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An Analysis of the Effect of Race, Socioeconomic Status and Center Size on Unrelated NMDP Donor Outcomes: Donor Toxicities are More Common at Low Volume Bone Marrow Collection Centers

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Abstract

Previous studies have shown that risks of collection-related pain and symptoms are associated with sex, body mass index (BMI), and age in unrelated donors undergoing collection at National Marrow Donor Program (NMDP) centers. We hypothesized that other important factors (race, socioeconomic status (SES), and number of procedures at the collection center) might affect symptoms in donors. We assessed outcomes in 2,726 bone marrow (BM) and 6,768 peripheral blood stem cell (PBSC) donors collected between 2004 and 2009. Pain/symptoms are reported as maximum levels over mobilization and collection (PBSC) or within 2 days of collection (BM) and at 1 week after collection. For PBSC donors, race and center volumes were not associated with differences in pain/symptoms at any time. PBSC donors with high SES levels reported higher maximum symptom levels 1 week post donation (p=0.017). For BM donors, black males reported significantly higher levels of pain (OR=1.90, CI=1.14-3.19, p=0.015). No differences were noted by SES groups. BM donors from low volume centers reported more toxicity (OR=2.09, CI=1.26-3.46, p=0.006). In conclusion, race and SES have a minimal effect on donation associated symptoms. However, donors from centers performing ≤1 BM collection every 2 months have more symptoms following BM donation. Approaches should be developed by registries and low volume centers to address this issue.

Keywords

Race; socioeconomic status; donor center; unrelated donor; donor toxicities; bone marrow; PBSC

Introduction

The pattern of acute toxicities associated with bone marrow (BM) and peripheral blood stem cell (PBSC) donation in unrelated donors have been well described in several recent studies from the National Marrow Donor Program (NMDP)[1-3]. Several pre-donation demographic factors from these and other studies have been associated with an increase in acute toxicity; specifically age, gender, body mass index (BMI) (in PBSC, but not BM donors), and anesthetic type[1-10]. It is important to fully understand factors predictive of increased donor risk as knowledge of their impact on post donation recovery helps us to tailor the pre-donation consent information to the specific donor, more closely follow at risk donors during the recovery period, or institute interventions to prevent symptoms in specific groups of donors.

Race/ethnicity and socioeconomic status (SES) have been linked to pain experience and perception in several studies in other areas of medicine such as orthopedics and chronic pain[11-13], but thus far neither have been addressed in the unrelated hematopoietic cell donor population. In addition, the impact on donor outcome of the number of collections performed annually by a center is unknown and recommendations for a minimum number of procedures per year by regulatory bodies are often not based on data. Collection centers vary tremendously in overall numbers of procedures performed and experience of individuals at that center performing BM collection procedures.

The aim of this study was to examine the relationship between donor race/ethnicity, donor SES and collection center volumes on the acute toxicities (up to 1 week) experienced by NMDP donors.

Methods

Study Population

The study population consisted of first time volunteer US donors from the NMDP who underwent Granulocyte Colony Stimulating Factor (G-CSF) (filgastrim, Neupogen, Amgen, Thousand Oaks, CA) mobilized PBSC collection or BM harvest from January 1, 2004 to July 31, 2009. Donors for whom data were available from baseline to the first day of apheresis on the NMDP data collection forms were included. Donors enrolled on BMT CTN protocol 02-01[14] and rare donors who donated bone marrow after G-CSF administration were excluded. Donors from centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses (n=534). Donor race/ethnicity was self-reported. Donor race and ethnicity were classified as non-Hispanic white, Hispanic-all races, non-Hispanic black, non-Hispanic Asian/non-Hispanic Pacific Islander and non-Hispanic-other. SES was defined as the median household income in the donor's census block group. Each donor address was geocoded using the ArcGIS 10.1

Business Analyst US address locater (Esri, Redlands CA, USA). The Esri Business Analyst 2012 dataset was used to extract median household income for each census block group. If the census block group could not be located from reported street address, median household income from donor's zip code was used instead. Collection center and apheresis center size were based on reaccreditation numbers using the total number of either BM collections for calendar years 2005-2008 or PBSC collections for calendar years 2004-2008 (regardless of whether autologous or allogeneic).

All donors included in the study provided written informed consent for participation in Center for International Blood and Marrow Transplant Research (CIBMTR) research studies approved by the NMDP Institutional Review Board. This study was conducted in accordance with the Declaration of Helsinki. Donors were evaluated for medical suitability, transplantation-transmissible infectious diseases, and contraindications for PBSC or BM donation using standardized NMDP criteria.

Data Collection

Data collection began at the time of the donor's medical evaluation to determine suitability to donate hematopoietic progenitor cells. For PBSC donations, the data collection occurred during each day of G-CSF and on the day of each apheresis procedure. For BM donations, the data collection occurred on the day of BM collection. Both BM and PBSC donors were contacted by the donor center 2 days after donation, 1 week after donation, and weekly thereafter until complete recovery. "Complete recovery" was assessed by the donor center coordinator/medical director and based on reports of return to baseline function with no ongoing symptoms. In view of the fact that this study addressed acute toxicity only day 2 and 1 week forms were analyzed. Detailed questions using the toxicity criteria modeled on Common Terminology Criteria for Adverse Events v4 were used to assess specific symptoms, to measure the donor's overall health, and to capture any toxicity the donor may have experienced as a result of the hematopoietic progenitor cells donation process. Symptoms assessed included fever, fatigue, rash, local reactions, nausea, vomiting, anorexia, insomnia, dizziness, syncope, pain, and infections. In addition, a complete blood count and white cell differential were performed at the initial medical evaluation, on the first day of G-CSF, the day(s) of collection, and at annual follow-ups.

PBSC Donation

All PBSC mobilizations were performed according to the NMDP-sponsored and Institutional Review Board-approved research protocol for manufacturing PBSC products, operated under an Investigational New Drug application with the United States Food and Drug Administration. G-CSF dose was approximately 10 μg/kg/day actual body weight rounded to combinations of 300 μg and 480 μg vials, as long as protocol defined targets of 13.3 μg/kg per day were not exceeded. Typically, donors received subcutaneous G-CSF daily for 4 days before and on the first day of apheresis. All donors underwent a maximum of 2 days of apheresis. The volume of whole blood processed was targeted to be between 12 and 24 L per collection. If the PBSC product could not be collected using peripheral veins, a central venous catheter was used.

BM Donation

One or two autologous blood units were potentially collected from the donor prior to donation, based on individual assessment. BM was collected from the donor's posterior iliac crests in an operating room under either general or regional (spinal or epidural) anesthesia. The NMDP guidelines recommend a duration of anesthesia of less than 150 minutes, and a maximum collection volume of 20ml/kg.

Endpoints and Statistical Analysis

The following end points were analyzed: incidence of grade 2 to 4 and grade 3 to 4 skeletal pain and highest toxicity level (Modified Toxicity Criteria, MTC) across selected body symptoms frequently associated with collection (fever in the absence of signs of infection, fatigue, skin rash, local reactions, nausea, vomiting, anorexia, insomnia, dizziness, and syncope). Skeletal pain was defined as pain in at least 1 of the following sites: back, bone, headache, hip, limb, joint, or neck. The severity of skeletal pain was defined as the maximum grade among these pain sites. Pain/symptoms are reported and analyzed as maximum levels over mobilization and collection (PBSC) or within 2 days of collection (BM), and at 1 week after collection. Donor and collection characteristics were described using frequencies/percentages or median/range as appropriate, separately by groups based on center volume. Variables were compared using the Pearson chi-squared test for categorical variables and the Kruskal-Wallis test for continuous variables. Incidence rates for pain and symptoms were described using frequencies and percentages. We examined the impact of the main effects of race, SES, and center volume in multivariate models on 4 outcomes for each donor type: grade 2-4 maximum skeletal pain at day 2 (BM) or from mobilization through collection (PBSC), grade 2-4 maximum skeletal pain at 1 week, grade 2-4 maximum MTC score at day 2 (BM) or from mobilization through collection (PBSC), and grade 2-4 maximum MTC score at 1 week. Other toxicity outcomes were generally too low in frequency for multivariate modeling. Generalized linear mixed models were used to fit logistic regression models to each outcome with random effects for collection center (BM) or apheresis center (PBSC). In each case, the 3 main effects were forced into the model, while other donor characteristics were added in a stepwise manner. The optimal cut point based on maximum likelihood was investigated for the number of BM performed and found to be ≤1 BM collection every 2 months. All model results use this optimal cut point. All statistical analyses were performed using SAS EG 4.3 and SAS 9.3 (Cary, North Carolina).

Results

Donor Demographics

The characteristics of 2,726 BM and 6,768 PBSC donors are shown in Tables 1 and 2 respectively, displayed in quartiles reflecting the total activity of all centers (as defined in the methods).

BM donations were facilitated by 81 donor centers and 83 collection centers. The median number of BM collections per center in this study population was 43 (range 0-573). The median volume harvested was 12.70 ml/kg of donor weight. In 4.12% of donors this

exceeded the recommended maximum collection volume. There were several significant differences between the donors based on center volume (Table 1); however this variation was not distributed in a linear fashion. For example while the lowest and highest volume centers had the largest proportion of non-Hispanic whites and highest median income, the low volume centers had older donors and more female donors compared to the highest volume centers. In addition, more collections occurred in low volume centers in the early years of the study.

PBSC donations were facilitated by 76 donor centers and 98 apheresis centers. The median number of apheresis procedures per center in this study population was 520 (range 0-5,953). We found that the lowest volume centers had more non-Hispanic whites and the lowest median household income. The lowest volume centers had the highest percentage of second day collections. Several differences existed between baseline blood counts (Table 2). As in BM, more collections occurred in low volume centers in the early years of the study.

Multivariate Analysis

Pain and Toxicity in PBSC Donors

As has been previously shown female (pain at day 2: OR=1.62, p<0.001; and 1 week: OR=1.53, p=0.048; MTC at day 2: OR=1.96, p<0.001; and 1 week: OR=1.67, p=0.014) and obese (pain at day 2: OR=1.31, p<0.001; MTC at day 2: OR=1.47, p<0.001) donors experienced more symptoms with donation. There was no impact of race/ethnicity or apheresis center volume on any pain or toxicity outcome of PBSC donors at any time. Of interest, donors in a higher income census block reported higher maximum toxicity levels 1 week post donation (p=0.025). We also found a differential effect of age, with donors over the age of 40 years having lower pain with donation compared to younger donors (p<0.001), but all donors over 30 years having greater pain at 1 week (p=0.003). Donors aged 30-39 had a higher MTC through donation compared to both younger and older donors (p=0.021). Finally, we found a white blood cell count (WBC) of >7.6 $\times 10^9$/L at baseline to be associated with higher MTC through donation (OR=1.21, p=0.004) and at 1 week post (OR=1.86, p=0.003) and a mononuclear cell count of >2.7 $\times 10^9$/L at baseline to be associated with higher pain levels through donation (OR=1.2, p=0.002).

Pain and Toxicity in BM Donors

All statistically significant outcomes related to pain and maximum toxicity on day 2 and 1 week post donation are displayed in Tables 3-6. Female donors experienced more symptoms with donation (pain at 1 week: OR=2.07, p<0.001; MTC at day 2: OR=2.08, p<0.001; and 1 week OR=2.28, p<0.001) and donors older than 30 years had significantly higher MTC at 1 week (p=0.020).There was no impact of SES on any pain or toxicity outcome at any time. The only significant impact associated with race/ethnicity was a higher incidence of grade 2-4 skeletal pain on day 2 post BM collection in black males (OR=1.91, p=0.014). The collection center volume had a significant impact on the MTC on day 2 (p=0.068) and 1 week (p=0.004) post donation (Tables 3 and 4, Figure 1). At 1 week, donors from any center performing fewer than 24 collections reported more toxicity (OR=2.09, CI=1.26-3.46, p=0.004) (Table 4). Finally, we found that donors with neutrophils >3.2 $\times 10^9$/L at baseline

had more pain on day 2 (p=0.002); those who were cytomegalovirus positive had more pain at 1 week (p=0.009) and normal/underweight donors had higher MTC at day 2 (p=0.029).

Discussion

The results of this study show that center volume was an important factor associated with acute toxicity for BM donors. In contrast, we did not find an impact of center volumes on recovery of PBSC donors, and race and SES had only a minor effect on acute toxicity symptoms associated with either PBSC or BM donation.

We were reassured to see little consistent impact of the additional demographic factors of race and SES on donor toxicities. Previous studies have demonstrated increased pain in African Americans[13,15] which we noted here only for a single outcome where black males had a significantly higher skeletal pain score on day 2 post BM donation (which resolved by 1 week). The reasons for this disparity are not clear. Likewise the finding of a higher MTC in donors with a higher SES at 1 week after PBSC donation was not found at other time points. Although SES has been shown to impact symptoms in some chronic conditions such as fibromyalgia[16] and arthritis[17], it is generally those in lower SES groups who have more troublesome symptoms. Interestingly, one study has shown that analgesia use is lower in those with a higher SES following a medical procedure[18], an outcome we did not examine in our study. Since SES assignment was based only on the census block group that the donor lived in at the time of donation, it is possible that we did not have enough information to properly understand this outcome. Education level and occupation were not considered in this study.

To date, a comprehensive study investigating the toxicity outcomes of donors has not looked at the variable of center size and experience, and our findings with regards to BM donors are of great interest and require further investigation. While a few studies have investigated a center effect or donor demographic factors on the quality of BM harvested[19-21], none of these have reported on the donor's outcome. This issue is of critical importance to the NMDP and other donor registries not only to ensure the best donor experience, but also to assist in accreditation of centers. This finding may represent a predictable result of less experience at a given center, warranting special attention and intervention to ensure appropriate outcomes for BM donors harvested at small centers.

The number of BM harvests performed in unrelated donors annually has reduced dramatically over the last decade, although there is some evidence of a plateau in recent years. Currently, 20% of unrelated donor transplants reported to the CIBMTR are performed using BM[22]. The percentage of donors undergoing BM harvest vs. PBSC is even lower in (adult) related donors, with the overall effect being that of a lack of exposure to this procedure for many hematologists/BMT specialists and other BM harvest team members. A recently published study by Remberger, et al,[23] reported a significant reduction in the number of CD34 cells harvested from BM in a more contemporary time period (2010-2011) compared to an earlier time period (1995-1997). In addition, a single center study has shown a marked downward trend in total nucleated cell numbers harvested from BM over time (Nicole L. Prokopishyn, personal communication, April 27, 2015). Authors of both of these

studies speculate that these effects are due to a reduction in operator expertise. Indeed, one study which assessed the impact of a new BM needle on harvest quality[24], reported a "learning effect" for the same operators performing more harvest over time, as larger collection volumes were consistently obtained in the later time period.

These diminishing numbers of BM collections have led the Foundation for the Accreditation of Cellular Therapy (FACT) standards committee to lower the minimum number of BM harvests required by a facility to be accredited such that: A minimum of one marrow collection procedure shall have been performed in the twelve month period immediately preceding facility accreditation, and a minimum average of one marrow collection procedure per year shall be performed within the accreditation cycle[25]. In this study we defined center size by the total number of collections performed (related and unrelated) and found that in those centers performing ≤1 BM collection every 2 months over a 3-4 year period donors had a longer time to recovery. This is well above the current minimum standard required by FACT for center accreditation, and suggests that the standard should be revised or that other measures should be taken to address this issue. Given the results of this study and the trends in BM harvesting volumes, we may not only see an increase in donor acute toxicities, but also a reduction in the quality of the harvest if practice is not changed. We were not able to accurately assess the number of BM harvests performed by individual practitioners at collection centers. However, we believe that the harvesting process is a composite one requiring expertise not only of the harvesting practitioner, but also the ancillary operating room staff and anesthesiologists.

Interestingly, the effects on BM donors were most marked at 1 week post donation for both MTC, with little or no effect for skeletal pain. It is thus possible that the increased symptoms are not only related to collection variables, but also to other factors. This may include factors not directly addressed in this study, such as hospitalization, advice on activities, use of and prescriptions for analgesia and iron supplementation and infusion of autologous blood units[26, 27]. Practice at NMDP centers is generally to collect one or more autologous unit prior to donation, but in many cases these units are not returned. It is unclear how this variable may impact the donor experience, but this may warrant further analysis. We also did not consider aspects of anesthesia (duration/method) in this study as this is extremely standardized at NMDP centers, following earlier studies showing the important impact of this variable on toxicities[3]. This study was only focused on short term toxicities and pain and was not designed to examine long term donor outcomes.

Several possible strategies to address the problems associated with collecting fewer BM could be proposed. First, knowledge of this issue by centers might lead to training and standardization of practices within centers to address this concern. If such interventions did not lead to improvements in low volume centers, a possible solution would be to consolidate collections into fewer facilities. This would be relatively easy to achieve for registries looking after unrelated donors, however, it would be a challenge for centers performing related donor collections. In some countries, registries have taken on the collection of BM from related donors for the transplant centers. Concerning the issue of lower total nucleated cell numbers over time, CIBMTR is undertaking a large study to explore this issue in more detail[28].

In conclusion, despite a reassuring lack of major impact of race and SES on acute toxicities in unrelated donors, we found an increase in toxicities in BM donors who donated at small volume BM harvesting centers. We speculate that this is part of a worrying trend towards reduction in the experience of the BM operators, which will impact not only on the donor (as we have shown), but also on the quality of the harvest, with obvious detriments to the patient. A global effort is required to address these issues.

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Highlights

- We investigate short term toxicities in donors by race, SES and donor center volume
- Race and SES have only a minor effect on toxicities
- Center volume was an important factor associated with acute toxicity for BM donors

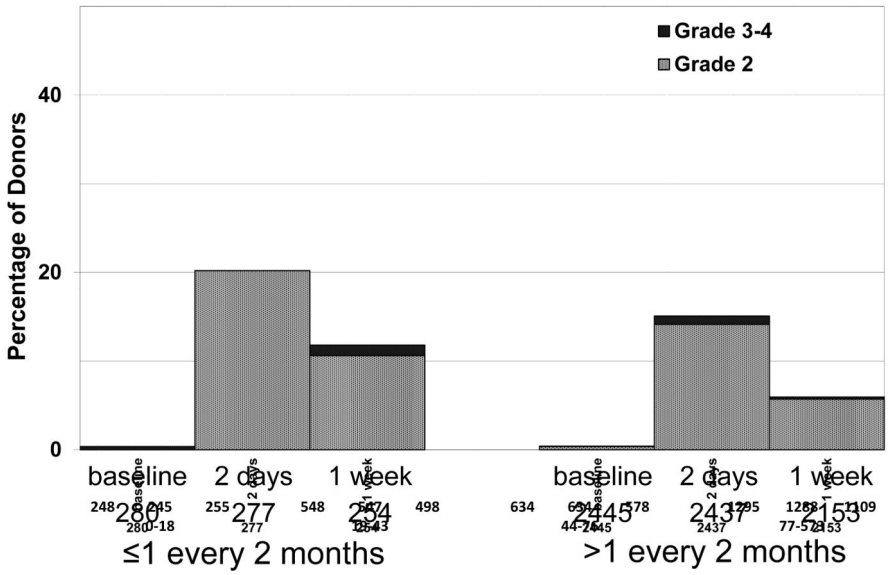

Figure 1. Highest Toxicity Level Across All Body Symptoms in BM Donors Depending on the Number of BM Collections in the Center

Highest toxicity level of key symptoms (fever in the absence of signs of infection, fatigue, skin rash, local reactions, nausea, vomiting, anorexia, insomnia, dizziness, and syncope) for BM donors by collection center volume: at baseline, during peri-collection period and post-donation.

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Table 1

Characteristics of First-Time NMDP Donors Who Donated BM Between January 1, 2004 and July 31, 2009 by Collection Center Size[a]

Variable	0-18 collections N (%)	19-43 collections N (%)	44-76 collections N(%)	77-573 collections N(%)	p-value
Number of donors	248	548	635	1295	
Number of centers	19	27	20	17	
Median household income in the donor's census block group, 2012[b,c]					0.059
0-25,000	4 (2)	16 (3)	25 (4)	33 (4)	
25,001-50,000	74 (30)	179 (35)	231 (37)	241 (30)	
50,001-100,000	118 (49)	245 (48)	274 (44)	415 (51)	
>100,000	40 (16)	63 (12)	72 (12)	108 (13)	
Unknown	7 (3)	11 (2)	20 (3)	16 (2)	
Donor race					<0.001
Non-Hispanic white	213 (86)	370 (68)	440 (69)	912 (70)	
Hispanic, all races	10 (4)	88 (16)	78 (12)	127 (10)	
Non-Hispanic black	11 (4)	40 (7)	32 (5)	82 (6)	
Non-Hispanic Asian/non-Hispanic Pacific Islander	7 (3)	23 (4)	46 (7)	68 (5)	
Non-Hispanic other, unknown	7 (3)	27 (5)	39 (6)	106 (8)	
Donor-related					
Donor age at donation					<0.001
18 to 29	72 (29)	143 (26)	206 (32)	466 (36)	
30 to 39	78 (31)	209 (38)	186 (29)	407 (31)	
40 to 49	68 (27)	151 (28)	171 (27)	329 (25)	
50+	30 (12)	45 (8)	72 (11)	93 (7)	
Median (Range)	37 (19-60)	36 (19-61)	36 (19-61)	34 (19-61)	0.007
Donor sex					<0.001
Female	105 (42)	243 (44)	299 (47)	441 (34)	
Male	143 (58)	305 (56)	336 (53)	854 (66)	
Donor BMI (kg/m^2)					0.166
Underweight (<18.5)	1 (<1)	4 (1)	5 (1)	4 (<1)	

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Variable	0-18 collections N (%)	19-43 collections N (%)	44-76 collections N(%)	77-573 collections N(%)	p-value
Normal (18.5-24.9)	71 (29)	187 (34)	193 (30)	374 (29)	
Overweight (25-29.9)	102 (41)	197 (36)	223 (35)	522 (40)	
Obese (30+)	74 (30)	160 (29)	214 (34)	395 (31)	
Median (Range)	27.5 (18.2-42.1)	27.0 (17.6-45.6)	27.7 (16.1-50.9)	27.4 (17.8-48.5)	0.314
Baseline WBC ($\times 10^9$/L)					
N Eval	248	548	635	1295	
Median (Range)	6.3 (2.9-12.3)	6.3 (2.3-14.2)	6.5 (3.1-12.9)	6.4 (3.0-14.2)	0.077
Baseline platelets ($\times 10^9$/L)					
N Eval	248	548	634	1295	
Median (Range)	259 (138-419)	254 (139-490)	256 (130-465)	252 (104-534)	0.374
Baseline hemoglobin (g/dL)					
N Eval	248	548	635	1295	
Median (Range)	14.6 (10.7-18.3)	14.6 (8.6-17.9)	14.7 (10.4-17.6)	14.7 (9.2-19.0)	0.129
Baseline neutrophils ($\times 10^9$/L)					
N Eval	247	548	635	1295	
Median (Range)	4.1 (1.5-9.9)	4.0 (1.0-12.5)	4.1 (1.6-9.9)	4.0 (1.2-10.3)	0.052
Baseline mononuclear cells ($\times 10^9$/L)					
N Eval	248	548	632	1289	
Median (Range)	2.2 (1.2-5.3)	2.3 (0.9-5.2)	2.3 (0.9-5.0)	2.3 (0.9-7.2)	0.473
Donor CMV					0.065
Negative	161 (65)	305 (56)	348 (55)	738 (57)	
Positive	86 (35)	243 (44)	287 (45)	555 (43)	
Unknown/Inconclusive	1 (<1)	0	0	2 (<1)	
Collection-related					
Year of donation					<0.001
2004	88 (35)	100 (18)	112 (18)	191 (15)	
2005	61 (25)	93 (17)	93 (15)	202 (16)	
2006	36 (15)	97 (18)	124 (20)	222 (17)	
2007	24 (10)	95 (17)	114 (18)	238 (18)	
2008	21 (8)	106 (19)	113 (18)	297 (23)	

Variable	0-18 collections N (%)	19-43 collections N (%)	44-76 collections N(%)	77-573 collections N(%)	p-value
2009	18 (7)	57 (10)	79 (12)	145 (11)	
Type of anesthesia					<0.001
Epidural	2 (1)	3 (1)	4 (1)	22 (2)	
General	229 (92)	533 (97)	608 (96)	1249 (97)	
Local	0	0	1 (<1)	0	
Spinal	17 (7)	12 (2)	22 (3)	23 (2)	
Unknown	0 N/A	0 N/A	0N/A	1N/A	

Abbreviations: NMDP – National Marrow Donor Program; BM – bone marrow; BMI – body mass index; WBC – white blood cells; CMV – Cytomegalovirus.

[a] Collection center size based on NMDP reaccreditation numbers: uses total number of bone marrow collections, regardless of donor source, for calendar years 2005-2008.

[b] Donors from the centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses.

[c] If the census block group could not be located from reported street address, median household income from donor's zip code was used instead.

Table 2

Characteristics of First-Time NMDP Donors Who Donated PBSC Between January 1, 2004 and July 31, 2009 by Collection Center Size[a]

Variable	0-204 collections N (%)	205-520 collections N (%)	521-1135 collections N (%)	1136-5953 collections N (%)	Unknown N(%)	p-value
Number of donors	543	1674	2845	1686	20	
Number of centers	22	24	24	22	6	
Median household income in the donor's census block group, 2012[b,c]						<0.001
0-25,000	27 (5)	37 (2)	75 (4)	43 (3)	0	
25,001-50,000	184 (34)	475 (30)	512 (30)	473 (31)	4 (57)	
50,001-100,000	251 (47)	813 (51)	827 (49)	713 (46)	2 (29)	
>100,000	56 (10)	205 (13)	252 (15)	276 (18)	0	
Unknown	19 (4)	55 (3)	34 (2)	32 (2)	1 (14)	
Donor race						<0.001
Non-Hispanic white	458 (84)	1168 (70)	2183 (77)	1258 (75)	16 (80)	
Hispanic, all races	26 (5)	202 (12)	241 (8)	139 (8)	1 (5)	
Non-Hispanic black	13 (2)	72 (4)	148 (5)	87 (5)	0	
Non-Hispanic Asian/non-Hispanic Pacific Islander	17 (3)	117 (7)	58 (2)	102 (6)	0	
Non-Hispanic other, unknown	29 (5)	115 (7)	215 (8)	100 (6)	3 (15)	
Donor-related						
Donor age at donation						<0.001
18 to 29	141 (26)	509 (30)	995 (35)	521 (31)	7 (35)	
30 to 39	185 (34)	531 (32)	935 (33)	550 (33)	6 (30)	
40 to 49	158 (29)	431 (26)	672 (24)	430 (26)	3 (15)	
50+	59 (11)	203 (12)	243 (9)	185 (11)	4 (20)	
Median (Range)	37 (19-60)	36 (18-60)	35 (19-61)	36 (19-61)	35 (20-61)	<0.001
Donor sex						<0.001
Female	230 (42)	746 (45)	908 (32)	706 (42)	8 (40)	
Male	313 (58)	928 (55)	1937 (68)	980 (58)	12 (60)	

Variable	0-204 collections N (%)	205-520 collections N (%)	521-1135 collections N (%)	1136-5953 collections N (%)	Unknown N(%)	p-value
Donor BMI (kg/m^2)						0.085
Underweight (<18.5)	2 (<1)	9 (1)	17 (1)	13 (1)	0	
Normal (18.5-24.9)	146 (27)	504 (30)	795 (28)	521 (31)	4 (20)	
Overweight (25-29.9)	202 (37)	641 (38)	1183 (42)	625 (37)	8 (40)	
Obese (30+)	193 (36)	520 (31)	849 (30)	527 (31)	8 (40)	
Unknown	0 N/A	0N/A	1N/A	0N/A	0N/A	
Median (Range)	28.0 (18.0-49.7)	27.4 (16.2-49.1)	27.4 (16.7-51.8)	27.4 (16.9-56.2)	27.7 (19.5-39.6)	0.082
Baseline WBC (×10^9/L)						
N Eval	543	1674	2845	1686	20	
Median (Range)	6.4 (3.2-14.0)	6.3 (2.9-15.6)	6.3 (2.4-16.0)	6.4 (2.3-14.5)	6.6 (4.5-11.0)	0.683
Baseline platelets (×10^9/L)						
N Eval	543	1673	2844	1686	20	
Median (Range)	252 (122-474)	257 (127-474)	251 (100-548)	257 (112-494)	242 (170-397)	0.002
Baseline hemoglobin (g/dL)						
N Eval	543	1674	2845	1686	20	
Median (Range)	14.7 (10.5-17.9)	14.5 (9.6-18.3)	14.9 (9.4-18.6)	14.6 (9.6-19.0)	14.6 (12.5-16.5)	<0.001
Baseline neutrophils (×10^9/L)						
N Eval	543	1673	2844	1686	20	
Median (Range)	4.1 (1.3-10.9)	3.9 (1.2-12.9)	3.9 (1.0-12.8)	4.0 (1.3-11.8)	3.8 (2.4-6.1)	0.152
Baseline mononuclear cells (×10^9/L)						
N Eval	538	1672	2836	1681	20	
Median (Range)	2.3 (1.1-4.9)	2.3 (0.7-7.3)	2.3 (0.8-5.9)	2.3 (0.3-5.0)	2.5 (1.4-5.0)	0.100
Donor CMV						<0.001
Unknown/Inconclusive	0	4 (<1)	3 (<1)	3 (<1)	0	
Negative	329 (61)	937 (56)	1790 (63)	1046 (62)	15 (75)	
Positive	214 (39)	733 (44)	1052 (37)	637 (38)	5 (25)	
Year of donation						<0.001
2004	107 (20)	169 (10)	356 (13)	176 (10)	6 (30)	
2005	111 (20)	258 (15)	426 (15)	303 (18)	4 (20)	

Variable	0-204 collections N (%)	205-520 collections N (%)	521-1135 collections N (%)	1136-5953 collections N (%)	Unknown N(%)	p-value
2006	90 (17)	294 (18)	504 (18)	299 (18)	1 (5)	
2007	79 (15)	331 (20)	574 (20)	307 (18)	6 (30)	
2008	88 (16)	393 (23)	648 (23)	367 (22)	1 (5)	
2009	68 (13)	229 (14)	337 (12)	234 (14)	2 (10)	
Two-day collection						<0.001
No	290 (53)	1288 (77)	2293 (81)	1058 (63)	15 (75)	
Yes	253 (47)	386 (23)	552 (19)	628 (37)	5 (25)	
Pre-collection WBC ($\times 10^9$/L)						
N Eval	543	1674	2845	1685	20	
Median (Range)	37.5 (9.6-98.9)	38.3 (11.3-93.4)	38.9 (11.2-117)	38.9 (10.6-89.7)	37.6 (18.9-64.3)	0.431
CD34+ at collection ($\times 10^6$)						
N Eval	409	1508	2430	1480	18	
Median (Range)	636.0 (7.1-3486.2)	611.4 (0.9-4013.6)	743.6 (2.8-5967.0)	657.2 (0.7-13428.1)	592.2 (77.8-1262.7)	<0.001
Day 1 G-CSF dose per donor weight (μg/kg)						
N Eval	543	1674	2836	1685	20	
Median (Range)	10.5 (5.3-14.6)	10.6 (7.1-14.5)	10.6 (2.5-15.7)	10.6 (4.5-17.7)	10.5 (9.0-12.8)	0.021
Total G-CSF dose per donor weight (μg/kg)						
N Eval	543	1674	2842	1686	20	
Median (Range)	52.3 (35.0-73.2)	52.9 (31.2-70.6)	52.7 (5.2-74.4)	52.7 (21.2-71.4)	52.3 (35.9-63.9)	<0.001

Abbreviations: NMDP – National Marrow Donor Program; PBSC – peripheral blood stem cell; BMI – body mass index; WBC – white blood cells; CMV – Cytomegalovirus.

[a] Apheresis center size based on reaccreditation numbers; uses total number of autologous, related and unrelated allogeneic PBSC collections for calendar years 2004-2008.

[b] Donors from the centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses.

[c] If the census block group could not be located from reported street address, median household income from donor's zip code was used instead.

Table 3

Multivariate Analysis of Grade 2-4 Maximum MTC Grade at Day 2 After BM Donation

Variable	n	OR	Lower	Upper	p-value
Median household income in the donor's census block group, 2012[a,b]					0.996
0-25,000	78	1.00			
25,001-50,000	721	1.01	0.51	2.00	0.985
50,001-100,000	1050	0.97	0.49	1.92	0.927
>100,000	281	0.93	0.44	1.95	0.839
Donor race					0.821
Non-Hispanic white	1920	1.00			
Hispanic, all races	302	0.81	0.54	1.20	0.294
Non-Hispanic black	165	0.98	0.62	1.56	0.937
Non-Hispanic Asian/non-Hispanic Pacific Islander	144	1.14	0.69	1.88	0.599
Non-Hispanic other, unknown	178	0.99	0.63	1.56	0.974
Collection center size					0.068
≥24 (≥1 every 2 months)	2138	1.00			
<24 (<1 every 2 months)	265	1.55	0.97	2.47	0.068
Sex					<0.001
Male	1627	1.00			
Female	1082	2.08	1.66	2.62	<0.001
Donor BMI (kg/m^2)					0.029
Normal/underweight (<24.9)	835	1.00			
Overweight (25-29.9)	1036	0.76	0.59	0.99	0.041
Obese (30+)	838	0.70	0.53	0.93	0.013

Abbreviations: MTC – modified toxicity criteria; BM – bone marrow; OR – odds ratio; BMI – body mass index.

[a] Donors from the centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses.

[b] If the census block group could not be located from reported street address, median household income from donor's zip code was used instead.

Table 4

Multivariate Analysis of Grade 2-4 Maximum MTC Grade at 1 Week After BM Donation

Variable	n	OR	Lower	Upper	p-value
Median household income in the donor's census block group, 2012[a,b]					0.599
0-25,000	70	1.00			
25,001-50,000	648	0.51	0.20	1.30	0.159
50,001-100,000	956	0.66	0.26	1.66	0.380
>100,000	254	0.60	0.22	1.68	0.331
Donor race					0.813
Non-Hispanic white	1720	1.00			
Hispanic, all races	272	0.87	0.49	1.55	0.634
Non-Hispanic black	137	0.71	0.33	1.53	0.383
Non-Hispanic Asian/non-Hispanic Pacific Islander	121	0.68	0.28	1.66	0.395
Non-Hispanic other, unknown	153	0.86	0.41	1.77	0.675
Collection center size					0.004
≥24 (≥1 every 2 months)	2138	1.00			
<24 (<1 every 2 months)	265	2.09	1.26	3.46	0.004
Sex					<0.001
Male	1432	1.00			
Female	971	2.28	1.62	3.22	<0.001
Age at donation					0.020
18 to 29	767	1.00			
30 to 39	783	1.62	1.02	2.56	0.040
40 to 49	633	2.05	1.29	3.25	0.002
50+	220	1.91	1.03	3.54	0.040

Abbreviations: MTC – modified toxicity criteria; BM – bone marrow; OR – odds ratio.

[a] Donors from the centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses.

[b] If the census block group could not be located from reported street address, median household income from donor's zip code was used instead.

Table 5

Multivariate Analysis of Grade 2-4 Maximum Skeletal Pain on Day 2 After BM Donation

Variable	n	OR	Lower	Upper	p-value
Donor race					0.001
Male					0.008
Non-Hispanic white	1220	1.00			
Hispanic, all races	146	0.75	0.48	1.18	0.213
Non-Hispanic black	71	1.91	1.14	3.20	0.014
Non-Hispanic Asian/non-Hispanic Pacific Islander	86	0.61	0.34	1.10	0.100
Non-Hispanic other, unknown	106	0.63	0.37	1.08	0.094
Female					0.136
Non-Hispanic white	702	1.00			
Hispanic, all races	156	0.81	0.54	1.23	0.323
Non-Hispanic black	94	0.57	0.34	0.95	0.030
Non-Hispanic Asian/non-Hispanic Pacific Islander	58	1.04	0.57	1.92	0.892
Non-Hispanic other, unknown	72	1.29	0.77	2.18	0.333
Median household income in the donor's census block group, 2012[a,b]					0.689
0-25,000	78	1.00			
25,001-50,000	722	0.68	0.40	1.16	0.160
50,001-100,000	1051	0.69	0.41	1.16	0.160
>100,000	281	0.66	0.37	1.17	0.154
Collection center size					0.338
≥24 (≥1 every 2 months)	2138	1.00			
<24 (<1 every 2 months)	265	1.25	0.79	1.95	0.338
Neutrophils at baseline ($\times 10^9$/L)					
<3.2	650	1.00			
>3.2	2061	1.38	1.13	1.70	0.002

Abbreviations: BM – bone marrow; OR – odds ratio.

[a] Donors from the centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses.

[b] If the census block group could not be located from reported street address, median household income from donor's zip code was used instead.

Table 6

Multivariate Analysis of Grade 2-4 Maximum Skeletal Pain at 1 Week After BM Donation

Variable	n	OR	Lower	Upper	p-value
Median household income in the donor's census block group, 2012[a,b]					0.114
0-25,000	70	1.00			
25,001-50,000	648	0.83	0.38	1.82	0.649
50,001-100,000	958	1.11	0.51	2.39	0.790
>100,000	254	0.59	0.24	1.44	0.248
Donor race					0.479
Non-Hispanic white	1720	1.00			
Hispanic, all races	273	0.78	0.49	1.23	0.280
Non-Hispanic black	137	1.25	0.76	2.07	0.383
Non-Hispanic Asian/non-Hispanic Pacific Islander	121	0.72	0.36	1.43	0.352
Non-Hispanic other, unknown	153	0.82	0.47	1.42	0.479
Collection center size					0.164
≥24 (≥1 every 2 months)	2138	1.00			
<24 (<1 every 2 months)	265	1.41	0.87	2.28	0.164
Sex					<0.001
Male	1432	1.00			
Female	972	2.07	1.59	2.70	<0.001
Donor CMV					0.009
Negative	1363	1.00			
Positive	1041	1.43	1.09	1.87	0.009

Abbreviations: BM – bone marrow; OR – odds ratio; CMV – Cytomegalovirus.

[a] Donors from the centers who provided only non-residential zip codes (e.g. work, university or donor center zip codes) were excluded from the SES analyses.

[b] If the census block group could not be located from reported street address, median household income from donor's zip code was used instead.