| Table | 1 |
|-------|---|
|       |   |

Donor Demographics and Outcomes

|                                  | Initial<br>Clearance<br>N=15 |     | Not Initially<br>Cleared<br>N=47 |     |
|----------------------------------|------------------------------|-----|----------------------------------|-----|
| Males                            | 8                            | 53% | 23                               | 49% |
| Age median (range)               | 47 (22-66)                   |     | 49 (20-72)                       |     |
| Family                           |                              |     |                                  |     |
| Single Donor Family              | 14                           | 93% | 38                               | 81% |
| Multi Donor Family               | 1                            | 7%  | 9                                | 19% |
| Туре                             |                              |     |                                  |     |
| Haplo-identical                  | 3                            | 20% | 11                               | 23% |
| Identical                        | 12                           | 80% | 36                               | 77% |
| Foreign Born                     | 1                            | 7%  | 13                               | 28% |
| Donated                          |                              |     |                                  |     |
| Yes                              | 13                           | 87% | 31                               | 66% |
| Ineligible but donated           | 0                            |     | 4                                |     |
| Ineligible for PBSC              | 1                            |     | 2                                |     |
| No                               | 2                            | 13% | 16                               | 34% |
| Ineligible & Deferred            | 0                            |     | 7                                |     |
| More suitable donor              | 2                            |     | 2                                |     |
| Recipient delay                  | 0                            |     | 3                                |     |
| Incomplete clearance             | 0                            |     | 2                                |     |
| Change in protocol               | 0                            |     | 1                                |     |
| Lab abnormalities                | 0                            |     | 1                                |     |
| Product                          |                              |     |                                  |     |
| PBSC                             | 4                            | 31% | 25                               | 81% |
| BM                               | 2                            | 15% | 4                                | 13% |
| MD requested                     | 1                            |     | 2                                |     |
| Per NMDP                         | 1                            |     | 2                                |     |
| Lymphocytes                      | 6                            | 46% | 1                                | 3%  |
| Combination                      | 1 (PB and BM)                | 8%  | 1 (PB and                        | 3%  |
|                                  | · · · · ·                    |     | Lymph)                           |     |
| End Eligibility                  |                              |     | 5 1 /                            |     |
| Eligible and donated             | 13                           | 87% | 27                               | 57% |
| Ineligible and donated           | 0                            |     | 4                                | 9%  |
| Eligible and did not donate      | 2                            | 13% | 5                                | 11% |
| Ineligible and did not<br>donate | 0                            |     | 8                                | 17% |
| Incomplete Eligibility           | 0                            |     | 3                                | 6%  |

Abbreviations: PBSC – Peripheral Blood Stem Cells; BM – Bone Marrow

#### Table 2

Additional Evaluations

|            | Abnormal | Consult | Further Testing |
|------------|----------|---------|-----------------|
| EKG        | 15       | 13      | 3               |
| Pits       | 5        | 5       | 4               |
| LFTs       | 15       | 10      | 9               |
| X-Ray      | 2        | 2       | 1               |
| Urinalysis | 10       | 4       | 8               |
| Other      | 8        |         |                 |

**Abbreviations:** EKG – Electrocardiogram; Pits – Platelets, LFTs – Liver Function Tests, Neuro – Neurology

**Conclusions:** 1) The process of donor clearance has become more complex and resource demanding. 2) Care should be taken in selecting donors for screening to avoid unnecessary added costs to the transplant.

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#### Recurrent Late Cytomegalovirus Disease after Hematopoietic Cell Transplantation (HCT): Incidence, Clinical Manifestations, Risk Factors and Outcome

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**Background:** Late cytomegalovirus (CMV) disease occurs in about 6% of patients (R+ or D+/R-) who survive the first three

months after HCT. We have previously identified steroid treatment after day 100 and CMV viremia before and after day 100 as risk factors for late CMV disease. Little is known, however, about the epidemiology and risk factors of recurrent late CMV disease. The objectives of this study were to describe the incidence, clinical characteristics, outcome, and risk factors for the development of recurrent late CMV disease.

**Methods:** We retrospectively analyzed medical records of 117 HCT patients, who developed CMV disease more than 100 days after their first allogeneic HCT between 2001 and 2011.We evaluated all CMV disease events occurring between the first late CMV disease and 2 years after HCT. Late CMV disease was considered recurrent if it occurred at least 6 weeks after the first late CMV disease.

**Results:** Among 117 patients with late CMV disease, 31 (26%) patients died within 6 weeks of diagnosis. Twelve of the eighty-six (14%) surviving patients developed a second late CMV disease event. Nine (75%) of the second late CMV disease cases were observed in the same organ, while three (25%) occurred in a different organ. There were 6 (50%) cases of gastrointestinal (GI) disease, 5 (42%) cases of pneumonia, and 1 (8%) episode of retinitis. Second late CMV disease episodes occurred at a median of 147 days [range 52-351] after the first late CMV disease and 374 days [range 212-679] after HCT. In addition, there were 4 cases of third late CMV disease (3 pneumonia and 1 GI).

All of the patients were receiving systemic immunosuppressive therapies at the time they developed recurrent late CMV disease. Nine of these twelve patients were undergoing weekly surveillance for viremia by PCR testing after their first late CMV disease event. Two patients developed CMV disease while receiving preemptive therapy for viremia. Three patients had low-level viremia below the threshold for starting treatment. However, four (33%) of the recurrent late CMV disease events (2 pneumonia, 2 GI) developed in the absence of viremia.

Two (17%) of the 12 patients with recurrent late CMV disease died within 6 weeks of their diagnosis; one additional patient died shortly after developing a third episode of CMV disease, and the remaining 9 patients survived at least to two years after HCT.

**Conclusions:** These data demonstrate that recurrent late CMV disease is not a rare event after allogeneic HCT. Patients who remain on systemic immunosuppressive therapy after a first episode of late CMV disease seem to be at particularly high risk for recurrence. While preemptive treatment of viremia might prevent some of these events, one-third of the cases developed in the absence of viremia including 2 cases of CMV pneumonia. Further study is warranted to prevent the morbidity and mortality associated with this late complication of HCT.

#### TRANSPLANT DATA MANAGEMENT

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Justifying the Construction of a Flexible, Functional Hematopoietic Cell Transplant (HCT) Database, BRAIN Diane Coyle<sup>1</sup>, Ryan Hillgruber<sup>2</sup>, Christine Gibson<sup>1</sup>, Noemi Feliciano<sup>1</sup>, Samantha McCormick<sup>1</sup>, Craig Linderman<sup>3</sup>, Miguel Restrepo<sup>3</sup>, Brenda Schlagenhauf<sup>3</sup>, Larry Kuba<sup>3</sup>, Amilcar Blake<sup>3</sup>, Ed Chwieseni<sup>3</sup>, Marcie L. Riches<sup>2</sup>. <sup>1</sup> Blood and Marrow Transplantation, H. Lee Moffitt Cancer Center, Tampa, FL; <sup>2</sup> Blood and Marrow Transplantation, H. Lee Moffitt Cancer

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In order to justify the resources to build an in-house database we performed a GAP analysis, Scope, Requirements, Schema and Dashboard Design assessment and plan. The GAP analysis identified the gap between current data fields and new data fields needed. Over 3200 fields are required to enter data for 40 CIBMTR forms. The GAP analysis included the following: 1) source of the data, 2) discreteness of the data, and 3) data interface capability versus manual entry required. The Scope of the project contained an Executive Summary describing the number of patients transplanted annually, the data sources, purposes of the data, current system limitation, and the number of additional FTE's needed to meet Continuous Process Improvement (CPI) if no new database system was devised. In addition to identification of systems to be replaced, users of the database, consumers of the data, project goals, new interfaces required, and migration of legacy data were assessed. A requirements document described the data and interface needs. This document consisted of the tables and their fields that would go into the database as well as the design of the screens. It also described how the data would be interfaced through staging tables from the Hospital Electronic Medical Record (EMR) to the Data warehouse to BMT Research and Analysis Informatics Network (BRAIN). A description of a dashboard was included for management of the CIBMTR forms that were due for each patient. Diagrams presented illustrate patient flow through our program, CIBMTR forms submission timeline, and the data flow into and from our database before and after the new system development.

Complete and thorough documentation is necessary to provide an audience of hospital and IT management an understanding of why a new database system is needed. Documentation reported the present state and its current problems and justified development of a new database system providing for future growth and flexibility.

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## Microsoft Access®: A Viable Blood and Marrow Transplant (BMT) Database Solution

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Background: Accurate and efficient BMT data collection is essential for outcomes analyses and program administration as well as for meeting external reporting requirements. As technological innovation has driven the transition from paper-based charts to electronic medical records (EMRs), a rapid development of software products designed to work alongside EMRs has taken place to provide programs with the ability to analyze and manipulate their electronic data in real-time. Although promising efforts are underway to improve current products and to integrate separate systems into one EMR platform, BMT programs may determine that a customizable database is needed to fulfill their present data needs until a more comprehensive solution arises. Our program turned to Microsoft Access® to create a BMT-specific database to fulfill our current data needs while we continue to advance development of program-specific solutions within Epic®, our hospital's EMR.

**Methods:** A spreadsheet of all transplants performed and the transplant essential data available from CIBMTR's Data Back to Centers (DBtC) portal were translated and uploaded into a Microsoft Access® database. A main data entry form was created to minimize errors and maximize efficiency of all necessary TED data required by the local program and CIBMTR. Combo boxes, validation properties, and simple Visual Basic (VBA) events were added to maximize functionality and standardize the data at the time of first entry. Tabs within the main form organize data by logical order, and a hyperlink can be clicked to bring the user to CIBMTR's reporting manuals. A separate form similar in appearance to the form 2450 was created to view all previously reported

| BMT Database Conse      | nt? CIBMTI   | R/NMDP Consent  | ? Can CIBMTR co    | ntact for research?    | Repository Con  | sent? Assented?                            | Double-click paper      |
|-------------------------|--------------|-----------------|--------------------|------------------------|-----------------|--|-------------------------|
| • Yes 11/3/2013         | • Yes        | 5 11/3/2013     | Yes                |                        | O Yes           | O Yes                                      | 0(1)                    |
| © No                    | ◯ No         |                 | © No               |                        | No              | No   | the second second       |
| O Not approached        |              | t approached    | O Not approa       | iched                  |                 |  |                         |
| O Unknown               | ⊙ Un         | known           | O Unknown          |                        |                 |  |                         |
| Date of Diagnosis       | 10/1/2013    | Disease         | Acute myeloge      | enous leukemia (AMI    | ) 🔻 Specify     | disease AML - AML with                     | t(9;11) (p22;q23); MLLT |
| CD34 Infused            | 5.54         | ANC Engraft Dat | te 1/11/2014 PI    | atelets Engraft Date   | 1/31/2014       | Engraftment notes                          |                         |
| Date of Last Contact    | 10/9/2014    | Data Coordinate | or LD 👻 Change     | s/Corrections to Rep   | orting Last A   | ction Taken/Notes                          | Referring MD Dr. A      |
|                         |              | Go to CIBMTR M  | anuals             |                        |                 | ed Tina for clarification<br>sease status. | Fax MD                  |
| atient/Donor Characteri | stics Pre-HC | T Comorbidities | Prep Pre-HCT Dise  | ase Markers and Post-F | ICT Best Respor | se GVHD, LOS, and Readn                    | nissions Forms          |
|                         |              |                 |                    |                        |                 |  |                         |
| NMDP Recip II           | 123-456-     | 7 NMDP D        | onor ID 1234-1234- | .1                     |                 |  |                         |

Figure 1. A partial view of the BMT Data Team's main data entry form.