform 25 – 100 transplants
– 8% perform <25 transplants
Who: How many full time positions?

The majority of centers reported 4 or less positions dedicated to completing CIBMTR forms.

- 34% have 1 dedicated employee
- 37% have 2-4 dedicated employees
## Training: Type of Training

<table>
<thead>
<tr>
<th>Training</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-study of CIBMTR Forms and/or Manuals</td>
<td>100%</td>
</tr>
<tr>
<td>Data Quality Audits</td>
<td>77.8%</td>
</tr>
<tr>
<td>Formal trainings led by data managers or supervisors</td>
<td>72.2%</td>
</tr>
<tr>
<td>Conferences (BMT Tandem, SOCRA, ACRP, etc.)</td>
<td>63.9%</td>
</tr>
<tr>
<td>Formal trainings led by clinical team (physicians, nurses, etc.)</td>
<td>16.7%</td>
</tr>
</tbody>
</table>
The majority of respondents reported the CIBMTR Forms Instruction Manual and CIBMTR eLearnings were resources used for training new data managers.

- CIBMTR eLearnings: 83.3%
- CIBMTR Forms Instruction Manual review: 94.4%
- Attendance at Tandem: 55.6%
- Training materials developed by your center: 50.0%
- Other (please specify): 16.7%
Training: Other Resources

Most centers (68%) reported that they do not use any training resources other than CIBMTR materials.
Training: Other Resources

- Of those that use other resources, examples include:
  - SOPs
  - Journal articles
  - Disease specific literature and bone marrow transplant education handbooks for patients
  - Tip sheets to navigate the EMR
Training: Other Resources

– Internal documents of notes and emails and responses to questions from CIBMTR compiled over time
– Weekly BMT Data Manager meetings
– New data managers round with transplant physician and view a bone marrow harvest and apheresis collection
Training: Training Length

Over half of centers reported their new data manager training is >8 weeks
  – 23% reported 4-8 weeks
  – 23% reported 1-3 weeks
Training: Additional Recommendations

• Clinical research experience
• “On the job” training
• Self-study
• Start with one disease at a time, then move on as staff feel competent
• Shadow primary data manager; 1 on 1 training
• Review of completed forms
Internal Audits

The majority of respondent centers conduct regular audits or review of their CIBMTR Research Data.
Internal Audits: Frequency

- Monthly: 12.5%
- Quarterly (once every 3 months): 31.3%
- Biannually (once every 6 months): 15.6%
- Annually: 18.8%
- Other: 21.9%
Internal Audits: Scope

• 56% of centers review up to 25% of all completed forms
• 6% review all completed forms
Internal Audits: Scope

- Randomly selected data fields on each form selected for review: 9.4%
- Only predetermined questions / reporting areas on the forms selected for review: 40.6%
- 100% of data fields on the forms selected for review: 40.6%
- Other: 9.4%
Internal Audits: Who?

Most centers reported Quality Managers and/or Data Managers (Peer Review) completed internal audits/review of CIBMTR Data.
Internal Audits

• 61% of centers reported that they have conducted data clean-ups based on internal audit findings

• Other comments:
  – Internal audits are very helpful, but time consuming
  – Monthly meetings to review internal audit findings
  – Focus on critical fields
Internal Audits: Case Study

• CCN 11122 (Baptist Blood and Marrow Transplant)
  – 25-50 transplants a year
  – TED only center
  – All Pre-TEDs audited by medical director
  – Minimum of 10 patients audited annually
  – Pre-TED Audit Tool developed
    • Revised as needed for new forms
      – AML and multiple myeloma form
    – Results are discussed at quality meeting
## Internal Audits: Case Study

### PRE TED vs MEDICAL RECORD AUDIT TOOL

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>CIBMTR I.D:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of HCT:</td>
<td>Date of Audit:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audit Item</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RECIPIENT IDENTIFICATION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
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</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
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<tr>
<td>Race</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>HEMATOPOIETIC CELLULAR TRANSPLANT (HCT)</strong></td>
<td></td>
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<tr>
<td>Date of this HCT</td>
<td></td>
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<tr>
<td>Was the number of prior HCTs correct?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the Cell Source for the prior HCT correct?</td>
<td></td>
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</tr>
<tr>
<td>Was the date of the last HCT correct?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(last before current)</td>
<td></td>
<td></td>
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<tr>
<td>Was the institution where the last HCT was performed correct?</td>
<td></td>
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</tr>
<tr>
<td><strong>DONOR INFORMATION</strong></td>
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<tr>
<td>If multiple donors, is the number correct?</td>
<td></td>
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<tr>
<td>Is the donor type correct?</td>
<td></td>
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<tr>
<td>Is the Allogeneic Donor Gender correct?</td>
<td></td>
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</tr>
<tr>
<td>Were all agents used in the mobilization event reported correctly?</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Donor CMV antibodies correct?</td>
<td></td>
<td></td>
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<tr>
<td><strong>CONSENT</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Has the recipient signed consent for research data to be submitted to the NMDP/CIBMTR?</td>
<td></td>
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</tr>
<tr>
<td>Has the Recipient signed consent to donate research blood samples to the NMDP/CIBMTR?</td>
<td></td>
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</tr>
<tr>
<td><strong>PRODUCT PROCESSING/MANIPULATION</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Was the product manipulated prior to infusion answered correctly?</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Was the portion of product answered correctly?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were the methods used to manipulate the product answered correctly?</td>
<td></td>
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</tr>
<tr>
<td><strong>CLINICAL STATUS OF RECIPIENT PRIOR to the PREPARATIVE REGIMEN (CONDITIONING)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karnofsky Scale prior to the preparative regimen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recipient CMV antibodies correct?</td>
<td></td>
<td></td>
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</tbody>
</table>
Tools and Resources

• About half of centers reported implementing tools, processes, and/or corrective action to address reporting issues during the past year.
Tools and Resources

• Reporting tools
  – GVHD templates in EMR
  – Disease staging sheets/tools
  – DLI Form
  – Cellular therapy data worksheet

• BMT Meetings
  – Physicians becoming more aware of the data points that need to be collected
  – Review internal audit results
Tools and Resources

• Re-training
  – Updating tools, creating guideline tools
  – Graphic aides
  – Provide access to helpful hints/examples of complicated reporting scenarios
Tools and Resources: CIBMTR Resources

- CIBMTR Forms Instruction Manual
- CIBMTR Staff (auditors, CRCs, etc.)
- PDF Versions of CIBMTR Forms
- CIBMTR eLearnings

Rank 4
Rank 3
Rank 2
Rank 1
Tools and Resources: Future
CIBMTR Resources

• Manuals for all forms
• Manual updates
  – Notifications when updates are made
  – More examples
• Additional training on Cellular Therapies
• Additional eLearnings
  – With more case studies
• Webinar or “live” training options
• Additional information on disease classification
• More user friendly 2006 Form
What’s Next?

• Manuals for all forms
  – Developed through the Form Revision process
  – Percent of completed disease inserts in the database for which a manual has been created is 93.73%

• Manual updates
  – Notifications when updates are made
    • As of December 2017, monthly eBlasts are sent summarizing manual updates for the past month.
    • Sent to CIBMTR Training email listserve
Manual Updates

2017 Manual Updates

December 2017
November 2017
October 2017
September 2017
August 2017
July 2017
June 2017
May 2017
April 2017
March 2017
February 2017
January 2017

Hyperlinks
Please note, hyperlinks on this page will not work for any manual sections which have been retired and / or replaced by new versions.

December 2017

<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>12/6/17</td>
<td>Aplastic Anemia</td>
<td>Add</td>
<td>Added the following instruction for question 31. If this is a report of a second or subsequent transplant for aplastic anemia and this baseline disease insert has previously been completed for a prior transplant, indicate if the recipient received treatment for aplastic anemia between Day 0 of the previous HCT and the start of the preparative regimen for the subsequent HCT.</td>
</tr>
</tbody>
</table>
Manual Updates

- **Manual updates**
  - **More examples**
    - The manual is updated continuously; suggestions for examples, clarifications, etc. for the manual can be submitted via the comments feature on the manual.
Manual Updates

Question 185-233: Was specific therapy given for acute GVHD?

Indicate whether systemic therapy was used to treat acute GVHD during the reporting period. If "yes," continue with question 186. Report any prophylactic drugs as therapy for acute GVHD if they were continued after the date of diagnosis. If no therapy was given, indicate "no" and continue with question 233. If systemic therapy was given to treat acute GVHD during the reporting period, specify the drugs given in questions 186-233.

When reporting the total dose, report the total delivered dose of each drug during the reporting period. Do not report the prescribed doses or daily doses. For example, if 50 mg/kg of ATGAM was given for 5 days, the center should report a total dose of 250 mg/kg. Drug doses must be reported in whole numbers. If the total dose includes a decimal, round to the nearest whole number.

When reporting the date started, report the first day the drug was given or after the GVHD diagnosis date (reported in question 158). For prophylaxis medications continued after the date of diagnosis of acute GVHD, report the date of diagnosis as the date started. If an acute GVHD treatment has continued from a previous reporting period, report the original start date and override the error in FormsNet3SM using the code "verified correct."

Feedback

Post your comment on this topic.

Was this helpful?

Yes

No
What’s Next?

• Additional training on Cellular Therapies
  – Cellular Therapies Form Submission eLearning released October 2017; currently being revised to reflect the changes made during the January 2018 revision

• Additional eLearnings
  – With more case studies
    • Lymphoma (2018/2118) in development – to be released Spring 2018
What’s Next?

• Webinar or “live” training options

• Additional information on disease classification
  – Appendix C: recently revised and updated with more information on cytogenetic assessments

• More user friendly 2006 Form
  – This form is currently up for revision in Spring 2018
    • cibmtrformfeedback@nmdp.org
Thank you!

• Acknowledgements
  – All centers who completed the Best Practices survey
    • Stephanie Boyd (Baptist Blood and Marrow Transplant)
    • Jun Cai (Children’s Hospital at Westmead)
    • Teresa Sylak and Polly Jensen (Mayo)
  – Audit and Monitoring Team
    • Will Affield
    • Kelli Basa
    • Ariana Hendrickson
    • Kelly Newport
    • Justin Peterson
    • Jenna Umar
Questions?