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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

A G E N D A
CIBMTR WORKING COMMITTEE FOR DONOR HEALTH AND SAFETY
Orlando, Florida
Saturday, February 22, 2020, 2:45 – 4:45 pm

Co-Chair:	**Nirali Shah, MD, MHSc, National Cancer Institute – NIH, Bethesda, MD; Telephone: 301-451-0390; E-mail: nirali.shah@nih.gov**
Co-Chair:	**Galen Switzer, PhD, University of Pittsburgh, Pittsburgh, PA; Telephone: 412-246-6564; E-mail: gswitzer@pitt.edu**
Co-Chair:	**Jack Hsu, MD, Shands HealthCare and University of Florida, Gainesville, FL; Telephone: 352-273-7539; E-mail: jack.hsu@medicine.ufl.edu**
Scientific Director:	**Bronwen Shaw, MD, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0700; E-mail: beshaw@mcw.edu**
Ex Officio Senior Advisor:	**Dennis Confer, MD, MS, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-3425; E-mail: dconfer@nmdp.org**
Statistical Director:	**Brent Logan, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-955-8849; E-mail: blogan@mcw.edu**
Statisticians:	**Stephanie Bo-Subait, MPH, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8515; E-mail: sbosuba2@nmdp.org** **Pintip Chitphakdithai, PhD, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8309; E-mail: pchitpha@nmdp.org**

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1. **Introduction**
   a. Minutes and Overview Plan from February 2019 meeting (Attachment 1)

2. **Accrual summary** (Attachment 2)

3. **Presentations, published or submitted papers**
   a. **DS13-01** Prokopishyn NL, Logan BR, Kiefer DM, Sees JA, Chitphakdithai P, Ahmed IA, Anderlini PN, Beitinjaneh AM, Bredeson C, Cerny J, Chhabra S, Daly A, Diaz MA, Farhadfar N, Frangoul HA, Ganguly S, Gastineau DA, Gergis U, Hale GA, Hematti P, Kamble RT, Kasow KA, Lazarus HM, Liesveld JL, Murthy HS, Norkin M, Olsson RF, Papari M, Savani BN, Szer J, Waller EK, Wirk B, Yared JA, Pulsipher MA, Shah NN, Switzer GE, O'Donnell PV, Confer DL, Shaw BE. The concentration of total nucleated cells in harvested bone marrow for transplantation has decreased over time. **Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation. 2019 Jul 1; 25(7):1325-1330. doi:10.1016/j.bbmt.2019.01.034. Epub 2019 Feb 2. PMC6615955.**
   b. **DS16-S1** Wiener L, Hoag JA, Pelletier W, Shah NN, Shaw BE, Pulsipher MA, Bruce J, Bader P, Willasch AM, Dalissier A, Guilcher G, Anthias C, Confer DL, Sees JA, Logan B, Switzer GE. Transplant center practices for psychosocial assessment and management of pediatric hematopoietic stem cell donors. **Bone Marrow Transplantation. doi:10.1038/ s41409-019-0515-3. Epub 2019 Apr 10.**

c. **DS17-01** Farhadfar N, Hsu JW, Logan BR, Sees JA, Chitphakdithai P, Sugrue MW, Abdel-Azim H, Anderlini PN, Bredeson C, Chhabra S, Diaz MA, Ganguly S, Hematti H, Kamble RT, Kasow KA, Lazarus HM, Lynch DK, Murthy HS, Olsson RF, Papari M, Przepiorka D, Savani BN, Schears R, Seo S, Solh MM, Spitzer T, Yared JA, Pulsipher MA, Shah NN, Switzer GE, Confer DL, Shaw BE, Wingard JR. Weighty choices: selecting optimal G-CSF doses for stem cell mobilization to optimize yield. ***In press Blood Advances.***

d. **DS18-01** Wong WH, Bhatt S, Trinkaus K, Pusic I, Elliott K, Mahajan N, Wan F, Switzer GE, Confer DL, Dipersio J, Pulsipher MA, Shah NN, Sees J, Bystry A, Blundell JR, Shaw BE, Druley TE. Engraftment of rare, pathogenic donor hematopoietic clones with mutations in unrelated hematopoietic stem cell transplantation. **In press *Science Translational Medicine.***

e. **DS16-S2** Seftel MD, Kuxhausen M, Burns L, Chitphakdithai P, Confer D, Kiefer D, Lee S, Logan B, O'Donnell P, Pulsipher M, Shah NN, Switzer G, Shaw BE. Clonal Hematopoiesis in Related Allogeneic Transplant Donors: Implications for Screening and Management. ***Submitted.***

f. **DS16-01** Hsu JW, Shaw BE, Kim S, Logan BR, Sees JA, Confer DL, Pulsipher MA, Shah N, Switzer GE, Abidi MH, Ahmed IA, Anderlini PN, Bredseon C, Chhabra S, Dandoy CE, Diaz MA, Farhadfar N, Ganguly S, Gergis U, Hale GA, Hematti P, Kamble RT, Kasow KA, Lazarus HM, Liesveld JL, Murthy HS, Olsson RF, Savani BN, Schears R, Seo S, Solh M, Spitzer T, Steinberg A, Sugrue M, Warkentin P, Wingard JR. Peripheral Blood Stem Cell Collection in One Day is Preferable to Two Days in Unrelated Donors. ***Submitted.***

g. **DS17-02** Farhadfar N, Murthy HS, Logan BR, Sees JA, Mouhab A, Battiwalla M, Beitinjaneh AM, Chhabra S, Diaz MA, Engles K, Frangoul H, Ganguly S, Gergis U, Kamani NR, Kamble RT, Kasow KA, Lazarus HM, Liesveld JL, Norkin M, O'Donnell PV, Olsson RF, Rossman SN, Savani BN, Schears R, Seo S, Solh MM, Spitzer T, Sugrue M, Yared JA, Linenberger M, Schwartz J, Pulsipher MA, Shah NN, Switzer GE, Confer DL, Shaw BE, Wingard JR. Impact of Autologous Blood Transfusion after Bone Marrow Harvest on Unrelated Donor's Health and Outcome: A CIBMTR Analysis. ***Submitted.***

h. **DS18-01** Wong WH, Young A, Druley T. Detection of rare, deleterious clonal mutations during unrelated allogeneic hematopoietic stem cell transplants using an error correction pipeline for NGS. ***Presented at AACR Annual Meeting 2019.***

i. **DS18-02** Panch SR, Logan BR, Sees JA, Savani BN, Shah NN, Hsu JW, Pulsipher MA, Switzer GE, Shaw BE, Stroncek DF. Lower Hematopoietic Progenitor Cell Counts and Yields at Subsequent Donations Is Influenced By a Shorter Inter-Donation Interval between the First and Subsequent Mobilizations. ***Presented at 62nd ASH Annual Meeting and Exposition.***

4. Studies in progress (Attachment 3)

a. **DS05-02d** RDSafe-d: QoL for related adult donors compared to unrelated adult donors (G Switzer/M Pulsipher) **Manuscript Prep**

b. **DS05-02g** RDSafe-g: Late toxicities and SAE for related donors (M Pulsipher) **Analysis**

c. **DS13-02** A retrospective analysis to understand the potential mechanisms underlying the clinical impact of ABO incompatibility on allogeneic transplant outcomes (G. Murthy/B Shaw) **Protocol Development**

d. **DS18-02** Factors Affecting CD34+ Cell Yields at Subsequent Marrow/PBSC Collections (SR Panch/DF Stroncek/B Savani/NN Shah) **Manuscript Prep**

e. **DS19-01** Effect of Donor Graft Cryopreservation on Allogeneic Transplant Recipient Outcomes (J Hsu/N Farhadfar/H Murthy/J Wingard) **Data file prep**

f. **DS19-02** The Impact of pre-apheresis Health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome (N Farhadfar/J Wingard/G Switzer) **Draft protocol received**

5. Future/proposed studies

a. **PROP 1911-16** Acute Toxicities of Bone Marrow or Peripheral Blood Stem Cell Donation in Donors with Sickle Cell Trait (N Farhadfar/J Wingard) (Attachment 4)

Dropped proposed studies

a. **PROP 1911-238** Improving Donor Education and Safety Programs by a Comprehensive Review of Donor Deferrals Based on Infection Risk identified in National Marrow Donor Program. *Dropped due to feasibility.*

6. Other business

a. **Review/guideline papers** L Gowda
b. **Biobank update** S Devine
c. **17-SIBS** Identifying Predictors of Poor Health-Related Quality of Life among Pediatric Hematopoietic Stem Cell Donors. G Switzer
d. **Additional business items** As needed and as time allows for discussion.

CIBMTR®
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MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR DONOR HEALTH AND SAFETY
Houston, TX
Saturday, February 23, 2019, 12:15 – 2:15 pm

Co-Chair:	**Michael Pulsipher, MD, Children's Hospital of Los Angeles, Los Angeles, CA; Telephone: 323-361-2121; E-mail: mpulsipher@chla.usc.edu**
Co-Chair:	**Galen Switzer, PhD, University of Pittsburgh, Pittsburgh, PA; Telephone: 412-246-6564; E-mail: gswitzer@pitt.edu**
Co-Chair:	**Nirali Shah, MD, MHSc, National Cancer Institute – NIH, Bethesda, MD; Telephone: 240-760-6199; E-mail: nirali.shah@nih.gov**
Scientific Director:	**Bronwen Shaw, MD, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0700; E-mail: beshaw@mcw.edu**
Ex Officio Senior Advisor:	**Dennis Confer, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-3425; E-mail: dconfer@nmdp.org**
Statistical Director:	**Brent Logan, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-955-8849; E-mail: blogan@mcw.edu**
Statisticians:	**Jennifer Sees, MPH, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8673; E-mail: jsees@nmdp.org** **Pintip Chitphakdithai, PhD, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8309; E-mail: pchitpha@nmdp.org**

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1. Introduction

Galen Switzer welcomed all attendees and called the meeting to order at 12:17 pm. Drs. Pulsipher, and Shah chaired the meeting; B Shaw, Scientific Director, D Confer, Ex Officio Senior Advisor, B Logan, Statistical Director, and P Chitphakdithai and J Sees, statisticians, where also present.

Dr. Switzer introduced and welcomed Dr. Hsu as a new chair of the committee, replacing Dr. Pulsipher who he thanked for this extensive input to the DSWC over the years since it first started. He also mentioned that the advisory metrics were not included in the slides, but that the working committee is in good standing and progressing in all studies. The Working Committee Leadership had no relevant conflicts of interest to disclose. Goals and expectations of the meeting were addressed. A reminder of the voting process, working committee membership and rules of authorship were summarized. The committee was reminded that it has been recommended that DSWC accept up to two proposals due to limited statistical hours. Minutes from Tandem 2018 were approved.

2. Accrual summary

Galen Switzer noted the accrual summaries (NMDP unrelated donors, NMDP related donors, RDSafe donors, and sample accruals) were available in the meeting materials found online.

3. Presentations, published or submitted papers

Nirali Shah provided recognition of the studies that were presented at national conferences and those studies submitted for publication in the past year, noting the great progress completed in all studies.

4. Studies in progress

Nirali Shah gave a brief overview of study statuses of active studies.
One study update was given during the meeting:

d. DS18-01 To quantify age-related clonal hematopoiesis in healthy marrow and blood donors that may affect the clinical outcome of recipients following hematopoietic stem cell transplantation (HCT) (T Druley)

Mr. Wing Hing Wong presented slides showing the results of their study, DS18-01. The manuscript has also been submitted.

As a person ages, they are more likely to develop mutations. Clonal Hematopoiesis of Indeterminate Potential (CHIP) can detect somatic mutations above 2% variant allele frequency in individuals. Mutations in leukemic genes have been found in 95% of healthy individuals.

Using 25 CIBMTR donor samples and Washington University recipients, somatic mutations were tracked from the donor to the recipient at multiple time-points post-transplant to (1) quantify and characterize the mutation burden and spectrum in healthy donors and, (2) examine engraftment dynamics of donor-derived somatic mutations in recipients.

The study found that 64% (N=16) of donors harbor at least 1 somatic mutation. DNMT3A and TET2 were the most commonly mutated genes, as observed in previous literature.

Mutated genes were evaluated as deleterious or not based on a CADD score above 15. In this study, deleterious mutations were more likely to engraft relative to non-deleterious mutations. Additionally, donor-derived DNMT3A is most commonly mutated in the recipient.

In this population, somatic mutations were not associated significantly with donor age.

The number of mutations in recipients that are in donor cells were found to be significantly higher in 30 days and 100 days post transplant when compared to the mutation burden in donor before transplant. This indicates either an increased rate of mutation, or a presence of positive selective force that drive some of these mutations to proliferate.

Finally, the somatic mutations in the donor were correlated with a higher rate of chronic Graft versus Host Disease (GVHD), however these were not significant due to small sample size.

The audience were interested in the turn around time for such testing. There was also a query about whether any of the subjects in the study had a donor-derived leukemia (there was not).

5. Future/proposed studies

a. PROP 1811-132 Effect of Donor Graft Cryopreservation on Allogeneic Transplant Recipient Outcomes (JW Hsu/ N Farhadfar/H Murthy/JR Wingard)

Dr. Jack Hsu presented the proposal "Effect of Donor Graft Cryopreservation on Allogeneic Transplant Recipient Outcomes".

Minimal information is available in the literature on the effect of cryopreservation on allogeneic donor grafts. Utilization of cryopreserved donors grafts could lower logistical issues associated with unrelated donors and expand the unrelated donor pool for quicker utilization. The hypothesis of the study is that there are no significant differences in transplant outcomes between cryopreserved and fresh grafts in donors. The primary transplant outcome to be explored is neutrophil and platelet engraftment. Secondary outcomes includes acute and chronic GVHD, relapse-free and overall survival, transplant related mortality, primary graft failure, and if available graft viability and alterations in cellular content.

The presentation was followed by a lively discussion from the audience. Throughout the discussion Dr. Jack Hsu and the Working Committee Leadership responded to questions.

In general there was enthusiasm for this study. It was noted that a similar proposal has been submitted a few years ago to this committee but had not proceeded due to low numbers of cryopreservation cases available. This number has increased in the intervening years, although the number of BM grafts which are cryopreserved remains low. It was suggested that this study would be a good pilot study on which to base further studies on the mechanisms involved in cryopreservation. There was interest in linking the infusion of the product with any reports of Adverse events (such as allergic reactions). Limitations to the study were raised for example whether data was available on the duration of cryopreservation (no) or the time from harvest to freezing (no). Also of interested was the reason for cryopreservation, but this is not captured.

In general, this proposal was very well received, and believed to be very timely, and would potentially alter practice. It was recognized that CIBMTR was the best mechanism to address this due to the rarity of cryopreservation at individual centers.

b. PROP 1812-06 The Impact of pre-apheresis Health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome (N Farhadfar/JR Wingard/GE Switzer)

Dr. Nosha Farhadfar presented the proposal "The Impact of pre-apheresis Health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome". This proposal aims to examine the association between greater emotional distress and poorer post procedural outcomes including longer hospital stays, more postoperative pain perception, and higher rates of re-hospitalization using RDSafe and BMT CTN 0201 data. Results of this proposal may help to identify donors at risk for poorer outcomes and delayed recovery. The findings of this proposal may also help guide interventions to minimize

donation associated toxicities and improve PBSC collection yield. The hypothesis of the study is that pre-donation HRQoL significantly influences donation associated toxicities, donor recovery time and PBSC collection yield.

The presentation was followed by a lively discussion from the audience. Throughout the discussion Dr. Nosha Farhadfar and Working Committee Leadership both responded to questions.

A major strength of this study is that it leverages not only clinical data but also patient-reported data which is available from previous studies. All felt this was a very good use of the resources and data available to us to answer an interesting and provocative question.

The link between stress and inflammation is well established, although not in this setting. The proposal includes only PBSC donors, however a suggestion was made to include BM donors too (data are available), analyses should be done separately to account t for different donor stressors. Relevant confounders were discussed – these are available (central line data, dose of GCSF). GCSF-primed procedures are available though these are very few. Donor medications that may also impact cell yield were raised and this data is likely to be available for some donors. A question about addressing donor mental health at registration or work up was raised, but these data appear to be differently collected.

In general, this proposal was very enthusiastically received as an examination of donor's mental and physical health on their own well-being as well as the viability of the product they produce. It was recognized that CIBMTR was the best mechanism to address this, due to the previously existing clinical and PRO data.

At the conclusion of the proposals being presented the co-chairs reminded members to vote on a scale of 1 (high scientific impact) to 9 (low scientific impact) and to turn in both their ballets and evaluation forms.

6. Other business

No other business was discussed
The meeting lasted fifty-eight minutes, concluding at 1:15pm.

Working Committee Overview Plan for 2019-2020

Study number and title	Current status	Goal with date	Total hours to complete	Total hours to goal	Hours allocated to 6/30/2018	Hours allocated 7/1/2018-6/30/2019	Total Hours allocated
DS05-02d RDSafe-d: QoL for related adult donors compared to unrelated adult donors	Manuscript Preparation	Submission – July 2019	N/A	N/A	N/A	N/A	N/A
DS05-02g RDSafe-g: Late toxicities and SAE for related donors	Analysis	Submission – July 2019	N/A	N/A	N/A	N/A	N/A
DS13-02 A retrospective analysis to understand the potential mechanisms underlying the clinical impact of ABO incompatibility on allogeneic transplant outcomes	Protocol Development	Submission – July 2019	N/A	N/A	N/A	N/A	N/A
DS16-01 Comparison between one and two day apheresis in unrelated donors	Manuscript Preparation	Submission – July 2019	70	**70**	210	140	**70**
DS16-S2 Survey of the screening and management for clonal disorders of hematopoiesis in related ALLO donors	Submitted	Accepted – July 2019	5	**5**	5	5	**5**
DS17-01 The impact of donor body mass index on collection of Filgrastim (G-CSF) mobilized peripheral blood progenitor cells from unrelated donors	Manuscript Preparation	Submission – July 2019	30	**30**	30	30	**30**

DS17-02 Impact of Collection of Autologous Blood prior to Bone Marrow Harvest on Unrelated Donor Heath and Outcome	Manuscript Preparation	Submission – July 2019	N/A	N/A	N/A	N/A	N/A
DS18-01 To quantify age-related clonal hematopoiesis in healthy marrow and blood donors that may affect the clinical outcome of recipients following hematopoietic stem cell transplantation (HCT)	Submitted	Accepted – July 2019	10	**10**	0	10	**10**
DS18-02 Factors Affecting CD34+ Cell Yields at Subsequent Marrow/PBSC Collections	Analysis	Submission – July 2019	150	**150**	0	150	**150**
DS19-01 Effect of Donor Graft Cryopreservation on Allogeneic Transplant Recipient Outcomes	Draft Protocol	Manuscript Preparation – July 2020	330	**330**	0	0	**0**
DS19-02 The Impact of pre-apheresis Health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome	Draft Protocol	Analysis – July 2020	270	**270**	0	0	**0**

Oversight Assignments for Working Committee Leadership (March 2019)

Bronwen Shaw	**DS13-02** Clinical impact of ABO incompatibility on alloHCT [Statistical Center Study]
Dennis Confer	**DS05-02 d, g** RDSafe
Galen Switzer	**DS05-02d** RDSafe **DS19-01** Effect of Donor Graft Cryopreservation on Allogeneic Transplant Recipient Outcomes
Jack Hsu	**DS05-02g** RDSafe **DS18-02** Factors Affecting CD34+ Cell Yields at Subsequent Marrow/PBSC Collections **DS19-02** The Impact of pre-apheresis Health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome
Nirali Shah	**DS16-01** One vs two day apheresis in URD **DS17-01** The impact of donor body mass index on collection of G-CSF mobilized peripheral blood progenitor cells from unrelated donors **DS17-02** The Impact of Pre-Operative Collection of Autologous Blood for Bone Marrow Harvest on Donor Health and Outcome [Statistical Center Study]

Accrual Summary for the Donor Health and Safety Working Committee

Characteristics of domestic unrelated NMDP donors donating between 1987 and September 2019[a]

	Bone marrow	PBSC	Total
Number of donors	24473	33911	58384
Donor age at time of donation			
Median (range)	34 (18-61)	31 (18-62)	33 (18-62)
18 to 29	8706 (36)	15497 (46)	24203 (41)
30 to 39	8238 (34)	9265 (27)	17503 (30)
40 to 49	5863 (24)	6452 (19)	12315 (21)
≥50	1666 (7)	2697 (8)	4363 (7)
Donor race / ethnicity			
Caucasian	17797 (73)	24738 (73)	42535 (73)
Hispanic	2368 (10)	3077 (9)	5445 (9)
Black / African American	1426 (6)	1360 (4)	2786 (5)
Asian / Pacific Islander	1165 (5)	1824 (5)	2989 (5)
American Indian / Alaska Native	286 (1)	284 (1)	570 (1)
Other / multiple race	1164 (5)	2365 (7)	3529 (6)
Decline / unknown	267 (1)	263 (1)	530 (1)
Donor sex			
Male	14764 (60)	21664 (64)	36428 (62)
Female	9709 (40)	12247 (36)	21956 (38)
Number of donations			
1	22038 (90)	31020 (91)	53058 (91)
2	2288 (9)	2786 (8)	5074 (9)
3	147 (1)	105 (<1)	252 (<1)
Donor CMV status			
Positive	9693 (40)	13525 (40)	23218 (40)
Negative	14502 (59)	19832 (58)	34334 (59)
Unknown / inconclusive	278 (1)	554 (2)	832 (1)
Year of donation			
1987	2 (<1)	0	2 (<1)
1988	80 (<1)	0	80 (<1)
1989	176 (1)	0	176 (<1)
1990	280 (1)	0	280 (<1)
1991	433 (2)	0	433 (1)
1992	541 (2)	0	541 (1)
1993	641 (3)	0	641 (1)
1994	793 (3)	5 (<1)	798 (1)

	Bone marrow	PBSC	Total
1995	867 (4)	21 (<1)	888 (2)
1996	1039 (4)	14 (<1)	1053 (2)
1997	1165 (5)	17 (<1)	1182 (2)
1998	1207 (5)	29 (<1)	1236 (2)
1999	1224 (5)	71 (<1)	1295 (2)
2000	1185 (5)	310 (1)	1495 (3)
2001	1056 (4)	454 (1)	1510 (3)
2002	1059 (4)	748 (2)	1807 (3)
2003	878 (4)	989 (3)	1867 (3)
2004	797 (3)	1084 (3)	1881 (3)
2005	645 (3)	1253 (4)	1898 (3)
2006	659 (3)	1374 (4)	2033 (3)
2007	641 (3)	1461 (4)	2102 (4)
2008	662 (3)	1693 (5)	2355 (4)
2009	661 (3)	1822 (5)	2483 (4)
2010	707 (3)	1926 (6)	2633 (5)
2011	748 (3)	2083 (6)	2831 (5)
2012	919 (4)	2470 (7)	3389 (6)
2013	900 (4)	2686 (8)	3586 (6)
2014	871 (4)	2590 (8)	3461 (6)
2015	796 (3)	2475 (7)	3271 (6)
2016	807 (3)	2255 (7)	3062 (5)
2017	810 (3)	2158 (6)	2968 (5)
2018	735 (3)	2227 (7)	2962 (5)
2019	489 (2)	1696 (5)	2185 (4)
Baseline form[b, c]			
700	11730 (48)	31083 (92)	-
Day of collection, marrow donors[b, d]			
732	11734 (48)	0	-
Day 1 of collection, PBSC donors[b, e]			
730	0	28843 (85)	-
Product form, marrow donors[b, f]			
772	11740 (48)	0	-
First product form, PBSC donors[b, g]			
770	0	30753 (91)	

[a] There have been 5450 bone marrow and 16825 PBSC international donors during this time frame.

[b] Completed with FormsNet1 or FormsNet2 (approximately 2004 and forward).

[c] Form 700 collects information related to vital signs, hematology, MTC, infection, pain, and venous access.

[d] Form 732 collects information related to MTC, infection, pain, vital signs, pre-collection hematology, post-collection hematology, and ABO typing.

[e] Form 730 collects information related to MTC, infection, pain, vital signs, pre-apheresis hematology, post-apheresis hematology, and ABO typing.

[f] Form 772 collects information related to marrow product analysis.

[g] Form 770 collects information related to PBSC product analysis.

Abbreviations: NMDP – National Marrow Donor Program; PBSC – Peripheral blood stem cell; CMV – Cytomegalovirus; MTC – Modified toxicity criteria.

Characteristics of domestic related NMDP donors donating between 1987 and September 2019[a]

	Bone marrow	PBSC	Total
Number of donors	41	157	198
Donor age at time of donation			
Median (range)	40 (19-60)	50 (19-61)	49 (19-61)
18 to 29	10 (24)	15 (10)	25 (13)
30 to 39	11 (27)	25 (16)	36 (18)
40 to 49	10 (24)	37 (24)	47 (24)
≥50	10 (24)	80 (51)	90 (45)
Donor race / ethnicity			
Caucasian	21 (51)	101 (64)	122 (62)
Hispanic	7 (17)	18 (11)	25 (13)
Black / African American	9 (22)	15 (10)	24 (12)
Asian / Pacific Islander	2 (5)	10 (6)	12 (6)
Other / multiple race	1 (2)	11 (7)	12 (6)
Decline / unknown	1 (2)	2 (1)	3 (2)
Donor sex			
Male	24 (59)	89 (57)	113 (57)
Female	17 (41)	68 (43)	85 (43)
Number of donations			
1	40 (98)	154 (98)	194 (98)
2	1 (2)	3 (2)	4 (2)
Donor CMV status			
Positive	19 (46)	64 (41)	83 (42)
Negative	20 (49)	71 (45)	91 (46)
Unknown / inconclusive	2 (5)	22 (14)	24 (12)
Year of donation			
2009	0	1 (1)	1 (1)
2012	0	1 (1)	1 (1)
2013	0	5 (3)	5 (3)
2014	1 (2)	2 (1)	3 (2)
2015	1 (2)	6 (4)	7 (4)
2016	4 (10)	11 (7)	15 (8)
2017	15 (37)	34 (22)	49 (25)
2018	13 (32)	55 (35)	68 (34)
2019	7 (17)	42 (27)	49 (25)

Baseline form[b, c]			
700	41 (100)	157 (100)	-
Day of collection, marrow donors[b, d]			
732	41 (100)	0	-
Day 1 of collection, PBSC donors[b, e]			
730	0	99 (63)	-
Product form, marrow donors[b, f]			
772	41 (100)	0	-
First product form, PBSC donors[b, g]			
770	0	155 (99)	-

[a] There have been 1 bone marrow and 13 PBSC international donors during this time frame.

[b] Completed with FormsNet1 or FormsNet2 (approximately 2004 and forward).

[c] Form 700 collects information related to vital signs, hematology, MTC, infection, pain, and venous access.

[d] Form 732 collects information related to MTC, infection, pain, vital signs, pre-collection hematology, post-collection hematology, and ABO typing.

[e] Form 730 collects information related to MTC, infection, pain, vital signs, pre-apheresis hematology, post-apheresis hematology, and ABO typing.

[f] Form 772 collects information related to marrow product analysis.

[g] Form 770 collects information related to PBSC product analysis.

Abbreviations: NMDP – National Marrow Donor Program; PBSC – Peripheral blood stem cell; CMV – Cytomegalovirus; MTC – Modified toxicity criteria.

Characteristics of Related Donors from the RCI-BMT 06-DON (RDSafe) Study

Variable	GMARROW[a] N (%)	MARROW N (%)	PBSC N (%)	Total N (%)
Number of donors	20	404	1256	1680
Donor age at time of donation				
0 to 5	2 (10)	59 (15)	1 (<1)	62 (4)
6 to 10	2 (10)	93 (23)	4 (<1)	99 (6)
11 to 17	5 (25)	115 (28)	13 (1)	133 (8)
18 to 30	3 (15)	59 (15)	122 (10)	184 (11)
31 to 40	1 (5)	21 (5)	149 (12)	171 (10)
41 to 50	2 (10)	22 (5)	278 (22)	302 (18)
51 to 55	2 (10)	12 (3)	221 (18)	235 (14)
56 to 60	3 (15)	14 (3)	212 (17)	229 (14)
61 to 65	0	6 (1)	147 (12)	153 (9)
66 to 70	0	2 (<1)	82 (7)	84 (5)
≥ 71	0	1 (<1)	27 (2)	28 (2)
Median (Range)	21 (4-57)	14 (0-77)	53 (6-79)	48 (0-79)
Donor race/ethnicity				
Caucasian	17 (85)	238 (59)	1048 (83)	1303 (78)
Hispanic	1 (5)	49 (12)	75 (6)	125 (7)
Black / African American	2 (10)	90 (22)	72 (6)	164 (10)
Asian / Pacific Islander	0	11 (3)	39 (3)	50 (3)
American Indian / Alaska Native	0	5 (1)	7 (1)	12 (1)
Other / multiple race	0	8 (2)	9 (1)	17 (1)
Decline / unknown	0	3 (1)	6 (<1)	9 (1)
Donor sex				
Female	11 (55)	194 (48)	568 (45)	773 (46)
Male	9 (45)	210 (52)	688 (55)	907 (54)
First or second donation				
First donation	19 (95)	396 (98)	1226 (98)	1641 (98)
Second donation	1 (5)	8 (2)	30 (2)	39 (2)
Year of donation				
2010	4 (20)	44 (11)	146 (12)	194 (12)
2011	10 (50)	105 (26)	399 (32)	514 (31)
2012	2 (10)	126 (31)	489 (39)	617 (37)
2013	3 (15)	88 (22)	219 (17)	310 (18)
2014	1 (5)	41 (10)	3 (<1)	45 (3)

[a] GCSF-primed marrow

Unrelated Donor HCT Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired samples, recipient only samples and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	39798	12259	7464
Source of data			
CRF	22542 (57)	6191 (51)	4354 (58)
TED	17256 (43)	6068 (49)	3110 (42)
Number of centers	251	224	338
Disease at transplant			
AML	13566 (34)	4431 (36)	2418 (32)
ALL	5866 (15)	1674 (14)	1232 (17)
Other leukemia	1340 (3)	349 (3)	235 (3)
CML	3283 (8)	894 (7)	747 (10)
MDS	6574 (17)	2328 (19)	1031 (14)
Other acute leukemia	408 (1)	138 (1)	80 (1)
NHL	3703 (9)	1012 (8)	606 (8)
Hodgkins Lymphoma	823 (2)	179 (1)	128 (2)
Plasma Cell Disorders, MM	793 (2)	235 (2)	128 (2)
Other malignancies	55 (<1)	13 (<1)	17 (<1)
Breast cancer	7 (<1)	3 (<1)	1 (<1)
SAA	1267 (3)	358 (3)	304 (4)
Inherited abnormalities erythrocyte diff fxn	697 (2)	222 (2)	136 (2)
SCIDs	694 (2)	223 (2)	204 (3)
Inherited abnormalities of platelets	38 (<1)	11 (<1)	10 (<1)
Inherited disorders of metabolism	270 (1)	72 (1)	84 (1)
Histiocytic disorders	354 (1)	93 (1)	78 (1)
Autoimmune disorders	16 (<1)	9 (<1)	5 (<1)
Other	44 (<1)	15 (<1)	20 (<1)
AML Disease status at transplant			
CR1	6997 (52)	2391 (54)	1108 (46)
CR2	2700 (20)	841 (19)	499 (21)
CR3+	259 (2)	73 (2)	53 (2)
Advanced or active disease	3459 (26)	1085 (24)	707 (29)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Missing	147 (1)	41 (1)	47 (2)
ALL Disease status at transplant			
CR1	2842 (48)	871 (52)	516 (42)
CR2	1699 (29)	456 (27)	358 (29)
CR3+	482 (8)	127 (8)	118 (10)
Advanced or active disease	798 (14)	206 (12)	206 (17)
Missing	45 (1)	14 (1)	33 (3)
MDS Disease status at transplant			
Early	1299 (20)	383 (17)	236 (23)
Advanced	4769 (73)	1811 (78)	644 (63)
Missing	465 (7)	121 (5)	140 (14)
NHL Disease status at transplant			
CR1	483 (13)	173 (17)	69 (11)
CR2	684 (19)	177 (18)	101 (17)
CR3+	316 (9)	86 (9)	51 (8)
PR	431 (12)	108 (11)	78 (13)
Advanced	1711 (47)	451 (45)	294 (49)
Missing	46 (1)	8 (1)	10 (2)
Recipient age at transplant			
0-9 years	3515 (9)	937 (8)	943 (13)
10-19 years	3639 (9)	969 (8)	867 (12)
20-29 years	4192 (11)	1199 (10)	907 (12)
30-39 years	4637 (12)	1282 (10)	950 (13)
40-49 years	6197 (16)	1806 (15)	1185 (16)
50-59 years	8253 (21)	2481 (20)	1335 (18)
60-69 years	7889 (20)	2914 (24)	1114 (15)
70+ years	1476 (4)	671 (5)	163 (2)
Median (Range)	47 (0-84)	50 (0-79)	41 (0-79)
Recipient race/ethnicity			
Caucasian, non-Hispanic	33122 (86)	10232 (86)	5529 (85)
African-American, non-Hispanic	1831 (5)	516 (4)	319 (5)
Asian, non-Hispanic	883 (2)	399 (3)	267 (4)
Pacific islander, non-Hispanic	53 (<1)	19 (<1)	16 (<1)
Native American, non-Hispanic	147 (<1)	54 (<1)	26 (<1)
Hispanic	2375 (6)	631 (5)	339 (5)
Other	44 (<1)	26 (<1)	21 (<1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Unknown	1343 (N/A)	382 (N/A)	947 (N/A)
Recipient sex			
Male	23241 (58)	7205 (59)	4411 (59)
Female	16557 (42)	5054 (41)	3053 (41)
Karnofsky score			
10-80	13300 (33)	4420 (36)	2281 (31)
90-100	24957 (63)	7241 (59)	4624 (62)
Missing	1541 (4)	598 (5)	559 (7)
HLA-A B DRB1 groups - low resolution			
<=3/6	22 (<1)	32 (<1)	1 (<1)
4/6	216 (1)	83 (1)	35 (1)
5/6	5551 (14)	1458 (14)	1056 (15)
6/6	33446 (85)	9188 (85)	5845 (84)
Unknown	563 (N/A)	1498 (N/A)	527 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	845 (2)	81 (1)	32 (1)
6/8	1667 (4)	115 (1)	125 (3)
7/8	7742 (20)	1454 (18)	1030 (22)
8/8	28076 (73)	6626 (80)	3395 (74)
Unknown	1468 (N/A)	3983 (N/A)	2882 (N/A)
HLA-DPB1 Match			
Double allele mismatch	9305 (30)	759 (24)	381 (28)
Single allele mismatch	16827 (54)	1585 (51)	711 (52)
Full allele matched	5008 (16)	779 (25)	273 (20)
Unknown	8658 (N/A)	9136 (N/A)	6099 (N/A)
High resolution release score			
No	11077 (28)	12118 (99)	7291 (98)
Yes	28721 (72)	141 (1)	173 (2)
KIR typing available			
No	26106 (66)	12174 (99)	7425 (99)
Yes	13692 (34)	85 (1)	39 (1)
Graft type			
Marrow	14829 (37)	4153 (34)	3357 (45)
PBSC	24923 (63)	7973 (65)	4081 (55)
BM+PBSC	11 (<1)	6 (<1)	2 (<1)
PBSC+UCB	19 (<1)	117 (1)	2 (<1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Others	16 (<1)	10 (<1)	22 (<1)
Conditioning regimen			
Myeloablative	25417 (64)	7348 (60)	4974 (67)
RIC/Nonmyeloablative	14204 (36)	4868 (40)	2389 (32)
TBD	177 (<1)	43 (<1)	101 (1)
Donor age at donation			
To Be Determined/NA	235 (1)	1392 (11)	77 (1)
0-9 years	6 (<1)	29 (<1)	1 (<1)
10-19 years	1105 (3)	397 (3)	157 (2)
20-29 years	17569 (44)	5031 (41)	2819 (38)
30-39 years	11434 (29)	3099 (25)	2318 (31)
40-49 years	7230 (18)	1763 (14)	1581 (21)
50+ years	2219 (6)	548 (4)	511 (7)
Median (Range)	31 (0-69)	30 (0-109)	33 (7-67)
Donor/Recipient CMV serostatus			
+/+	9790 (25)	3362 (28)	1809 (25)
+/-	4731 (12)	1591 (13)	939 (13)
-/+	13067 (33)	3680 (31)	2305 (32)
-/-	11653 (30)	3208 (27)	2043 (29)
CB - recipient +	1 (<1)	11 (<1)	0
CB - recipient -	1 (<1)	4 (<1)	0
CB - recipient CMV unknown	0	1 (<1)	0
Unknown	555 (N/A)	402 (N/A)	368 (N/A)
GvHD Prophylaxis			
Ex vivo T-cell depletion	1114 (3)	288 (2)	309 (4)
CD34 selection	723 (2)	313 (3)	127 (2)
Post-CY + other(s)	1071 (3)	643 (5)	171 (2)
Post-CY alone	72 (<1)	31 (<1)	19 (<1)
Tacrolimus + MMF +- others	4732 (12)	1276 (10)	619 (8)
Tacrolimus + MTX +- others (except MMF)	17262 (43)	5492 (45)	2083 (28)
Tacrolimus + others (except MTX, MMF)	2077 (5)	794 (6)	297 (4)
Tacrolimus alone	962 (2)	327 (3)	120 (2)
CSA + MMF +- others (except Tacrolimus)	2654 (7)	637 (5)	613 (8)
CSA + MTX +- others (except Tacrolimus, MMF)	6541 (16)	1701 (14)	2276 (30)
CSA + others (except Tacrolimus, MTX, MMF)	996 (3)	303 (2)	286 (4)
CSA alone	466 (1)	115 (1)	293 (4)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Other GVHD prophylaxis	702 (2)	218 (2)	123 (2)
Missing	426 (1)	121 (1)	128 (2)
Donor/Recipient sex match			
Male-Male	16408 (41)	4862 (40)	2936 (40)
Male-Female	10010 (25)	2981 (25)	1703 (23)
Female-Male	6681 (17)	2171 (18)	1421 (19)
Female-Female	6450 (16)	1941 (16)	1307 (18)
CB - recipient M	10 (<1)	68 (1)	0
CB - recipient F	12 (<1)	57 (<1)	2 (<1)
Unknown	227 (N/A)	179 (N/A)	95 (N/A)
Year of transplant			
1986-1990	349 (1)	45 (<1)	85 (1)
1991-1995	1795 (5)	448 (4)	619 (8)
1996-2000	3149 (8)	1111 (9)	902 (12)
2001-2005	5001 (13)	988 (8)	1437 (19)
2006-2010	9204 (23)	1853 (15)	1418 (19)
2011-2015	12925 (32)	3555 (29)	1805 (24)
2016-2019	7375 (19)	4259 (35)	1198 (16)
Follow-up among survivors, Months			
N Eval	17027	5940	3016
Median (Range)	60 (0-365)	36 (0-336)	49 (1-350)

Unrelated Cord Blood Transplant Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired, recipient only and cord blood only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006-recipient only), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	5444	1351	1276
Source of data			
CRF	4129 (76)	1025 (76)	858 (67)
TED	1315 (24)	326 (24)	418 (33)
Number of centers	146	132	195
Disease at transplant			
AML	2044 (38)	451 (33)	409 (32)
ALL	1121 (21)	287 (21)	289 (23)
Other leukemia	91 (2)	26 (2)	24 (2)
CML	117 (2)	33 (2)	31 (2)
MDS	520 (10)	143 (11)	106 (8)
Other acute leukemia	85 (2)	18 (1)	22 (2)
NHL	378 (7)	83 (6)	85 (7)
Hodgkins Lymphoma	92 (2)	25 (2)	22 (2)
Plasma Cell Disorders, MM	35 (1)	10 (1)	7 (1)
Other malignancies	10 (<1)	0	1 (<1)
SAA	89 (2)	31 (2)	24 (2)
Inherited abnormalities erythrocyte diff fxn	157 (3)	48 (4)	31 (2)
SCIDs	236 (4)	71 (5)	97 (8)
Inherited abnormalities of platelets	17 (<1)	4 (<1)	5 (<1)
Inherited disorders of metabolism	332 (6)	93 (7)	84 (7)
Histiocytic disorders	100 (2)	26 (2)	33 (3)
Autoimmune disorders	9 (<1)	0	1 (<1)
Other	11 (<1)	2 (<1)	5 (<1)
AML Disease status at transplant			
CR1	1048 (51)	242 (54)	199 (49)
CR2	569 (28)	114 (25)	116 (28)
CR3+	50 (2)	6 (1)	12 (3)
Advanced or active disease	370 (18)	86 (19)	80 (20)
Missing	7 (<1)	2 (<1)	2 (<1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
ALL Disease status at transplant			
CR1	507 (45)	122 (43)	130 (45)
CR2	421 (38)	108 (38)	103 (36)
CR3+	120 (11)	39 (14)	31 (11)
Advanced or active disease	72 (6)	18 (6)	25 (9)
Missing	1 (<1)	0	0
MDS Disease status at transplant			
Early	163 (31)	36 (26)	48 (46)
Advanced	323 (62)	99 (70)	46 (44)
Missing	33 (6)	6 (4)	11 (10)
NHL Disease status at transplant			
CR1	59 (16)	5 (6)	16 (19)
CR2	71 (19)	18 (22)	24 (29)
CR3+	42 (11)	10 (12)	9 (11)
PR	65 (17)	12 (14)	11 (13)
Advanced	138 (37)	37 (45)	23 (27)
Missing	0	1 (1)	1 (1)
Recipient age at transplant			
0-9 years	1635 (30)	499 (37)	474 (37)
10-19 years	705 (13)	145 (11)	175 (14)
20-29 years	515 (9)	96 (7)	104 (8)
30-39 years	526 (10)	119 (9)	123 (10)
40-49 years	578 (11)	132 (10)	116 (9)
50-59 years	763 (14)	163 (12)	150 (12)
60-69 years	629 (12)	170 (13)	125 (10)
70+ years	93 (2)	27 (2)	9 (1)
Median (Range)	27 (0-83)	23 (0-77)	19 (0-78)
Recipient race/ethnicity			
Caucasian, non-Hispanic	3033 (59)	802 (62)	704 (62)
African-American, non-Hispanic	783 (15)	181 (14)	147 (13)
Asian, non-Hispanic	315 (6)	85 (7)	81 (7)
Pacific islander, non-Hispanic	27 (1)	3 (<1)	14 (1)
Native American, non-Hispanic	36 (1)	6 (<1)	13 (1)
Hispanic	981 (19)	208 (16)	174 (15)
Other	0	1 (<1)	1 (<1)
Unknown	269 (N/A)	65 (N/A)	142 (N/A)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Recipient sex			
Male	3007 (55)	783 (58)	736 (58)
Female	2437 (45)	568 (42)	540 (42)
Karnofsky score			
10-80	1408 (26)	332 (25)	311 (24)
90-100	3885 (71)	928 (69)	886 (69)
Missing	151 (3)	91 (7)	79 (6)
HLA-A B DRB1 groups - low resolution			
<=3/6	73 (1)	33 (3)	8 (1)
4/6	2139 (41)	433 (41)	444 (37)
5/6	2324 (45)	430 (41)	566 (48)
6/6	666 (13)	150 (14)	168 (14)
Unknown	242 (N/A)	305 (N/A)	90 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	2560 (56)	440 (57)	510 (54)
6/8	1104 (24)	172 (22)	237 (25)
7/8	621 (14)	101 (13)	134 (14)
8/8	304 (7)	53 (7)	70 (7)
Unknown	855 (N/A)	585 (N/A)	325 (N/A)
HLA-DPB1 Match			
Double allele mismatch	725 (40)	55 (41)	55 (37)
Single allele mismatch	924 (51)	67 (50)	76 (52)
Full allele matched	169 (9)	12 (9)	16 (11)
Unknown	3626 (N/A)	1217 (N/A)	1129 (N/A)
High resolution release score			
No	3954 (73)	1301 (96)	1262 (99)
Yes	1490 (27)	50 (4)	14 (1)
KIR typing available			
No	4194 (77)	1345 (>99)	1264 (99)
Yes	1250 (23)	6 (<1)	12 (1)
Graft type			
UCB	5135 (94)	1234 (91)	1213 (95)
BM+UCB	1 (<1)	0	0
PBSC+UCB	279 (5)	117 (9)	54 (4)
Others	29 (1)	0	9 (1)
Number of cord units			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
1	4572 (84)	0	1066 (84)
2	870 (16)	0	210 (16)
3	2 (<1)	0	0
Unknown	0 (N/A)	1351 (N/A)	0 (N/A)
Conditioning regimen			
Myeloablative	3579 (66)	870 (64)	828 (65)
RIC/Nonmyeloablative	1855 (34)	476 (35)	444 (35)
TBD	10 (<1)	5 (<1)	4 (<1)
Donor age at donation			
To Be Determined/NA	173 (3)	86 (6)	72 (6)
0-9 years	4843 (89)	1055 (78)	1117 (88)
10-19 years	254 (5)	116 (9)	51 (4)
20-29 years	50 (1)	30 (2)	6 (<1)
30-39 years	50 (1)	29 (2)	13 (1)
40-49 years	33 (1)	16 (1)	5 (<1)
50+ years	41 (1)	19 (1)	12 (1)
Median (Range)	3 (0-72)	5 (0-73)	3 (0-72)
Donor/Recipient CMV serostatus			
+/+	1259 (23)	273 (20)	260 (20)
+/-	543 (10)	129 (10)	116 (9)
-/+	1011 (19)	249 (18)	238 (19)
-/-	681 (13)	165 (12)	173 (14)
CB - recipient +	1112 (20)	285 (21)	246 (19)
CB - recipient -	755 (14)	201 (15)	198 (16)
CB - recipient CMV unknown	83 (2)	49 (4)	45 (4)
GvHD Prophylaxis			
Ex vivo T-cell depletion	28 (1)	9 (1)	4 (<1)
CD34 selection	219 (4)	93 (7)	45 (4)
Post-CY + other(s)	7 (<1)	6 (<1)	2 (<1)
Tacrolimus + MMF +- others	1476 (27)	357 (26)	210 (16)
Tacrolimus + MTX +- others (except MMF)	202 (4)	53 (4)	57 (4)
Tacrolimus + others (except MTX, MMF)	213 (4)	55 (4)	48 (4)
Tacrolimus alone	135 (2)	43 (3)	23 (2)
CSA + MMF +- others (except Tacrolimus)	2549 (47)	557 (41)	636 (50)
CSA + MTX +- others (except Tacrolimus, MMF)	93 (2)	27 (2)	38 (3)
CSA + others (except Tacrolimus, MTX, MMF)	313 (6)	109 (8)	138 (11)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CSA alone	56 (1)	16 (1)	44 (3)
Other GVHD prophylaxis	127 (2)	16 (1)	19 (1)
Missing	26 (<1)	10 (1)	12 (1)
Donor/Recipient sex match			
CB - recipient M	3007 (55)	783 (58)	734 (58)
CB - recipient F	2437 (45)	568 (42)	540 (42)
CB - recipient sex unknown	0	0	2 (<1)
Year of transplant			
1996-2000	0	2 (<1)	4 (<1)
2001-2005	105 (2)	82 (6)	30 (2)
2006-2010	1757 (32)	406 (30)	438 (34)
2011-2015	2574 (47)	494 (37)	575 (45)
2016-2019	1008 (19)	367 (27)	229 (18)
Follow-up among survivors, Months			
N Eval	2649	729	653
Median (Range)	60 (1-168)	47 (3-192)	51 (1-217)

Related Donor HCT Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired, recipient only and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	7714	1121	483
Source of data			
CRF	2971 (39)	349 (31)	219 (45)
TED	4743 (61)	772 (69)	264 (55)
Number of centers	86	68	52
Disease at transplant			
AML	2519 (33)	367 (33)	140 (29)
ALL	1219 (16)	215 (19)	83 (17)
Other leukemia	170 (2)	30 (3)	18 (4)
CML	256 (3)	26 (2)	11 (2)
MDS	1294 (17)	182 (16)	85 (18)
Other acute leukemia	102 (1)	16 (1)	3 (1)
NHL	747 (10)	102 (9)	65 (13)
Hodgkins Lymphoma	161 (2)	24 (2)	18 (4)
Plasma Cell Disorders, MM	230 (3)	33 (3)	18 (4)
Other malignancies	21 (<1)	0	0
Breast cancer	1 (<1)	0	0
SAA	346 (4)	40 (4)	13 (3)
Inherited abnormalities erythrocyte diff fxn	413 (5)	51 (5)	18 (4)
SCIDs	160 (2)	28 (2)	7 (1)
Inherited abnormalities of platelets	9 (<1)	0	0
Inherited disorders of metabolism	12 (<1)	2 (<1)	1 (<1)
Histiocytic disorders	38 (<1)	5 (<1)	2 (<1)
Autoimmune disorders	7 (<1)	0	1 (<1)
Other	9 (<1)	0	0
AML Disease status at transplant			
CR1	1570 (62)	243 (66)	86 (61)
CR2	391 (16)	42 (11)	15 (11)
CR3+	28 (1)	6 (2)	1 (1)
Advanced or active disease	520 (21)	73 (20)	36 (26)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Missing	10 (<1)	3 (1)	2 (1)
ALL Disease status at transplant			
CR1	765 (63)	136 (63)	56 (67)
CR2	326 (27)	49 (23)	16 (19)
CR3+	62 (5)	9 (4)	6 (7)
Advanced or active disease	66 (5)	20 (9)	5 (6)
Missing	0	1 (<1)	0
MDS Disease status at transplant			
Early	203 (16)	21 (12)	16 (19)
Advanced	1051 (81)	151 (83)	67 (79)
Missing	40 (3)	10 (5)	2 (2)
NHL Disease status at transplant			
CR1	126 (17)	19 (19)	11 (17)
CR2	141 (19)	20 (20)	11 (17)
CR3+	84 (11)	9 (9)	2 (3)
PR	65 (9)	13 (13)	7 (11)
Advanced	324 (44)	40 (40)	34 (52)
Missing	2 (<1)	0	0
Recipient age at transplant			
0-9 years	754 (10)	91 (8)	27 (6)
10-19 years	866 (11)	90 (8)	39 (8)
20-29 years	632 (8)	123 (11)	41 (8)
30-39 years	589 (8)	98 (9)	43 (9)
40-49 years	1006 (13)	150 (13)	66 (14)
50-59 years	1785 (23)	253 (23)	115 (24)
60-69 years	1817 (24)	278 (25)	139 (29)
70+ years	265 (3)	38 (3)	13 (3)
Median (Range)	50 (0-78)	50 (0-76)	53 (0-77)
Recipient race/ethnicity			
Caucasian, non-Hispanic	4973 (67)	622 (59)	323 (70)
African-American, non-Hispanic	906 (12)	118 (11)	45 (10)
Asian, non-Hispanic	342 (5)	90 (9)	20 (4)
Pacific islander, non-Hispanic	26 (<1)	3 (<1)	1 (<1)
Native American, non-Hispanic	29 (<1)	2 (<1)	1 (<1)
Hispanic	1119 (15)	214 (20)	71 (15)
Unknown	319 (N/A)	72 (N/A)	22 (N/A)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Recipient sex			
Male	4528 (59)	665 (59)	285 (59)
Female	3186 (41)	456 (41)	198 (41)
Karnofsky score			
10-80	2680 (35)	462 (41)	194 (40)
90-100	4846 (63)	628 (56)	266 (55)
Missing	188 (2)	31 (3)	23 (5)
Graft type			
Marrow	2221 (29)	259 (23)	137 (28)
PBSC	5443 (71)	841 (75)	336 (70)
BM+PBSC	6 (<1)	4 (<1)	0
BM+UCB	26 (<1)	7 (1)	1 (<1)
PBSC+UCB	0	0	8 (2)
Others	18 (<1)	10 (1)	0
Conditioning regimen			
Myeloablative	4418 (57)	649 (58)	257 (53)
RIC/Nonmyeloablative	3256 (42)	464 (41)	220 (46)
TBD	40 (1)	8 (1)	6 (1)
Donor age at donation			
To Be Determined/NA	18 (<1)	4 (<1)	3 (1)
0-9 years	535 (7)	60 (5)	21 (4)
10-19 years	770 (10)	95 (8)	38 (8)
20-29 years	980 (13)	151 (13)	60 (12)
30-39 years	1004 (13)	178 (16)	79 (16)
40-49 years	1247 (16)	185 (17)	69 (14)
50+ years	3160 (41)	448 (40)	213 (44)
Median (Range)	45 (0-81)	44 (0-79)	46 (0-76)
Donor/Recipient CMV serostatus			
+/+	3114 (41)	509 (46)	201 (43)
+/-	872 (11)	87 (8)	48 (10)
-/+	1890 (25)	264 (24)	110 (24)
-/-	1719 (23)	239 (22)	104 (22)
Unknown	119 (N/A)	22 (N/A)	20 (N/A)
GvHD Prophylaxis			
Ex vivo T-cell depletion	93 (1)	28 (2)	8 (2)
CD34 selection	123 (2)	32 (3)	9 (2)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Post-CY + other(s)	1568 (20)	215 (19)	107 (22)
Post-CY alone	34 (<1)	8 (1)	3 (1)
Tacrolimus + MMF +- others	793 (10)	70 (6)	27 (6)
Tacrolimus + MTX +- others (except MMF)	3165 (41)	392 (35)	217 (45)
Tacrolimus + others (except MTX, MMF)	619 (8)	224 (20)	49 (10)
Tacrolimus alone	64 (1)	6 (1)	2 (<1)
CSA + MMF +- others (except Tacrolimus)	206 (3)	27 (2)	7 (1)
CSA + MTX +- others (except Tacrolimus, MMF)	623 (8)	76 (7)	31 (6)
CSA + others (except Tacrolimus, MTX, MMF)	80 (1)	9 (1)	2 (<1)
CSA alone	68 (1)	9 (1)	1 (<1)
Other GVHD prophylaxis	118 (2)	12 (1)	8 (2)
Missing	160 (2)	13 (1)	12 (2)
Donor/Recipient sex match			
Male-Male	2525 (33)	399 (36)	159 (33)
Male-Female	1662 (22)	219 (20)	97 (20)
Female-Male	1978 (26)	253 (23)	120 (25)
Female-Female	1516 (20)	233 (21)	97 (20)
CB - recipient M	20 (<1)	12 (1)	6 (1)
CB - recipient F	8 (<1)	4 (<1)	4 (1)
Unknown	5 (N/A)	1 (N/A)	0 (N/A)
Year of transplant			
2006-2010	570 (7)	66 (6)	49 (10)
2011-2015	3617 (47)	469 (42)	194 (40)
2016-2019	3527 (46)	586 (52)	240 (50)
Follow-up among survivors, Months			
N Eval	4876	688	306
Median (Range)	33 (1-131)	24 (2-124)	26 (2-124)

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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

TO: Donor Health and Safety Working Committee Members

FROM: Bronwen Shaw, MD, PhD; Scientific Director and Dennis Confer, MD; Ex Officio Senior Advisor for the Donor Health and Safety Working Committee

RE: Studies in Progress Summary

DS05-02d: RDSafe-d: HRQoL for related adult donors compared to unrelated adult donors (G Switzer/M Pulsipher) This study compared health related quality of life differences between related and unrelated adult donors. Currently this study is in manuscript preparation with a goal of submission by July 2020. No update.

DS05-02g: RDSafe-g: Late toxicities and SAE for related donors (M Pulsipher) This analysis will describe any late toxicities or severe adverse events for the related donors followed in RDSafe. This study completed data collection in September 2015 and is in analysis with a goal of submission by July 2020. No update.

DS13-02: Clinical impact of ABO incompatibility on alloHCT (G Murthy/B Shaw) The primary aim of this this study is to examine the impact of ABO mismatching (match, major mismatch, minor mismatch, bidirectional mismatch) on overall survival; secondary effects to examine are the association of ABO matching on graft manipulation method (none vs plasma removal/depletion vs red cell depletion method vs other) and the impact of graft manipulation on infused cell count (CD34/TNC) and transplant outcome. This study is currently in protocol development with a goal of analysis by July 2020. No update.

DS16-01: One vs two day apheresis in URD (J Hsu/J Wingard) This study proposes to analyze the outcomes of PBSC donors by one-day vs. two-day collections. The manuscript has been submitted. No update.

DS16-S2: Survey of the screening and management for clonal disorders of hematopoiesis in related ALLO donors (M Seftel) The primary aims of this survey are to 1) establish whether HCT centers that evaluate related allogeneic donors screen for CDH; 2) understand, if CDH is detected, whether the donor is deferred; 3) understand what other steps donor centers take in order to manage the donor with a CDH. The data has been analyzed and an abstract submitted to EBMT. The manuscript has been submitted. No update.

DS17-01 The impact of donor body mass index on collection of Filgrastim (G-CSF) mobilized peripheral blood progenitor cells from unrelated donors (N Farhadfar/J Hsu/JR Wingard) The primary aim of this study is to evaluate the impact of donor BMI on G-CSF mobilized peripheral blood progenitor cells yield in healthy volunteer donors. The secondary objective of this study is (1) to evaluate whether overweight and obese healthy unrelated donors elicit an appropriate marrow response with a lower G-CSF dose than current standard, and (2) to examine whether there is an 'upper limit' G-CSF dose above which

overweight or obese donors have already provided sufficient cells, but experience more side effects. The manuscript was accepted to Blood Advances. No update.

DS17-02 Impact of Collection of Autologous Blood prior to Bone Marrow Harvest on Unrelated Donor Heath and Outcome (N Farhadfar/JR Wingard/H Murthy) The aim of this study is to assess the impact of autologous blood transfusion on donor outcomes. This manuscript has been submitted. No update.

DS18-01 To quantify age-related clonal hematopoiesis in healthy marrow and blood donors that may affect the clinical outcome of recipients following hematopoietic stem cell transplantation (HCT) (T Druley) This sample-based study uses donor whole blood, recipient blood/marrow pre-HCT, and recipient's blood/marrow post-HCT following engraftment to determine whether genetic alterations found in the donor are transmitted to the recipient' post-HCT. This study is in collaboration with the Druley lab at Washington University School of Medicine. The manuscript was accepted to Science Translational Medicine. No update.
Wong WH, Bhatt S, Trinkaus K, Pusic I, Elliott K, Mahajan N, Wan F, Switzer GE, Confer DL, DiPersio J, Pulsipher MA, Shah NN, Sees J, Bystry A, Blundell JR, Shaw BE, Druley TE. Engraftment of rare, pathogenic donor hematopoietic mutations in unrelated hematopoietic stem cell transplantation. Science Translational Medicine. DOI: 10.1126/scitranslmed.aax6249. Epub 2020 Jan 15.

DS18-02 Factors Affecting CD34+ Cell Yields at Subsequent Marrow/PBSC Collections (SR Panch/DF Stroncek/B Savani/NN Shah) This study examines the impact of inter-donation intervals on CD34+ cell and mononuclear cell (PBSC) or TNC (BM) yields of unrelated NMDP donors making two PBSC donations, or two BM donations. Presented at ASH 2020. This study is currently in manuscript preparation with the goal to be submitted by July 2020. Update to be given at the meeting.

DS19-01 Effect of Donor Graft Cryopreservation on Allogeneic Transplant Recipient Outcomes (J Hsu/N Farhadfar/H Murthy/J Wingard) This study examines the effect of donor graft cryopreservation on transplant outcomes in allogeneic transplant recipients. This study is currently in data file preparation with a goal to be in manuscript preparation by July 2020. No update.

DS19-02 The Impact of pre-apheresis Health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome (N Farhadfar/J Wingard/G Switzer) This study aims to determine the impact of pre-procedural health related quality of life(HRQoL) on peri-collection pain and acute toxicities experienced in PBSC donors, and to determine the impact of pre-apherisis HRQoL on post-donation complete recovery. A draft protocol has been received for this study, and the goal is to begin data file preparation by July 2020. No update.

Proposal: 1911-16

Title:
Acute Toxicities of Bone Marrow Donation in Donors with Sickle Cell Trait

Nosha Farhadfar, University of Florida
John R. Wingard, University of Florida

Hypothesis:
Donors with and without sickle cell trait (SCT) experience roughly the same levels of peri-collection pain, toxicities and adverse events.

Specific aims:
The aim of this study is to compare stem cell donation associated toxicities and adverse events between donors with and without sickle cell trait.
Primary aim:

- Incidence of grades 2 to 4 skeletal pain on day 2

Secondary aims:

- Incidence of grades 2 to 4 skeletal pain, fatigue, and highest toxicity level across selected body symptoms frequently associated with collection
- Time to recovery from donation which is defined as the time in days from the marrow collection to report of complete recovery
- Incidence of serious adverse events defined as one that is fatal or immediately life threatening, or that causes prolonged hospitalization
- Incidence of vascular events
- TNC/mL harvested

Scientific impact:
To ensure donor and recipient safety as well as the quality of the cellular product, the Worldwide Network for Blood and Marrow Transplantation (WBMT) and National marrow donor program (NMDP) have established an eligibility criteria and recommendations for evaluation of unrelated donors (1,2). Based on the World Marrow Donor Association (WMDA), subjects with sickle cell β-thalassemia minor may be suitable for BM donation. However, the recommendation is to avoid G-CSF in donors with sickle cell β-thalassemia, sickle cell disease, or other complex sickle hemoglobinopathies which may lead to development of sickle cell crisis (2). Based on current NMDP recommendation individuals with sickle cell trait are eligible to donate bone marrow or peripheral blood. Although sickle cell trait (SCT) is a relatively benign condition, there are reports of veno-occlusive crisis during conditions of severe stress (3). Current literature regarding stem cell donation-associated pain and toxicity in donors with SCT is limited to a few relatively small studies with methodological weaknesses including lack of standardized pain scales or CTCAE elements. In a single center case-control study, Kang et al evaluated feasibility and safety of stem cell mobilization in 8 donors with SCT and 8 control subjects. The study concluded that G-CSF mobilized peripheral blood stem cell (PBSC) collection appears to be safe in donors with SCT (4). More recently, Alkhabori et al compared safety of stem cell mobilization between 12 donors with SCT and matched control cohort without SCT. Based on the results, (PBSC) mobilization using G-CSF was well tolerated among the SCT donors and collection associated adverse events were not different than in non-SCT donors (5). In a single center experience from the Eastern Mediterranean region including 11 G-CSF mobilized

PBSC donors with SCT, there was no significant difference in donors with and without SCT in regard to early and late adverse events (6). No study to date evaluate donation associated toxicities in SCT bone marrow donors.

Scientific justification:
There is a paucity of data regarding safety and efficacy of stem cell donation in donors with SCT. This study sought to explore donor symptoms and adverse events in donors with SCT.

Patient eligibility population:
Unrelated or related donors with SCT who donated marrow will be included. Donors who made 2 or more donations, or who received G-CSF and then donated bone marrow will be excluded.
This is a matched case control study. Therefore, age and gender matched donors without sickle cell trait (controls) will be included.

Data requirements:
Donor-related:
- Gender
- Age
- Ethnicity
- Actual body weight
- Body mass index (BMI)

Donation-related variables:
- Volume of marrow collected per donor weight, mL/kg
- Total volume of marrow collected mL
- Type of anesthesia for BM donors
- Year of donation

Sample requirements:
None

Study design:
This is a matched case control study comparing the stem cell donation associated adverse events between donors with sickle cell trait (cases) and age and gender matched donors without sickle cell trait (controls). A variety of donor and collection characteristics by product type with be quantified. Variables will be compared between cases and controls using the Pearson χ^2 test for categorical variables and the Kruskal-Wallis test for continuous variables. Logistic regression will be used to compare the two cohorts for the incidence of bone pain, highest toxicity, and fatigue, and adverse events after adjusting for donor characteristics and baseline measurements. Univariate probabilities of complete recovery from donation were calculated using the Kaplan-Meier estimator.

Non-CIBMTR data source:
Related donor with sickle cell trait (if any) from RDSafe database

Conflicts of interest:
None

References:

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6. Gereklioglu C, Asma S, Korur A, Tepebaşı S, Aytan P, Yeral M, et al. Granulocyte-colony stimulating factor administration among hemoglobin S trait donors: A single center experience from the Eastern Mediterranean region. J Clin Apher. 2018 Feb;33(1):65–71.

NMDP unrelated bone marrow donors in the United States between 2009 and 2018[a,b]

	Sickle Cell Hemoglobin Test Result	
Characteristic	**Positive**	**Negative**
No. of patients	95	7476
Number of donations - no. (%)		
1	94 (98.9)	7186 (96.1)
2	1 (1.1)	285 (3.8)
3	0	5 (0.1)
Age at collection - no. (%)		
Median (range)	34.7 (19.2-57.6)	29.2 (18.5-61)
18 - 30	35 (36.8)	4271 (57.1)
31 - 49	52 (54.7)	2836 (37.9)
≥ 50	8 (8.4)	369 (4.9)
Sex - no. (%)		
Female	48 (50.5)	2796 (37.4)
Male	47 (49.5)	4680 (62.6)
Race – no. (%)		
African American	62 (65.3)	493 (6.6)
Caucasian	8 (8.4)	4687 (62.7)
Other	25 (26.3)	2296 (30.7)
Adverse event form submitted - no. (%)		
No	94 (98.9)	7041 (94.2)
Yes	1 (1.1)	435 (5.8)
Serious adverse event - no. (%)	1 (1.1)	118 (1.6)
Serious adverse event related to the donation process - no. (%)	1 (1.1)	109 (1.5)
Collection year - no. (%)		
2009	0	216 (2.9)
2010	9 (9.5)	707 (9.5)
2011	14 (14.7)	739 (9.9)
2012	13 (13.7)	916 (12.3)
2013	16 (16.8)	901 (12.1)
2014	3 (3.2)	884 (11.8)
2015	10 (10.5)	779 (10.4)
2016	9 (9.5)	797 (10.7)
2017	7 (7.4)	810 (10.8)
2018	14 (14.7)	727 (9.7)
Pain data available		
Baseline	95 (100)	7464 (99.8)
2 days	91 (95.8)	6864 (91.8)
1 week	86 (90.5)	6340 (84.8)
1 month	89 (93.7)	6758 (90.4)
6 months	75 (78.9)	6048 (80.9)
Toxicity data available		
Baseline	94 (98.9)	7463 (99.8)
2 days	91 (95.8)	6863 (91.8)
1 week	86 (90.5)	6340 (84.8)

Characteristic	Sickle Cell Hemoglobin Test Result	
	Positive	**Negative**
1 month	89 (93.7)	6757 (90.4)
6 months	75 (78.9)	6047 (80.9)

[a] Still need to exclude patients with more than one donation

[b] There were 13 PBSC donors with a positive Sickle Cell hemoglobin test, and 21432 with a negative Sickle Cell hemoglobin test