CORRECTIVE ACTION PLAN

A root-cause analysis for patient outcomes that did not meet benchmarks for survival in the years 2012-2015 was performed to determine patterns that may be used as a basis for corrective actions.

One year survivals approaching but not meeting benchmarks were identified in multiple years, including 2012, 2014 and 2015. 100 day survival also approached but did not meet benchmarks in two of the four assessed years. Please refer to corresponding figures for review.

Review of mortality cases revealed that the specific causes of death were predominantly due to progression of disease. A large proportion of patients with progression may not have undergone optimal cytoreduction prior to transplantation. In addition, complications related to transplant were identified as contributing to the cause of death despite adhering to standards of cancer treatment protocols. Treatment related complications were difficult to avoid and included early events [septic shock] as well as late events [presumed chemotherapy associated pulmonary fibrosis, secondary AML].

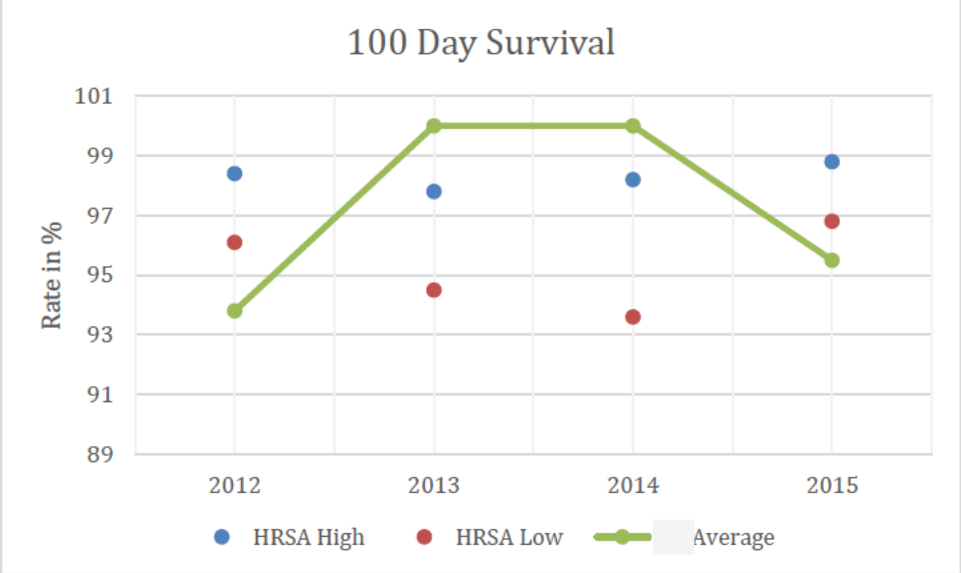
Specific corrective actions to address these issues include the following.

1. Re-assessing disease response in the immediate period prior to transplantation [30 days] as there are often delays in progressing to transplantation expediently. Patients who lose disease response will need to be re-induced prior to undergoing consolidation with high dose therapy and stem cell transplantation.
2. Implementing more stringent criteria for transplantation including consideration of physiologic age and associated co-morbidities, confirming chemosensitivity prior to transplantation, and perhaps attaining better quality responses prior to consideration of transplant [e.g. VGPR or better for myeloma; or CR for Hodgkin and aggressive lymphomas]
3. Considering which [if any] primary refractory aggressive lymphomas are suitable for transplantation and implementing more stringent selection. Increased early mortality due to disease progression appears to be evident in patients with primary refractory disease despite achieving responses with subsequent lines of chemotherapy regimens and demonstrating chemosensitivity.
4. Participating in novel clinical trials involving transplantation that incorporate novel agents in the conditioning regimen.
5. Consensus review of challenging cases and referral to external institutions for consideration of more optimal treatment choices [e.g. allogeneic stem cell transplantation for transformed lymphoma].

Our overall average 100 day survival for 2012-2015 was 96.9%, meeting the risk-adjusted, expected survival range for our patient population according to data published by the HRSA mean of 97.3% (95% CI 95.3% to 98.3%). See **100 Day Survival Table** below:

100 DAY SURVIVAL			
Year	Number of Transplants	Average Survival	HRSA Expected Average Survival (95% CI Range)
2012	32	*93.8%	97.6% (96.1% - 97.6%)
2013	19	100.0%	96.7% (94.5% - 97.8%)
2014	24	100.0%	96.8% (93.6% - 98.2%)
2015	22	*95.5%	98.2% (96.8% - 98.8%)

*Falls below expected survival range



Our overall average one-year survival for 2012-2015 was 80.2%. Compared to data published by the HRSA, the mean expected one year survival rate was 88.2% (95% CI 84.6% to 90.6%). Our survival rate falls 4.4% below the 95% CI range. Since our survival rate did not fall within the expected survival range, an in-depth root-cause analysis is warranted to determine existing trends and/or other factors that may have contributed to lower than expected survival rates. Based on this analysis, an appropriate corrective action plan (CAP) was developed to address areas of concern. **See One Year Survival Table** below:

ONE YEAR SURVIVAL			
Year	Number of Transplants	Average Survival	HRSA Expected Average Survival (95% CI Range)
2012	32	*80.6%	88.0% (84.7% - 90.1%)
2013	19	89.5%	84.8% (81.2% - 87.6%)
2014	24	*83.3%	89.4% (85.2% - 92.1%)
2015	22	*72.7%	90.5% (87.3% - 92.5%)

*Falls below expected survival range