CIBMTR Monthly Internal Assessment Improves Quality of Registry Data

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Conflicts of Interest

No relevant financial conflicts of interest
Objectives

Three objectives of our presentation for participants:

1) Understand how an additional internal monthly assessment ensures the validity and quality of registry data.
2) Discover 10 data points that are essential to any CIBMTR internal assessment.
3) Highlight 3 common causes of inaccurate data.
Important health decisions about oncology are often based on data, therefore the accuracy of data used in decision-making is of utmost importance.

Inaccurate data can affect the results of a study and eventually lead to invalid results.
Aim

• In order to ensure the highest degree of accuracy of CIBMTR data, the University of Maryland Blood and Marrow Transplant team implemented an additional internal monthly assessment to ensure the validity and quality of the registry data collected.
Methods

• The Blood and Marrow Transplant Program Manager and data managers developed an internal assessment tool to assess for discrepancies in the following CIBMTR data points collected about patients:
CIBMTR Data Points

- Transplant Date
- Diagnosis Date
- Karnofsky Performance Status
- Conditioning Regimen
- Disease Status
- Engraftment of ANC
- Engraftment of Platelets
- Onset of Acute GVHD
- Onset of Chronic GVHD
- Latest Follow-up Date
The CIBMTR forms audited included the following:

- 2400: Pre-TED (Transplant Essential Data)
- 2450: Post-TED (Transplant Essential Data)
- 2000: Recipient Baseline Data with Disease Insert
- 2100: 100 day Post-HSCT Data
- 2200: 6 Months to 2 Years Post-HSCT Data
- 2300: Yearly F/U for Greater than 2 Years Post-HSCT Data
Selected Forms for Auditing

• From February to July of 2011 the CIBMTR forms of four subjects per month (40%) were randomly selected for audit.

• These forms were then audited using an original internal assessment form by the data managers.
## Internal Assessment Form

### BMT INTERNAL ASSESSMENT

<table>
<thead>
<tr>
<th>Patient Unique ID</th>
<th>Date of TX</th>
<th>Type of TX</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ITEMS ASSESSED</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>BMT Chart</th>
<th>MR Chart</th>
<th>HPF</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Onset of Acute GVHD w/ diagnosis date if applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Onset of Chronic GVHD w/ diagnosis date if applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Disease Status (CR/Relapse/Progression etc.) at time of transplant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Functional Status/Performance Score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Date of HSCT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Disease diagnosis date &amp; pathology</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Engraftment - ANC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Engraftment - Platelet Recovery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Conditioning Regimen and correct dose reporting for applicable forms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Date of last follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This assessment is considered acceptable?  □ Yes  □ No

Comments/Corrective Action:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Assessor Signature ___________________________  Date ___________  Medical Director ___________________________  Date ___________
# Table of Data Points

<table>
<thead>
<tr>
<th>Data Points</th>
<th>Correct</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant Date</td>
<td>24</td>
<td>24</td>
<td>100</td>
</tr>
<tr>
<td>Diagnosis Date</td>
<td>6</td>
<td>8</td>
<td>75</td>
</tr>
<tr>
<td>Karnofsky Performance Status</td>
<td>10</td>
<td>13</td>
<td>77</td>
</tr>
<tr>
<td>Conditioning Regimen</td>
<td>9</td>
<td>9</td>
<td>100</td>
</tr>
<tr>
<td>Disease Status</td>
<td>12</td>
<td>12</td>
<td>100</td>
</tr>
<tr>
<td>Engraftment of ANC</td>
<td>14</td>
<td>15</td>
<td>93</td>
</tr>
<tr>
<td>Engraftment of Platelets</td>
<td>9</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td>Onset of Acute GVHD</td>
<td>11</td>
<td>12</td>
<td>92</td>
</tr>
<tr>
<td>Onset of Chronic GVHD</td>
<td>12</td>
<td>12</td>
<td>100</td>
</tr>
<tr>
<td>Latest Follow-Up Date</td>
<td>10</td>
<td>15</td>
<td>67</td>
</tr>
</tbody>
</table>
Results

Percentage of Data Points Correct
Corrective Action

- Corrective action involved:
  (1) reviewing all incorrect responses and
  (2) correcting the data in the electronic database.

- Our problematic area identified was: engraftment of platelets. The definition of “engraftment of platelets” was reviewed. Therefore, all CIBMTR Forms with “engraftment of platelets” responses were reviewed and corrected in the electronic database.
Common Causes of Inaccurate Data

- The recording of transfusion dates other than platelet infusions.

- Incorrect timing of follow-up dates.

- Difficulty obtaining pathology reports from referring physicians.
Conclusions

• The internal audit process demonstrated that despite following standard CIBMTR processes for data entry, some data was inaccurate.
• Utilization of an additional monthly internal assessment resulted in a higher degree of accuracy.
• The accuracy of the CIBMTR forms meet the quality of the Foundation for the Accreditation of Cellular Therapy (FACT) standards.
• The CIBMTR monthly internal assessment of data is now routinely performed in our organization.
• Organizations that do not currently perform regular internal auditing for accuracy of CIBMTR data may want to consider this.