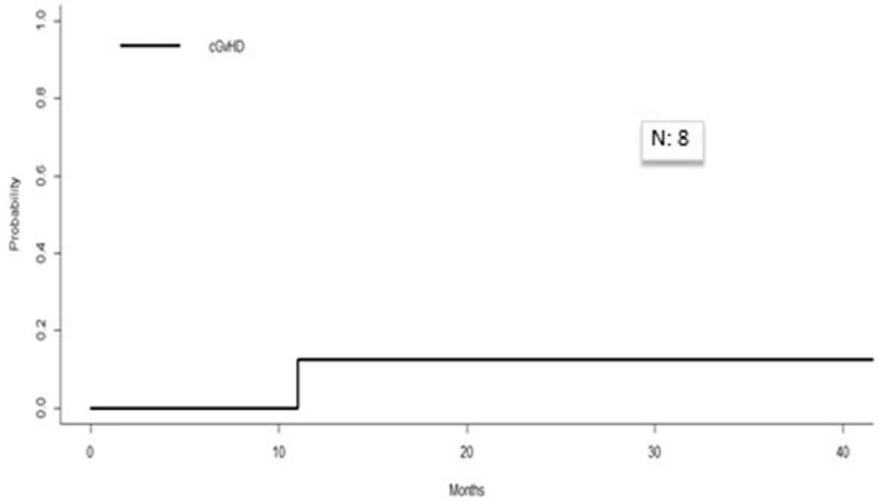

Figure 2b. Cumulative incidence of c-GVHD after reduced toxicity conditioning with ATG-BU-FLU and allogeneic sibling HSCT for patients with sickle cell disease (n:8).

Results: Median F/U was 22 mo (3.5-45 mo). All patients tolerated prednisone-hydroxyurea; only one episode of short (3days) neurtopenic fever occured before protocol evolution; no case of VOC or ACS or stroke or worsening of AVN (cumulative 109 weeks-patients).

There was no (0%) transplant related mortality (TRM) and all are alive (OS 100%) and free of VOC and transfusion (TFS 100%). **Engraftment**: ANC recovery occurred in all (100%) at a median of 19 days (range 0-26 d), Platelet recovery to 20,000/ul in 100% at a median of 16d (10-36) and to 50,000 in 100% at a median of 16d (11-50 d); 8 patients (89%) reached 50,000 in 21d. Hb electrophoresis changed to donor type. **Chimerism**: All patient (100%) had full (100%) myeloid chimerism. Lymphoid chimerism was high (>50% donor) in 6 (67%), intermediate in 1 (11%) and fluctuated between 15-31% in 2 (22%).

GVHD: One (11.1%) patient developed grade II a-GVHD, responded to steroids and only one (12.5%) of the 8 evaluable patients developed cGVHD that responded to steroids. **Peri-transplant morbidities**: Mucositis occurred in 4 (44%; grade I in 22%, grade II in 11% and Grade III in 11%); one (11%) patient bled due to gastritis, delayed serum sickness in 1 (11%). 4 (44%) had culture-neg neutropenic fever without sepsis and 1 (11.1%) developed line related infection. No reported invasive fungal disease or hemorrhagic cystitis.

Conclusions: Conditioning for allo-sib-HSCT for adults with SCA could safely and effectively be divided into: **1) Preconditioning phase** with steroids and Hydroxyurea to help reduce the chronic inflammatory status and **2)Reduced Toxicity Conditioning** with ATG-Bu-FLU which allowed engraftment of all patients with no peri-transplant mortality and low rate of acute and chronic GVHD.

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The Effect of Race, Socioeconomic Status, and Collection Center Size on Bone Marrow (BM) and Peripheral Blood Stem Cell (PBSC) Donor Experiences at National Marrow Donor Program (NMDP) Collection Centers

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Previous studies have identified risks of collection-related pain and symptoms associated with sex, BMI, and age in unrelated donors undergoing collection at NMDP centers. We hypothesized that other important factors (race, socioeconomic status [SES], and collection center experience as reflected by numbers of procedures performed) might affect rates of pain/symptoms in donors. We assessed outcomes by 5 race categories (see Table 1), 4 SES levels, and collection center volume. The study cohort included 2726 BM and 6768 PBSC donors collected between 2004 and 2009. Skeletal pain and 10 symptoms were measured and scaled 1-4 as published previously (Pulsipher, Blood 2013 121:197). Pain/symptoms are reported as peak levels over mobilization and collection (PBSC) or within 2 days of collection (BM) and at 1 week after collection. Generalized linear mixed models were used to fit logistic regression models with random effects by center; the 3 main effects of race, SES, and center volume were forced into the model, while other donor characteristics were added in a stepwise manner.

For PBSC donors, race was not associated with differences in pain/symptoms during collection or 1-week post donation. PBSC donors in higher SES levels reported higher peak

Table 1
Multivariate analysis of BM donors for grade 2-4 pain by race/sex: Odds Ratio (p-value).

(overall p-value)	Hispanic	Asian/ Pacific Islander	Black	White	Other/ Unknown
Male (<0.01)	0.75 (0.21)	0.61 (0.10)	1.91 (0.01)	1.0	0.63 (0.09)
Female (0.14)	0.81 (0.30)	1.04 (0.90)	0.57 (0.03)	1.0	1.29 (0.30)

Table 2
Multivariate analysis of BM donors by collection center experience: Odds Ratio (p-value).

BM Collection frequency	Grade 2-4 pain, collection	Grade 2-4 symptoms, collection	Grade 2-4 pain, 1-wk post-collection	Grade 2-4 symptoms, 1-wk post-collection
>1 every 2m	1.0	1.0	1.0	1.0
≤1 every 2m	1.25 (<0.01)	1.41 (0.16)	1.55 (0.07)	2.09 (<0.01)

symptom levels 1-week post donation (p=0.02). No pattern of increased pain/symptoms was associated with centers that performed smaller number of PBSC collections. For BM donors, Black males reported significantly higher levels of pain after the procedure (Table 1). No differences were noted by SES groups after BM collection. Different levels of BM collection experience were tested to determine cutpoints; the optimal cutpoint was noted to be 1 or fewer collections every 2 months. BM donors from centers collecting less than this frequency were more likely to have persistent symptoms (Table 2).

Conclusions: In general, race and SES have a minimal effect on symptoms associated with donation. Of note, however, centers performing ≤1 BM collection every 2 months have more symptoms reported after BM collection, and approaches should be developed by low volume centers to address this issue.

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Related PBSC Donors Experience Higher Levels of Pain and Donation-Related Symptoms and Less Complete Rates of Recovery Compared to Unrelated Donors: Primary Analysis of the Related Donor Safety Study (RDSafe)

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Table 1
Baseline and 1 year post-donation pain/MTC, and rates of recovery to baseline levels

	BM			PBSC		
	URDs	RDs	p-value	URDs	RDs	p-value
Baseline skeletal pain grade 2-4	0.46%	2.42%	0.039	0.61%	8.38%	<0.001
Baseline skeletal pain grade 3-4	0%	0%	1.000	0%	1.85%	<0.001
Baseline max MTC 2-4	0.82%	0.81%	1.000	0.51%	2.57%	<0.001
1yr skeletal pain 2-4	5.00%	10.64%	0.033	5.37%	14.27%	<0.001
1yr MTC 2-4	4.61%	7.45%	0.211	3.79%	6.04%	0.012
% back to baseline pain at 1 yr	77.11%	78.72%	0.795	78.32%	68.51%	<0.001
% back to baseline MTC at 1 yr	84.61%	87.10%	0.646	88.22%	83.31%	<0.001

Table 2
MV analysis of RDs vs. URDs pain/MTC. URDs OR = 1.0

	OR RDs BM	p-value	OR RDs PBSC	p-value
Donation pain 2-4	1.20	0.352	1.63	<0.001
Donation pain 3-4			11.00	<0.001
Donation MTC 2-4	1.32	0.230	2.38	<0.001
Recovery to baseline pain 2-4	1.18	0.535	0.79	0.031
Recovery to baseline MTC 2-4	1.15	0.672	0.68	0.001

Prospective data regarding donation related toxicities in related donors (RDs) of bone marrow (BM) and peripheral blood stem cells (PBSC) are limited. To address this, the NHLBI-funded Related Donor Safety Study (RDSafe; NCT00948636) prospectively enrolled adult RDs between 2010 and 2013 at 54 transplant centers in the United States. RDs were assessed for baseline health status and followed for 1 year after donation, collecting detailed information on adverse events, pain levels and 10 donation-related modified NCI-CTC symptoms (MTC). A concurrently enrolled cohort of NMDP unrelated donors (URDs) was assessed as a comparator. This report compares baseline, donation, and 1 year post-donation pain/MTC for RDs aged 18-60: 124 BM (38 centers, med age 33, 48% female) and 919 PBSC (42 centers, med age 49, 44% female) to URDs: 1098 BM (18 centers, med age 31, 42% female) and 3119 PBSC (20 centers, med age 31, 40% female).

Results: RDs of PBSC had higher levels of baseline grade 2-4 pain and MTC compared to URDs; RDs of BM had higher baseline levels of pain, but not MTC (Table 1). Multivariable analysis (Table 2) showed similar donation-related pain and MTC rates of recovery for RDs and URDs of BM. In contrast, RDs of PBSC had significant increases in risk of

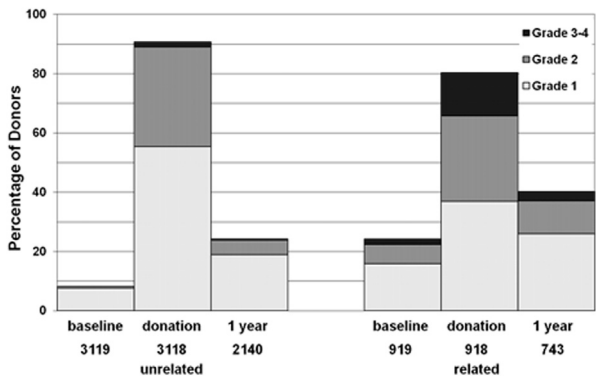

Figure 1. Skeletal Pain experienced by PBSC donor, by unrelated vs related, at baseline, donation, and 1 year post-donation. (Skeletal pain represents pain in at least one of the following sites: back, bone, headache, hip, limb, joint, and neck.) The severity of skeletal pain is defined as the maximum grade among these pain sites.