A Culture of Continuous Quality Improvement Improves 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 implementing internal audits on a regular basis ensures the validity and quality of registry data.
2) Review the 10 data points that are essential to any CIBMTR internal audit.
3) Discover new methods to test and improve data in order to better prepare for the challenges of external audits.

Background
• To ensure the highest degree of accuracy of CIBMTR data, the University of Maryland Blood and Marrow Transplant team established a culture of continuous quality improvement.

10 Commonly Used CIBMTR Data Points
1. Transplant Date
2. Diagnosis Date
3. Karnofsky Performance Status
4. Conditioning Regimen
5. Disease Status
6. Engraftment of ANC
7. Engraftment of Platelets
8. Onset of Acute GVHD
9. Onset of Chronic GVHD
10. Latest Follow-up Date

Aim
• The Blood and Marrow Transplant Program Manager and Data Managers continued to evaluate the quality of the data by selecting 19 additional data points for audit to assess the significance of adding these additional data points to the 10 commonly used ones.
Additional Data Points

- CMV-antibodies status
- Significant Comorbid Conditions
- GVHD Prophylaxis
- Post HSCT disease planned therapy
- Other Toxicity Modifying Regimen
- Maximum Grade of AGVHD
- Maximum Extent of CGVHD
- New Malignancy w/ diagnosis date if applicable
- CR achieved in response to HSCT

Additional Data Points

- Date of relapse or progression
- Date of last disease assessment
- Organ Function Prior to the Preparative Regimen
- Hematologic Findings Prior to the Prep. Regimen
- Testing for serological evidence of prior viral exposure / infection
- Did patient receive IVIG? If so indication?
- Subsequent HSCT or DCI?
- Date of subsequent HSCT or DCI
- Stage & Grade of AGVHD
- Stage & Severity of CGVHD

Methods

- The CIBMTR forms of four subjects per month (40%) were randomly selected for audit from August 2011 to August 2012, for a total of 48 charts.

- These forms were then audited using an original internal assessment form by the data managers.

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

2400 Internal Assessment Form

2450 Internal Assessment Form
Our results demonstrated that adding the extra data points covers 90% of the data reported while the commonly used data points cover only 50% of the data reported; thereby demonstrating a more comprehensive review of the information reported.

Implementing the regular internal audit using 10 commonly used data points demonstrated better percentage (range 89% to 100%) of data accuracy from that previously reported before implementing the regular internal audit.
Results

• A total of 139 additional data points were reviewed and 134 of these data points were correct, resulting in a **96%** accuracy rate.

Corrective Action

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

• Education is provided on the individual level and for the group as trends become prevalent.

Cost-Effectiveness of the Additional Data Points

• When analyzing the cost-effectiveness of the additional data points, we found that approximately 5 out of 19 additional data points are reviewed on each CIBMTR form.

• Therefore, if it takes an average of 5 minutes for each data point, it would take an extra 25 minutes to review these 5 additional data points.

Fact Inspection

• FACT re-accreditation occurs every 3 years, so the accuracy of the CIBMTR Forms are important for meeting FACT standards.

• On January 8th, we underwent our 6th FACT Inspection. Our clinical inspector gave no indication that we have less than 100% accuracy!

Conclusions

• Implementing internal audits on a regular basis using the commonly used data points and the 19 additional data points have improved the accuracy of the data from what has been previously reported.

• By maintaining a regularly scheduled comprehensive review, we are able to track trends on an individual and group basis.

• Therefore, developing new methods to improve our data prepares us better for challenges of external audits, such as CIBMTR and FACT (Foundation for the Accreditation of Cellular Therapy).