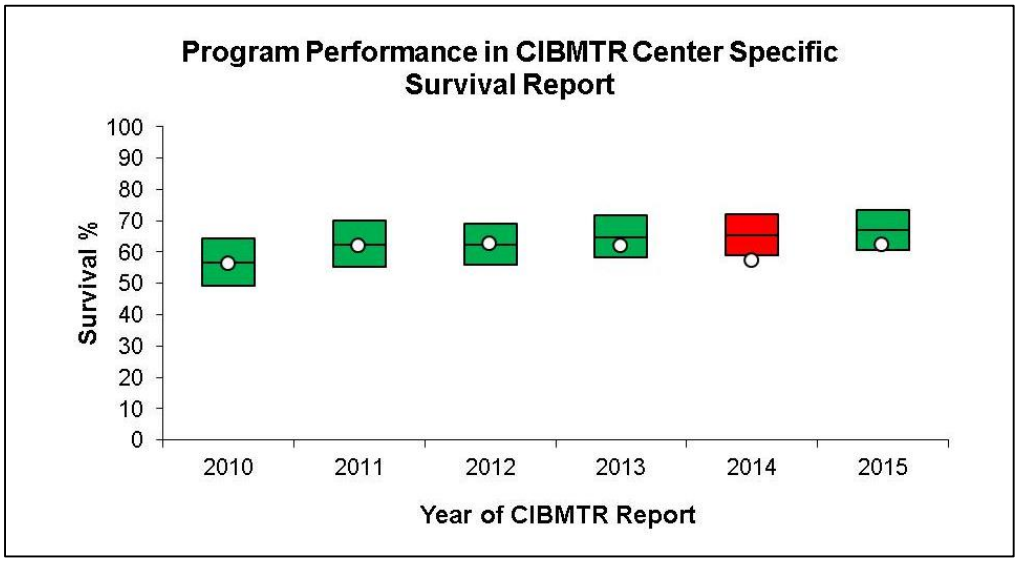
Response to FACT Deficiencies from 4/15/16

ADULT

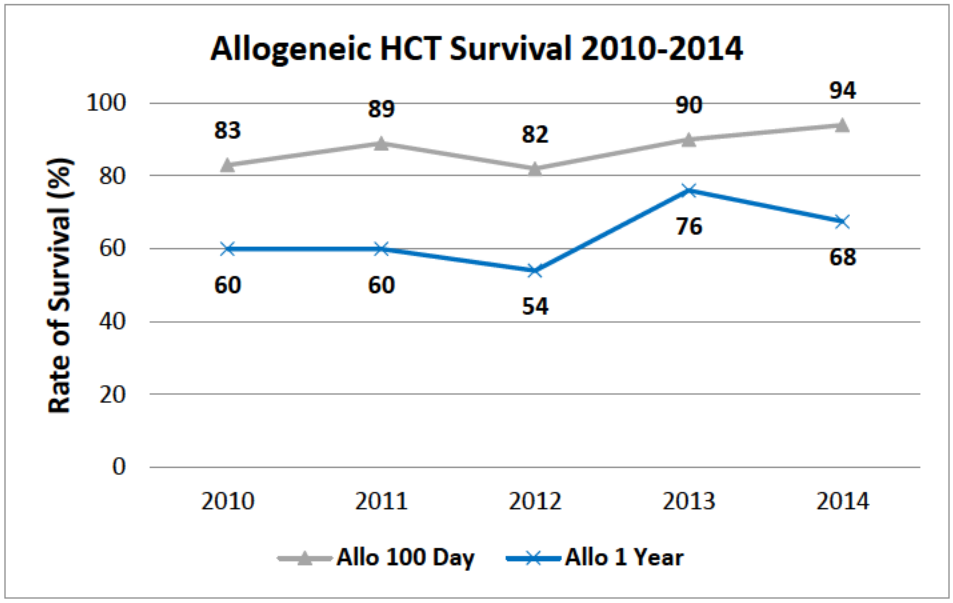
B4.7.5.1 One-Year Survival Outcomes- The program must submit overall mortality at 100 days and 1 year after transplant; Causes of death and whether they were treatment-related and corrective actions that were completed and any demonstrated improvements as a result of those actions

Response:

In the 2014 CIBMTR Center Specific Survival Report, 1-year survival for allogeneic transplants was below expected for our program (observed survival 57%, expected survival 65.5% [95% CI: 58.9-72.0%]). Our program's 1-year survival is back within the expected range in the 2015 CIBMTR Center Specific Survival Report. Irrespective, we did perform a thorough review of our program data, outcomes and processes in response to the 2014 CIBMTR report. This was shared with the FACT inspectors during our introductory presentation, and a summary is provided below, including mortality rates and causes of death. Furthermore, our findings and actions were presented as a poster at the 2016 BMT Tandem Meeting

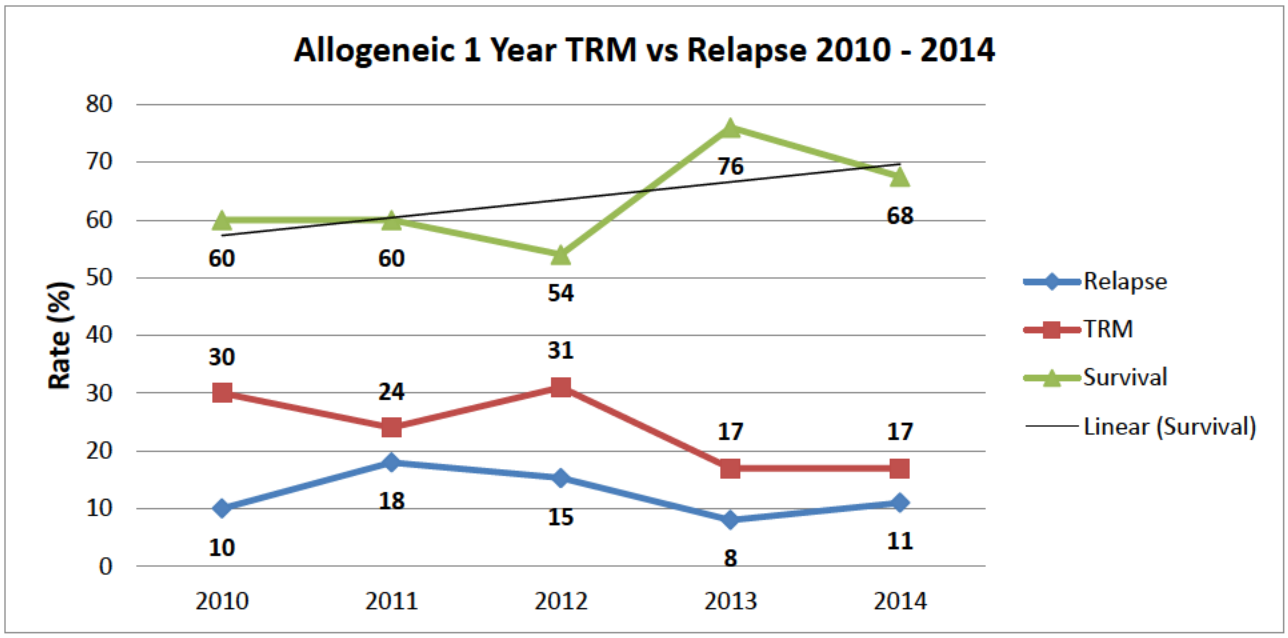


1. **Data review:** We performed an extensive data analysis on the patients that were included in the 2014 CIBMTR report (allogeneic transplants performed 2010-2012). We confirmed that there were no substantial errors in the data submitted to the CIBMTR. Survival for patients transplanted in 2012 was lower than expected, and it was primarily driven by a higher rate of treatment related mortality. However, no common themes or trends were identified amongst elements such as pre-transplant performance status, comorbidity scores, psychosocial assessments or disease status for patients transplanted that year. Similarly, 1-year survival in 2012 was comparable among patients receiving different donor sources (related vs. unrelated) and conditioning regimen intensity (myeloablative vs. reduced-intensity). Overall, we did not identify and systemic issues in patient selection for transplantation.
   a. 100-day and 1-year survival rates for patients transplanted in our program (2010-2014) are presented below. The allogeneic overall survival is steadily increasing and within the expected outcome range in 2013 and 2014.

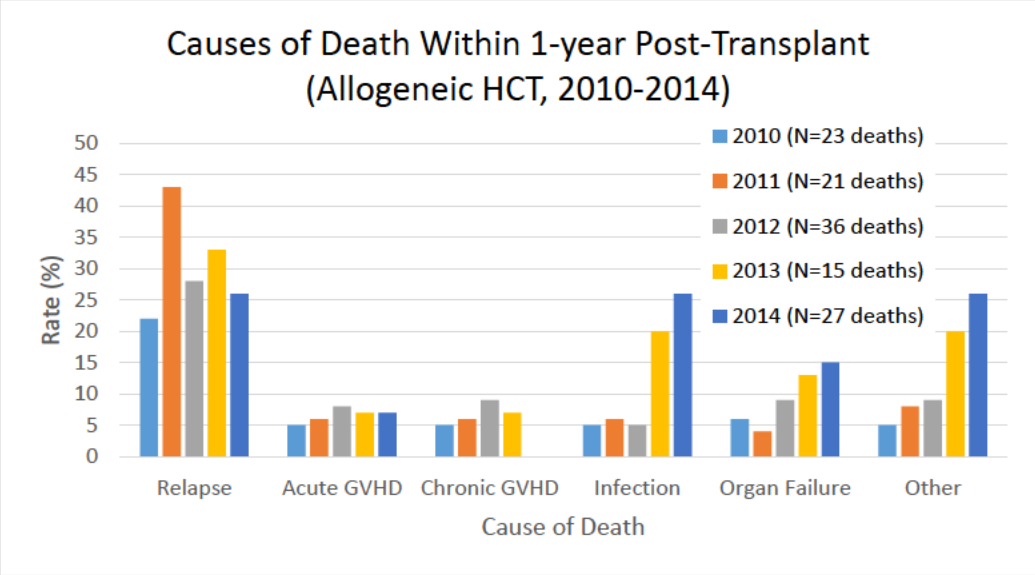


b. The figure below presents data on causes of treatment failure at 1-year for allogeneic transplants at our program from 2010-2014 (treatment related mortality vs. relapse).

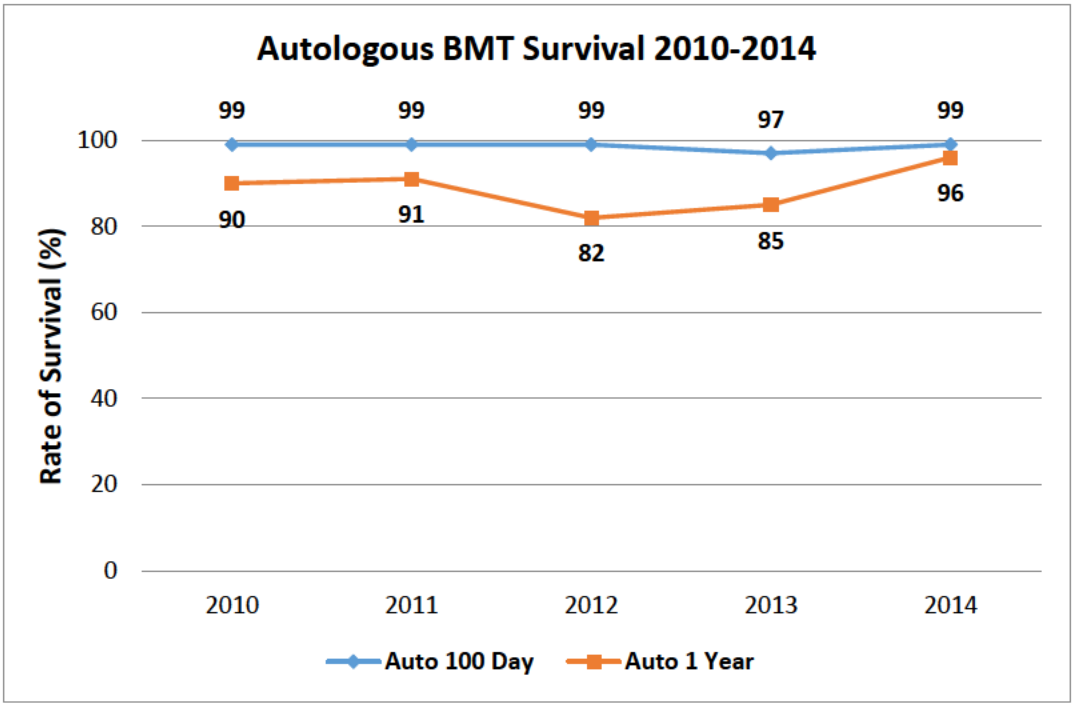
c.



d. The figure below highlights causes of death for allogeneic transplants performed in our program from 2010-2014. Relapse continued to be the major cause of treatment failure within the first year post-transplant.



e. Of note, our program 1-year survival outcomes for autologous transplantation continue to be high, as highlighted in the figure below.



2. **Corrective actions:** After a comprehensive review of program processes, several changes have been implemented or will soon be implemented:
   a. Expanded our mortality review to patients expiring within 1 year of transplant (was previously up to 100 days).
   b. Held a program retreat that included several pertinent individuals (physicians, advanced practice providers, social workers, nurse coordinators, financial counselors, and representation from other supporting programs) to brainstorm ideas on improving patient selection and program outcomes. Projects were identified and prioritized. Follow up actions from this have been:
      i. Refined our pre-transplant case discussion forum, to a more formalized structure with documentation where patients with psychosocial issues (e.g., caregiving concerns, substance

abuse issues, psychological issues) are discussed in a small group setting (physicians, nurse coordinators and social workers) prior to transplantation. A decision is made on patient candidacy for transplantation, and if needed, additional evaluations or requirements that need to be met before the patient can proceed with transplantation.

ii. Created assessment tool to be used close to Day 100 to identify patients that might be at high-risk for a poor transplant outcome. All allogeneic patients are reviewed with the team (physician, nurse, advanced practice provider and social worker at minimum) to complete the tool ending with a "score". Those with a high score are followed more closely by their nurse coordinator and physician. We are using information technology to aid in this task where patients can do a "telemedicine" visit with their nurse coordinator.

iii. Ongoing initiatives are focusing on decreasing time from diagnosis to transplantation in collaboration with our leukemia program. One example is where we have worked with the cytogenetics lab at our institution, where the lab will identify and expedite cytogenetic and molecular testing for patients with newly diagnosed acute leukemia and MDS. We have created a web-based donor registration page for related donors, decreasing the time for family members to get registered for tissue typing.

iv. Created physician specific dashboards with metrics, one of which is survival (by transplant type and conditioning regimen). These are reviewed every 6 months with each physician, with the premise being that data will help physicians assess their outcomes and metrics in comparison to the whole program and will help them identify any issues for improvement (other metrics included are time to consult, number of patients enrolled on clinical trials, number of bone marrow harvests performed and harvest yield).

c. Visited a transplant center that has performed consistently above the expected range on the CIBMTR survival report to see if there are practices which we could implement to improve our outcomes. Projects presently under review based on this visit include assessment of structure of our patient selection meetings, greater emphasis on assessment of psychosocial risk, and enhancing patient and caregiver education post-transplant and methods used for the same.