	In-Utero	Ex-Utero	In+Ex Utero	In-Utero vs. Ex-Utero	In-Utero vs. In+Ex Utero	Ex-Utero vs. In+Ex Utero
				P value	P-value	P-value
Volume (ml)	N=8,906	N=6,305	N=17,527	<0.0001	<0.0001	<0.0001
Median	64.0	54.0	77.1			
(Range)	(0.5-225.3)	(0.2-289.0)	(2.0-289.1)			
Pre-Processing TNC (x10^7)	N=6,133	N=3,514	N=14,321	< 0.0001	< 0.0001	< 0.0001
Median	108.8	101.0	118.9			
(Range)	(15.3-1144.8)	(13.7-829.5)	(9-1359.1)			
Post-Processing TNC (x10^7)	N=4,009	N=2,124	N=9,559	< 0.0001	< 0.0001	< 0.0001
Median	113.4	105.4	118.4			
(Range)	(13.4-602.0)	(3.8-459.8)	(28.9-679.7)			
Post-processing CD34+ cells (x10^6)	N=3,857	N=2,009	N=9,069	< 0.0001	0.7670	< 0.0001
Median	5.03	4.26	4.93			
(Range)	(0.36-57.64)	(0-53.03)	(0.03-63.36)			
Microbial Contamination (%)	N=4,051	N=2,107	N=9,503	< 0.0001	0.8278	< 0.0001
	2.0	0.5	2.0			

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Chemo-Mobilization of Autologous Hematopoietic Progenitor Cells (HPCs) with a Single Dose of Pegfilgrastim and Supplemental Filgrastim in Patients with Multiple Myeloma and Lymphoma: A Practical Schema

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Hematopoietic Progenitor Cell (HPC) mobilization should take into consideration efficacy, predictability, convenience and cost. Despite many different schemas available, the optimal growth factor regimen for chemo-mobilization is still debatable. The standard growth factor used in HPC mobilization is filgrastim (G-CSF) 10mcg/kg/day, administered subcutaneously. Patients usually receive daily G-CSF injections after chemotherapy in average of 10 days before starting apheresis. Medicare patients have to go to hospital or clinic every day to have their G-CSF injections given. We retrospectively evaluated our experience with pegylated-filgrastim given in conjunction with a subsequent short course G-CSF in 15 patients (8F/7M) with multiple myeloma (n=6) and lymphoma (n=9) who underwent chemo-growth factor HPC mobilization for high-dose chemotherapy and autologous stem cell transplantation. Median age was 68 (52-78). Chemotherapy regimen used for mobilization was at the discretion of the transplant physician and included cyclophosphamide (n=2), DV-PACE (n=5), DHAP (n=2), ESHAP (n=2), EPOCH (n=2), ICE (n=1), mostly combined with Rituximab. We planned ahead of time that chemotherapy is completed by the end of the week so that the patient could spend the weekend at home and receive pegfilgrastim at a single fixed dose (6 mg) subcutaneously in the following week with a median 3 (2-4) days after the last day of chemotherapy. At the time of recovery when median WBC was 0.6/mcL (0.1-3.8), daily G-CSF, at a median dose of 6 mcg/kg/day (5-12) was initiated in 5 (4-7) days after the dose of pegfilgrastim. Five patients (33%) received additional Plerixafor. HPC collection was started based on peripheral CD34 count in a median 3 days (1-6) after the initiation of G-CSF and in 16 days (11-18) after the initial chemotherapy administration. After 2 days (1-3) of apheresis, all patients but one had adequate (>2 x 10^6) CD34+ cells/kg in HPC product. Median CD34+ cell count on peripheral blood on day+1 apheresis was 32 (4.6-407) x 10^6/kg. All patients had full myeloid recovery and median time to ANC>500 x 3 consecutive days was 11 days (10-18) days. No graft failure was observed. All patients tolerated the mobilization regimen well with no serious side effects. Our preliminary data suggest that single dose pegfilgrastim in conjunction with low dose short course G-CSF can provide satisfactory HPC mobilization and be considered an alternative convenient growth factor regimen for select patients. A prospective study is currently underway in our institution.

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Quality Analysis of Cord Blood Unit (CBU) Segments at the Bank Correlates with the Post-Thaw Transplant Center Results after Albumin-Dextran Dilution

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Background: MSKCC analyses have shown that the infused viable CD34+ cell dose is the critical determinant of neutrophil engraftment after CB transplantation (Purtill et al, *Blood* 2014). However, currently, CD34+ cell viability can only be obtained on transplant day at unit thaw. Whether testing of the segment attached to the freezing bag at the Bank prior to unit release can predict the post-thaw CBU quality/potency at the transplant center is not established.
Methods: We compared the post-thaw results of 68 NCBP CBU, AXP-processed, stored in BioArchive freezers, shipped, and thawed at MSKCC, with their respective segment and

Table
Correlation of MSKCC post-thaw results with NCBP pre-cryopreservation CBU and segment evaluation

VCD34+ cells	Specimen, Lab	Specimen, Lab	N	R^2	p
	pre-cryo, NCBP	segment, NCBP	68	0.85	<0.0001
	segment, NCBP	post-thaw, MSKCC	68	0.72	<0.0001
	pre-cryo, NCBP	post-thaw, MSKCC	68	0.70	<0.0001
CFU	**Specimen, Lab**	**Specimen, Lab**			
	pre-cryo, NCBP	segment, NCBP	43	0.52	<0.001
	segment, NCBP	post-thaw, MSKCC	63	0.22	<0.001
	pre-cryo, NCBP	post-thaw, MSKCC	42	0.20	0.0017

v. viable CD34+ cells: N: number of CBU (not all CBU had pre-cryopreservation CFU data).

pre-cryopreservation data. NCBP has developed methodology to analyze cells from the thawed segment (~100 ul) for CD34+ cell count and percent viability by flow cytometry (7-AAD exclusion using ISHAGE gating), and colony-forming units (CFU) using high resolution digital imaging (Albano et al, ASH 2008). At MSKCC, units were thawed using albumin-dextran dilution, evaluated for CD34+ cell count & viability (4-color flow cytometry using modified ISHAGE gating (Scaradavou et al, BBMT 2010), & CFU assays.

Results: At NCBP there was a high correlation between the viable CD34+ cell counts and CFU in pre-cryopreservation and segment data (Table). In the 68 CBU thawed at MSKCC, the average decrease in CD34+ cell viability post-thaw compared to that of the segment was 1.9% (SD:+/-3.9%; $p < 0.001$) & ranged -11.0% to +12.0% with the lowest post-thaw CD34+ cell viability being 82% (Figure 1). Moreover, despite potential differences in laboratories and flow cytometric gating, the number of viable CD34+ cells in the unit post-thaw correlated with both the pre-cryopreservation viable CD34+ counts and the results of the segment (Table). The median viable CD34+ cell recovery (ratio of post-thaw to segment viable CD34+ counts) was 128% (SD:+/-43.2). In contrast, however, post-thaw CFU had weak correlation with pre-cryopreservation and segment values (Table).

Conclusions: Testing of CBU segments can accurately measure the potency of the frozen CB products, & segment calculations may even underestimate the post-thaw CBU CD34+ cell content. Although the decrease in post-thaw CBU CD34+ cell viability was statistically significant, this difference was too low to be clinically relevant. The poor correlation between segment and post-thaw CFU likely reflects significant inter-laboratory assay variability. These findings indicate that the processing procedures, cryopreservation technology and thaw/dilution methodology generate high quality units and that testing segment CD34+ cell counts and the percentage of viable cells can predict the post-thaw potency. Whether these findings can be generalized to other CB banks and transplant centers requires further investigation.

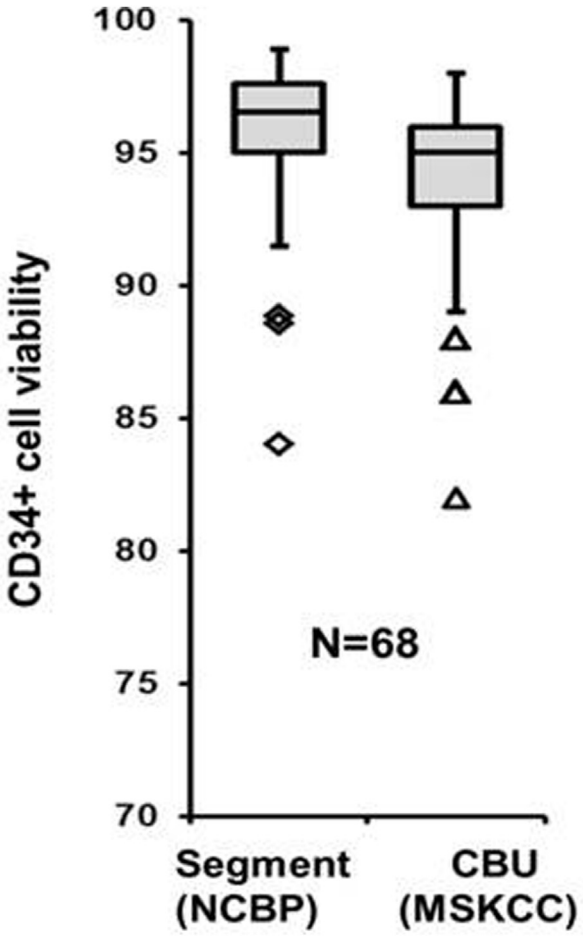

Figure 1. Comparison of segment and post-thaw CBU CD34+ cell viability.

HISTOCOMPATIBILITY/ALTERNATIVE STEM CELL SOURCES

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MHC Class I Chain-Related Gene a (MICA) Donor-Recipient Mismatches and MICA-129 Polymorphism in Unrelated Donor Hematopoietic Stem Cell Transplants (HSCT) for Hematological Malignancies: A CIBMTR Study

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Background: Previous reports from single centers suggested that MICA polymorphism and donor/recipient MICA mismatches are associated with chronic graft versus host disease (GVHD) and acute GVHD (respectively) after unrelated donor HSCT. MICA is both a transplantation antigen and a ligand recognized by the activating receptor NKG2D expressed by NK, NKT, CD8+ and TCRγδ+ T cells. Allelic variants of MICA due to a single amino acid substitution at position 129 result in significant differences in NKG2D binding. MICA alleles with a methionine (M) or valine (V) have been classified as having strong or weak binding affinity for NKG2D, respectively.

Methods: We studied the association of MICA polymorphism (MICA-129) and MICA mismatches with unrelated donor HSCT with 10/10 HLA match (n=552 pairs) or 9/10 (HLA-B mismatch only, n=161 pairs), reported to the CIBMTR between 2000 and 2011. Included were adult patients who had undergone a first unrelated bone marrow or peripheral blood HSCT for ALL, AML, or MDS. Pre-transplant samples were obtained from the NMDP Research Repository. MICA typing was performed using rSSOP (One Lambda Thermo Fisher, Canoga Park, CA). Study outcomes included overall survival, disease-free survival, treatment-related mortality, relapse, acute graft vs. host disease (GVHD), chronic GVHD, and engraftment. Variables considered in multivariate analyses included patient, disease and transplant characteristics. A p value < 0.01 for the main effect was considered significant.

Results: Of the recipients 101 were MICA-129 MM (14%), 363 MV (52%), and 239 VV (34%). Of the donors 106 were MICA-129 MM (15%), 375 MV (53%), and 229 VV (32%). 27% of the pairs were MICA mismatched, 9 pairs had double (one 10/10 and eight 9/10) and 182 had single mismatches (83 10/10 and 99 9/10). At 0.01 significance level, there was no association between any outcome and MICA mismatch or MICA-129