

Arthur P. Rabinowitz, MD Director, ASCT Program



Introduction

Since its inception in 1996 the Lahey Hospital & Medical Center ASCT Program has performed autologous peripheral blood transplants for patients with hematological malignancies and select solid tumors. The inpatient unit located on the 7th floor of the hospital (7-West) was specifically designed for the care of immunocompromised patients. Outpatient care of transplant patients is provided in the hematology outpatient clinic located in the Sophia Gordon Cancer Center on the 3rd floor of the clinic building (3-SE). The cancer center opened in January 2007.

Hematopoietic progenitor cells are mobilized by chemotherapy and G-CSF as well as growth factor alone. Apheresis is performed in the outpatient clinic or on 7-West hospital by nurses trained in therapeutic apheresis. Cells are processed in the University of Massachusetts Medical Center Cryopreservation lab and stored in liquid nitrogen freezers in the Blood Bank of the Lahey Hospital & Medical Center..

Patients are cared for by a multidisciplinary team which includes board certified hematologists, a nurse practitioner, nurses who are chemotherapy/biotherapy certified by the Oncology Nursing Society and who have successfully completed training in the care of transplant patients, dietitian, social worker and physical therapist. During the inpatient confinement the multidisciplinary team reviews each patient's progress on daily rounds. Consultation from all medical and surgical subspecialties is available from hospital based physicians.

Indications for high-dose therapy

Acute Myelogenous Leukemia: Patients in 1st remission who are not appropriate for an allogeneic transplant. A single cycle of high dose cytarabine is given following induction as "in vivo purging" and to mobilize stem cells. Patients in 2nd or greater remission are also appropriate.

<u>Hodgkin lymphoma</u>: Autologous transplantation is recommended for patients who fail to achieve remission with standard chemotherapy or who relapse after initial remission.

<u>Diffuse Large B-cell lymphoma</u>: High dose therapy is the preferred treatment for patients with relapsed lymphoma that remains chemosensitive.

<u>Mantle Cell lymphoma:</u> Patients in 1st remission following induction with R-CHOP or similar chemotherapy.



<u>T-Cell lymphoma/ALK (-) Anaplastic large cell lymphoma</u>: Patients in 1st remission following induction with CHOP.

<u>Multiple Myeloma</u>: High dose therapy as part of initial treatment for newly diagnosed myeloma. Tandem transplants are offered to patients who do not achieve at least a very good partial remission after first transplant. Previously treated patients who remain responsive to chemotherapy and patients with refractory disease are considered on an individual basis.

Number of transplants performed

In 2012 ten (10) autologous transplants were performed. The diagnoses transplanted were: myeloma (4), lymphoma (2), Germ Cell Tumor (2) and, AML (1) Hodgkin lymphoma (1).

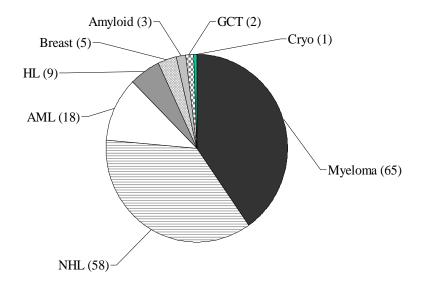
Since the start of the program 172 transplants have been performed in 161 patients: 10 patients with myeloma and 1 patient with germ cell tumor received 2 transplants.

	Annual number	Cumulative number
1996	3	3
1997	15	18
1998	6	24
1999	11	35
2000	11	46
2001	11	57
2002	15	72
2003	4	76
2004	8	84
2005	13	97
2006	10	107
2007	6	113
2008	5	118
2009	16	134
2010	13	147
2011	15	162
2012	10	172



Indications for transplant

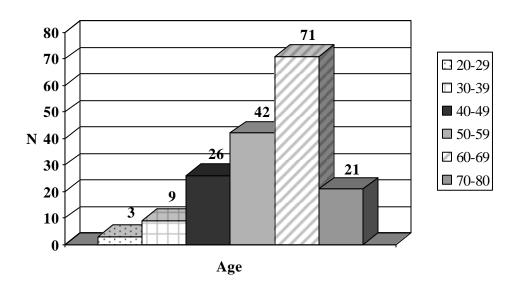
Diagnoses of patients transplanted 8/96 – 12/31/12 (n=161)



Patient age at time of transplant

The youngest patient transplanted in 2012 was 47 years old, and the oldest patient was 75 years old. Since 1996 patient age has ranged from 26 to 80 years. Ninety-two patients (53.5%) were 60 years or older and 21 patients (12.2%) were 70 years or older at time of transplant.

Patient Ages 8/96 – 12/31/12 (n=172)



Engraftment and transfusions (2012)

	Median	Range
AGC >500 (day post- ASCT)	+10	+9 - +12
Plt >20,000 (day post- ASCT)	+14	+10 - +22
RBC units (number)	2	0 – 5
Plt transfusions (number)	2	0 – 6

Febrile days, antibiotic use and LOS (2012)

Number of days:	Median	Range
T >101°	1	0 - 9
Antibiotics	8	0 - 11
LOS	16	14 – 24

Infections (2012)

Three patients had bloodstream infections, (one patient had 2 organisms identified), but none were due to MRSA or VRE. The organisms recovered were: Pseudomonas aeruginosa (1), Klebsiella pneumoniae (1), coagulase negative staphylococcus (1), and Streptococccus viridans (1).

There were 2 cases of *C. difficile*.

Bacteremia 8/96-12/31/12

Bloodstream infections were documented during 37 of 172 transplant hospitalizations. More than 1 organism was identified in blood cultures from 6 patients. Gram positive cocci were recovered in 26 patients and in 17 patients the isolate was a gram negative organism.

Gram Positive Bacteria (n=26)	N
Streptococcus viridans	11
Coagulase negative staphylococcus	8
Staphylococcus aureus	4 (MRSA = 2)
Enterococcus	3 (VRE = 2)

Gram Negative Bacteria (n=17)	N
Klebsiella pneumoniae	6
Enterobacter cloacae	2
Pseudomonas aeruginosa	3
Escherichia coli	3
Moraxella catarrhalis	1
Moraxella nonliquefaciens	1
Stenotrophomonas	1

Adverse events

The following areas are monitored for adverse events: apheresis catheter complications, reactions (>grade 2) to progenitor cell collection and infusion, medication reactions, readmission to hospital within the first 100 days post transplant, and transplant related mortality (non-relapse death within the first 100 days post-transplant).

In 2012 there were two adverse events: patient 155 was readmitted for fever and patient 161 had an Acinetobacter infection of the pheresis catheter which was removed.

Transplant related mortality

There were no transplant related deaths in 2012.

Survival

Patient Survival 8/96-12/31/12

Diagnosis (no. of pts)	Transplants	Patients alive as of 12/31/12	Lost to follow-up
Myeloma (65)	75 ¹	29	0
NHL (58)	58	24	1
AML (18)	18	7	1
Hodgkin lymphoma (9)	9	4	1
Solid Tumor (7)	8 ²	0	0
Amyloid (3)	3	1	0
Cyroglobulinemia (1)	1	1	0
Total (161)	172 ^{1,2}	66	3

6

¹ 10 patients with myeloma had 2 transplants

² 1 patient with germ cell tumor had 2 transplants



Accomplishments

The Program was inspected by the Foundation for the Accreditation of Cellular Therapy (FACT) in May. This was the third time the Lahey ASCT Program had successfully completed the inspection and received FACT accreditation. Accreditation is attained through evaluation of submitted documentation and on-site inspection to determine if an organization is in compliance with current FACT standards Accreditation acknowledges compliance with the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration* and FDA current rules for Good Tissue Practice. The award is a sign of a quality program. In addition, the Commonwealth of Massachusetts DPH requires FACT accreditation for all stem cell transplant programs, and accreditation is necessary to be competitive in the field of cellular therapy.

In July the Program underwent a site visit by representatives from the Center for International Blood and Marrow Transplant Research (CIBMTR). The CIBMTR is a combined research program of the National Marrow Donor Program® and the Medical College of Wisconsin, and outcome data on patients transplanted at Lahey are submitted to the CIBMTR under an IRB approved protocol. No significant deficiencies were discovered and the ASCT Program maintains is approved standing as a Registration Center in CIBMTR.