Date: June 16, 2016

To: FACT Clinical Outcomes Improvement Committee

From:

Please see the attached Corrective Action Plan. After noting our CIBMTR survival outcomes reported in December 2015, we collaborated with the to assess our BMT program and review our data management and clinical outcomes in January 2016. The initial findings and corrective action plan are attached. Our BMT program has already reviewed and implemented most of the corrective actions.

Please contact me if any further information is required.

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Issue:

The 2015 Center for International Blood and Marrow Transplant Research (CIBMTR) Transplant Center-Specific Survival Report includes both unrelated and related donor transplants facilitated by the Program between January 1, 2011, and December 31, 2013. The reported actual one-year survival for our program was **%** one-year. The predicted survival was **%** with a 95% confidence interval of - **%**. Our program's actual one-year survival % fell below the lower limit of the expected 95% confidence interval.

Aim:

is committed to ensuring quality patient care through appropriate patient selection, optimal transplant care and long term follow-up. The program will continue existing processes or develop and deploy new processes which will improve actual risk-adjusted survival, meeting or exceeding the lower limit of the predicted 95% confidence interval as calculated and reported by CIBMTR.

Measure of Success:

The program's actual risk-adjusted survival will meet or exceed the lower limit of 95% confidence interval as calculated and reported by CIBMTR in 2018, for transplants facilitated by the Program between January 1, 2014, and December 31, 2016, and in subsequent report years thereafter.

Investigation: staff collaboratively audited 100% of adult and pediatric allogeneic transplants from 2011 - 2013 (213 health records).

A summary of findings from these audits follows:

1. The data review exposed issues which impacted on data integrity, resulting in inaccurate reporting of the patient's risk for transplant to CIBMTR.
    - Discrepancies were identified in reporting of the patient's comorbidity index as compared to information available in source documents within the patient's health record. The program had already identified this issue in 2015 and implemented both a documentation tool and a new process to capture the comorbidity index scores accurately[1].
    - Discrepancies were identified in reporting of the patient's disease status at the time of transplant as compared to information which was available in source documents within the patient's health record.
    - The data management team was unable to find evidence of pulmonary function tests (PFTs) in approximately 25% of the patient health records which were reviewed. PFTs should be included in the pre-transplant work-up for all patients.
    - Karnofsky Performance Scores which were reported to CIBMTR appeared to be assigned inconsistently and generally scored higher than would be expected based on information available in source documents within the patient's health record. It was also observed that the program's reported aggregated scores were higher when compared to the national average.
    - Preparative regimens (Bu[2]/Flu and Bu[4]/Flu) were not consistently reported to the CIBMTR as myeloablative versus reduced intensity conditioning regimens.
2. A focused review of the patients who had expired prior to one-year revealed that these patients had met the program's selection criteria and were deemed appropriate for transplant.
    - A higher than expected rate of graft failure was observed when compared to published data on cord blood product transplantation. The program is currently re-evaluating the use of cord blood products for adult stem cell transplantation.

[1] NOTE: Due to rolling 3-year sampling with > year lag time to reporting, this change in process can't be expected to impact the outcomes in the CIBMTR Transplant Center-Specific Survival Report until the 2017 report.

- In contrast to the lower than predicted one-year survival, the unadjusted 100-day survival after transplant fell within the acceptable range. This suggested opportunity for improvement exists in long term follow-up processes.

3. Data Management
    - During the reported time period, physician documentation in the patient health records, which would serve as source documentation for TED forms was determined to be inconsistent. The result was that the data management team was unable to consistently and accurately complete the required reporting documents for CIBMTR.
    - Source documents which support the co-morbidity scoring on TED forms were found lacking in data manager shadow records. Searches for additional information in the patient's health record to support co-morbidity scores was often unsuccessful.
    - Internal audits by the program's department supervisor, comparing source documents to data which were submitted to the CIBMTR, confirmed processes in place were not adequately addressing issues with data integrity and needed to be reviewed for improvement.
    - The data management department was not integrated into the BMT program. It was recognized that alignment of the data management department within the program will improve communication with physicians and, ultimately, the data management reporting.
    - It was discovered that data management staff were struggling to obtain needed source documents from physician documentation to support reporting to CIBMTR. The program recognized that a process was needed to secure the source documents for the data managers at the time of patient referral to the BMT program.
    - CIBMTR completed an onsite mandatory audit in 2015, comparing completed Pre-TED forms information to source documents. During the course of review of a sample from 2011-2013 records, CIBMTR identified 102 critical field errors which were not corrected prior to publication of the Transplant Specific Survival Report. Data that directly impacted risk adjustment performed for outcome analysis (e.g. disease classification and characteristics, latest disease assessment, and disease status at transplant) represented approximately 25% of the critical errors.

4. Patient Selection Process
    - The team attended a weekly patient selection meeting and interviewed members of multidisciplinary team. It was identified that the multidisciplinary transplant team lacked structure and processes to coordinate patient care throughout the continuum of the pre-transplant process.
        - There was not a standardized presentation of each patient at specific milestones when patients were 1) discussed and approved to move forward with transplantation followed by 2) work-up review(s) with the team prior to the patient's admission for transplantation.
        - The program realized that the meetings needed to evolve to include robust multidisciplinary discussions regarding BMT candidates.

Corrective Action: Based on the findings above, the following corrective action plan was established:

- Comorbidity Index
    - The data management team will educate all providers regarding Sorror comorbidity scoring by July 2016.
    - The data management team has already implemented and will continue procedures for auditing documentation on the co-morbidity tool to assure correct scoring.
    - The program will implement Velos module/Comaiba[2] alerts for comorbidity scoring. The data management and providers have already implemented and will continue procedures for ensuring organ function testing is completed within 60 days of stem cell transplant.
- Disease Status
    - The clinical informatics team for Meditech, the facility's electronic health record, and program leadership will create a pre-transplant dictation template for providers.
    - The data management team and providers have already implemented and will continue procedures to ensure disease status verification occurs within 60 days of stem cell transplant.

[2] Velos is a BMT patient and product tracking software solution with Comaiba as the compliance module.

    - The program has already implemented and will continue to utilize Velos clinical module in real-time.
    - The program will implement Velos module/Comaiba alert system.
- Karnofsky Performance Status
    - The data management team will educate all providers regarding Karnofsky Performance Status scoring to the CIBMTR criteria by July 2016.
    - The clinical informatics team for Meditech will include Karnofsky Performance Status in the pre-transplant dictation template.
    - The program will implement Velos module/Comaiba alert system.
- Adult Cord Blood Transplantation
    - The program has already implemented and will continue to perform adult cord blood transplants only "on study" with careful review by pediatric colleagues to assure appropriate patient and product type selection.
- Haploidentical Donor Transplantation
    - Quality improvement personnel have already begun and will continue to review and track haploidentical donor transplantation outcomes.
- Patient Selection
    - The program director/designee and quality manager have already begun and will continue to review and approve pre-transplant checklists by prior to the patient's admission for transplantation.
    - The program has already begun implementation of disease pathways and review for compliance.
- Long Term Follow-up (LTF) Clinic
    - LTF Clinic started seeing patients in May 2016 to include allogeneic donor transplant patients from November 2015 forward.
- Data Management
    - The team and the program's data management team and completed health record audits for patients transplanted during the years 2011-2015.
    - Data Management has been fully integrated into the BMT Program.
    - The program will participate in cross-center audits when opportunities are made available through the network.

- The data management team and physicians have already begun and will continue to review critical fields data, primarily risk-adjusted elements, prior to TED form submission
- The program will retain shadow health records for a minimum of 6 years in order to support audits procedures.
- The clinical informatics team for Meditech will create a pre-transplant and discharge dictation template for providers.

- Quality
  - The program will continue to trend, report and discuss outcomes at monthly BMT QI meeting. These discussions will be documented in meeting minutes as well as reported up through the hospital quality improvement structure and the QM committee.
- Weekly Patient Tracking
  - The program has already initiated and will continue weekly physician/coordinator meetings to discuss patient status.
  - The program has already standardized meeting processes and will continue these processes which include use of the Velos/Excel tracking tool.
  - Providers have already begun and will continue to present patients to the multidisciplinary team according to Velos milestone alerts.
- Velos
  - Velos has been fully implemented for use by adult program physicians and coordinators. Velos for the pediatric program is anticipated to be implemented by end of 2016.

The program plans to re-evaluate its progress against this CAPA, at minimum, when the CIBMTR 2016 report is published and annually thereafter. In the interim, as a proxy for lack of access to risk-adjusted survival outcomes, at least quarterly, the program will track and trend unadjusted 100-day and 1-year survival, engraftment outliers, selection criteria, and co-morbidity/Sorror scores to monitor progress toward its aim. Once the aim, as evidenced by attainment of the measure of success identified previously, the program will continue this monitoring to prevent a recurrence of less than predicted one-year survival for its patients.