prompt engraftment and relatively low associated transportation costs. This experience may improve accessibility to graft manipulated products for pediatric programs without an on-site stem cell processing laboratory.

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Use of Laboratory Data to Enhance Donor Experience and Implement a New Collection Device for HPC, Apheresis

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Background: About 80% of unrelated, allogeneic donations for bone marrow transplant are collected as HPC, Apheresis from peripheral blood using the National Marrow Donor Program mobilization protocol, BB-IND #6821-0297 for filgrastim (Amgen, Thousand Oaks, CA). The aging COBE Spectra (Terumo, Inc., Golden, CO) was widely used for decades. This collection method pre-dated most predictive $CD34^+$ counting, and collection orders were written requesting a run of 24 liters of whole blood. Over-collections of $CD34^+$cells are seen with this method (mean=225.17%, n=247), often as high as 3X to 6X. Terumo introduced a replacement apheresis collection device, the Optia, with updated electronic controls and a different method of mononuclear cells extraction. The COBE will no longer be supported in the near future, forcing collection centers to make a device change.

Problem Statement: The collection efficiency of the COBE device and operators was learned through experience. The relationship of the previous collection estimation using "liters processed" as a measure for the new device was unknown. A process to allow training and use on the Optia device while assuring the patient's $CD34^+$ cell collection goal was required.

Materials and Methods: An implementation plan used the Optia according to manufacturer's instructions, using only ACDA as the anticoagulant (no heparin, no aspirin), after staff training by the vendor. The cell therapy laboratory supported the implementation by testing the apheresis product at 2 hours into the procedure in order to calculate the size of the collected product.

Results:

	Average	Range
Determined by 2-hour HPC, Apheresis product sample ("Mid") $CD34^+$ value N=48*		
Actual Collection Volume (Inlet Volume)	14.655 L ± 4.848 L	5.596 L – 27.207 L
% to target	142.44 % ± 60.26 %	61.40 % - 335.17 %
Collection Efficiency (CE)	53.14 % ± 17.40 %	20.52 % - 90.00 %
Prospective prediction by peripheral blood $CD34^+$ ("Pre") and Predictive Equation		
Collection Volume	16.368 L ± 6.003 L	5.477 L – 24.000 L
% to target	149.08 % ± 49.46 %	56.88 % - 267.67 %

*Excluded two poorly mobilized outliers, each with a peripheral blood $CD34^+$ counts of $<15x10^3$/mL.

Conclusion: Concurrent CD34+ cell counting facilitated implementation of the Optia collection method to meet the collection goals. Frequent over-collection was corrected with yields collections closer to prescription targets (with slight over collection), mean of 142%. Use of yield information improved collection efficiencies from around 20% to 60% with device adjustment. A predictive equation using pre-CD34+ donor counts was mathematically tested with the 48 collections and found to be highly predictive. The average inlet volume was reduced by >40% and the use of ACDA as the sole anticoagulant further improved safety for the donor.

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Ex-Utero Plus in Utero Collection of Umbilical Cord Blood (CB) for Banking Yields Higher Total Nucleated Cell Counts (TNC) Compared to Either Procedure Alone

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Background: Collecting high quality cord blood units (CBU) is important because the TNC and CD34+ cell dose of a CBU correlates with transplant outcomes. There are 2 techniques for collecting CBU: while the placenta is still in-utero by midwives/obstetricians or after placental delivery by trained personal (ex-utero). The MD Anderson Cord Blood Bank uses a combination of the 2 (in+ex utero) techniques whenever feasible. The aim of this analysis was to compare the 3 techniques (in-utero, ex-utero, in+ex-utero).

Methods: CBUs collected between 04/2005 and 7/2011 were retrospectively analyzed. If logistically feasible, an in-utero collection followed immediately by ex-utero collection was performed. The total volume, pre- and post-processing TNC, viable CD34+ cells and microbial contamination was evaluated in the 3 groups. Analysis of variance methods was used to compare the 3 groups with respect to pre- and post-processing TNC and total viable $CD34^+$ cells. Tukey's honestly significant difference method was used for pair-wise comparisons of the 3 groups. Microbial contamination between the groups was compared using chi square test.

Results: Total of 32,738 CBUs were collected and 23,968 units were processed. The pre-processing TNC was significantly higher in the in-utero vs. ex-utero collections. There was also a significantly higher pre-processing TNC in the in+ex utero collection vs. the in-utero collection. Similar results were noted in the post-processing TNC. The median viable CD34+ cells collected were 5.03, 4.26, and 4.93 (x 10^6) respectively in the in-utero, ex-utero and in+ex utero groups, respectively ($P< 0.0001$ for in-utero vs. ex-utero and ex-utero vs. in+ex-utero groups). There was no statistically significant difference in the microbial contamination in the in-utero vs. in+ex utero groups, however it was lower in the ex-utero collection as compared to either the in-utero or in+ex utero collections.

Conclusion: We conclude that in+ex utero collection of umbilical CB for banking is safe and results in significantly higher TNCs than either technique alone.

	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).