



A G E N D A

CIBMTR WORKING COMMITTEE FOR DONOR HEALTH AND SAFETY

Orlando, FL

Wednesday, February 15, 2023, 1:00 p.m. – 3:00 p.m. (EST)

Co-Chair:	Galen Switzer, PhD, University of Pittsburgh Medical Center, 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
Co-Chair:	Sandhya Panch, MD, MPH, University of Washington and Seattle Cancer Care Alliance; Seattle, WA Telephone: 206-606-4336; E-mail: srpanch@uw.edu
Scientific Director:	Heather Stefanski, MD, PhD, Be The Match/NMDP, Minneapolis, MN; Telephone: 763-406-8495; E-mail: hstefans@nmdp.org
Statistical Director:	Brent Logan, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-955-8849; E-mail: blogan@mcw.edu
Statistician:	Stephanie Bo-Subait, MPH, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8515; E-mail: sbosuba2@nmdp.org

1. Introduction

- a. 2022 Tandem DSWC session minutes ([Attachment 1](#))

2. Accrual Summary ([Attachment 2](#))

3. Presentations, Published or Submitted Papers

- a. **DS13-02** Murthy GSG, Logan BR, Bo-Subait S, Beitinjaneh A, Devine S, Farhadfar N, Gowda L, Hashmi S, Lazarus H, Nathan S, Sharma A, Yared JA, Stefanski HE, Pulsipher MA, Hsu JW, Switzer GE, Panch SR, Shaw BE. Association of ABO mismatch with the outcomes of allogeneic hematopoietic cell transplantation for acute leukemia. ***Accepted to American Journal of Hematology.***
- b. **DS19-02** Farhadfar N, Ahn KW, Bo-Subait S, Logan B, Stefanski HE, Hsu JW, Panch S, Confer D, Liu H, Badawy SM, Beitinjaneh A, Diaz MA, Hildebrandt GC, Kelkar AH, Lazarus HM, Murthy HS, Preussler JM, Schears RM, Sharma A, Poel M, Bruce JG, Pulsipher MA, Shaw BE, Wingard JR, Switzer GE. The impact of pre-apheresis Health Related Quality of Life on peripheral blood progenitor cell yield and donor's health and outcome: Secondary analysis of Patient-Reported Outcome Data from the RDSafe and BMT CTN 0201 Clinical Trials. ***Transplantation and Cellular Therapy. 2022 Sep 1; 28(9):603.e1-603.e7. doi:10.1016/j.jtct.2022.05.042. Epub 2022 Jun 7. PMC9427696. Published.***

4. Studies in Progress ([Attachment 3](#))

- a. **DS20-01** Acute toxicities of bone marrow donation in donors with sickle cell trait (Nosha Farhadfar; John Wingard) **Data File Preparation.**

5. Review paper

- a. Reducing the Risk of Transmission of Donor Derived Malignancy: Consensus Guidelines for Donor Genetic Screening Prior to Allogeneic Stem Cell Transplant and Detection of Leukemia Origin in Relapse After Transplant (Lacey Scott Williams; Catherine Lai; Lucy Godley)

6. Future/Proposed studies

- a. **PROP 2210-205** Unrelated donor collection efficiency and adverse events during the COVID-19 pandemic (Matthew Seftel; David Allan) ([Attachment 4](#))

Proposals dropped due to feasibility or overlap with existing studies

- a. **PROP 2210-143** Understanding the fates of cryopreserved unrelated stem cell grafts since the start of the COVID-19 pandemic (Joshua A. Fein; Alexandra Gomez Arteaga)
- b. **PROP 2210-150** Evaluation of Hematopoietic Stem Cell Donor Characteristics and Factors Associated with Donor Adverse Outcomes in This Era (Kehinde Adekola; Oluwatobi Odetola)
- c. **PROP 2210-204** Implications of umbilical cord blood-derived pathogenic mutations revealed by pre- and-post transplant genomics assessment (Satyajit Kosuri; Gregory Roloff)

7. Other business

- a. **Additional business items** As needed and as time allows for discussion.



MINUTES

CIBMTR WORKING COMMITTEE FOR DONOR HEALTH AND SAFETY

Salt Lake City, Utah

Monday, April 25, 2022, 12:15 – 1:45 pm

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
Co-Chair:	Sandhya Panch, MD, MPH, University of Washington and Seattle Cancer Care Alliance; Seattle, WA Telephone: 206-606-4336; E-mail: srpanch@uw.edu
Scientific Director:	Heather Stefanski, MD, PhD, Be The Match/NMDP, Minneapolis, MN; Telephone: 763-406-8495; E-mail: hstefans@nmdp.org
Statistical Director:	Brent Logan, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-955-8849; E-mail: blogan@mcw.edu
Statistician:	Stephanie Bo-Subait, MPH, CIBMTR Statistical Center, Minneapolis, MN; Telephone: 763-406-8515; E-mail: sbosuba2@nmdp.org

1. Introduction

- a. 2021 TCT Combined WC session minutes (Attachment 1)

The CIBMTR Donor Health and Safety Working Committee meeting was called to order by Dr. Galen Switzer at 12:20pm MST, on Monday, April 25th. The CIBMTR COI policy along with working committee leadership was introduced. The processes of participating in the working committee, voting guidance, and rules of authorship were outlined.

2. Accrual summary (Attachment 2)

The accrual summary can be found in the materials which were linked to the online Tandem agenda.

3. Presentations, published or submitted papers

Recently published or submit worked from the committee were announced.

- a. **DS05-02g** Seftel MD, Chitphakdithai P, Miller JP, Kobusingye H, Logan BR, Linenberger M, Artz AS, Haight AE, Jacobsohn DA, Litzow MR, Magalhaes-Silverman M, Selby GB, Vusirikala M, Horowitz MM, Switzer GE, Confer DL, Shaw BE, Pulsipher MA. Serious adverse events in related donors: A

- report from the Related Donor Safe Study. *Transplantation and Cellular Therapy*. 2021 Apr 1; 27(4):352.e1-352.e5. doi:10.1016/j.jtct.2021.01.009. Epub 2021 Jan 15. PMC8036235. **Published.**
- b. **DS18-02** Panch SR, Logan B, Sees JA, Bo-Subait S, Savani B, Shah NN, Hsu JW, Switzer G, Lazarus HM, Anderlini P, Hematti P, Confer D, Pulsipher MA, Shaw BE, Stroncek DF. Shorter interdonation interval contributes to lower cell counts in subsequent stem cell donations. *Transplantation and Cellular Therapy*. 2021 Jun 1; 27(6):503.e1-503.e8. doi:10.1016/j.jtct.2021.03.008. Epub 2021 Mar 9. PMC8217152. **Published.**
- c. **DS19-01** Hsu JW, Farhadfar N, Murthy H, Logan BR, Bo-Subait S, Frey N, Goldstein SC, Horowitz MM, Lazarus H, Schwanke JD, Shah NN, Spellman SR, Switzer GE, Devine SM, Shaw BE, Wingard JR. The effect of donor graft cryopreservation on allogeneic hematopoietic cell transplantation outcomes: A Center for International Blood and Marrow Transplant Research Analysis. Implications during the COVID-19 pandemic. *Transplantation and Cellular Therapy*. 2021 Jun 1; 27(6):507-516. doi:10.1016/j.jtct.2021.03.015. Epub 2021 Mar 22. PMC8217124. **Published.**
- d. **DS13-02** Murthy GSG, Logan BR, Bo-Subait S, Beitinjaneh A, Devine S, Farhadfar N, Gowda L, Hashmi S, Lazarus H, Nathan S, Sharma A, Yared JA, Stefanski HE, Pulsipher MA, Hsu JW, Switzer GE, Panch SR, Shaw BE. Major ABO Incompatibility Significantly Influences the Survival and Outcomes after Allogeneic Hematopoietic Cell Transplantation in Leukemia - CIBMTR Analysis **Oral Presentation at 63rd ASH Annual Meeting and Exposition.**
- e. **DS19-02** Farhadfar N, Bo-Subait S, Ahn KW, Logan BR, Stefanski HE, Hsu JW, Panch SR, Confer DL, Anasetti C, Pulsipher MA, Shaw BE, Wingard JR, Switzer GE. The Impact of Pre-Apheresis Health Related Quality of Life on Peripheral Blood Progenitor Cell Yield and Donor's Health and Outcome: Secondary Analysis of Rdsafe and BMT CTN 0201. **Poster Presentation at 63rd ASH Annual Meeting and Exposition. Submitted.**
4. **Studies in progress** (Attachment 3)
- a. **DS13-02** A retrospective analysis to understand the potential mechanisms underlying the clinical impact of ABO incompatibility on allogeneic transplant outcomes (Guru Murthy; Bronwen Shaw) **Submitted. Update presentation to be given.**

Dr. Jack Hsu introduced Dr. Murthy, who provided an update on DS13-02. This study is currently in manuscript preparation and aimed to investigate the impact of donor-recipient ABO match on recipient outcomes. Multivariable models were constructed, and the overall p-value was significant for overall survival, acute GVHD grade II-IV in peripheral blood cohort, primary graft failure, and platelet engraftment. When looking at individual comparisons of minor mismatch, major mismatch, and bi-directional mismatch versus the reference group of ABO matched, some groups were at an increased risk for some outcomes. Conclusions were that pre-transplant ABO status is significantly associated with survival and other post-transplant outcomes in AML and ALL; major ABO mismatch is associated with

inferior OS, inferior platelet engraftment and higher risk of primary graft failure. There is limited information available on graft manipulation strategies, this needs to be investigated in future studies.

- b. **DS19-02** The impact of pre-apheresis health related quality of life on peripheral blood progenitor cells yield and donor's health and outcome (Nosha Farhadfar; John Wingard; Galen Switzer)
Manuscript preparation. Update presentation to be given.

Dr. Jack Hsu introduced Dr. Nosha Farhadfar, who gave an update of DS19-02. This study is currently submitted to JTCT and aimed to evaluate whether pre-donation health related quality of life markers predict toxicity profile and stem cell yield following stem cell donation. The conclusions of this study were that pre-donation QoL markers are significantly associated with the toxicity profile after PBSC donation in the related donor setting; adult RD with lower pre-donation physical QoL experience increased levels of pain after PBSC procedure, RDs with mean PCS score of < 45 experience increased post-donation pain. These findings may help clinicians to identify donors at higher risk of pain with donation, and lead to personalized information and interventions for specific donors. A future study with a larger sample is required to validate these results.

- c. **DS20-01** Acute toxicities of bone marrow donation in donors with sickle cell trait (Nosha Farhadfar; John Wingard) **Data file preparation**

5. Future/proposed studies

Proposals dropped due to feasibility or overlap with existing studies

- a. **PROP 2103-01** Impact of SARS-COV-2 (COVID 19) pandemic on cellular therapy practices and outcomes (Mariam T. Nawas; Roni Tamari; Miguel-Angel Perales)
- b. **PROP 2110-154** Impact of Cryopreservation on Immune Reconstitution in Allogeneic Hematopoietic Cell Transplantation (Hemant Murthy; Nosha Farhadfar)
- c. **PROP 2110-233** Impact of the COVID-19 pandemic on unrelated donor availability in different racial and ethnic groups (Nosha Farhadfar; John R. Wingard)

6. Other business

Our committee has a new initiative to encourage submission of review or guideline consensus proposals. Each year there is a call for proposal that will be sent out to the full working committee which includes a brief form. Additionally, Stephanie can be contacted for this information. We plan to discuss these proposals at Tandem each year. Scoring for these use the same scale as other proposals. In person attendees can vote using the paper that was handed out when they entered the room, for those joining the meeting virtually an email can be send to Stephanie at sbosuba2@nmdp.org by April 29th.

a. Review/guideline proposals

- i. **Review Proposal 2022-02** (Attachment 4) Reducing the Risk of Transmission of Donor Derived Malignancy: Consensus Guidelines for Donor Genetic Screening Prior to

Allogeneic Stem Cell Transplant and Detection of Leukemia Origin in Relapse After Transplant (Lacey Scott Williams; Catherine Lai)

Lacey Williams presented this proposal which aims to complete a comprehensive review of donor derived malignancy (AML, ALL, MDS) to include donor sources, biology, treatment and maintenance strategies. The second component of this proposal is to develop guidelines for increased screening of donors prior to allogeneic stem cell transplant to reduce the likelihood of relapse with donor derived malignancy where the PIs plan to convene a panel of 10-20 international experts to weight recommendation.

Currently, donor derived malignancies are screened for in many ways and may be a challenge with this proposal. An important aspect of this study would be to inform on how we should be screening for this within the donor, but also to focus on instances where the recipient relapses to see if that is DDM. It could also help the field know when to report DDM to NMDP, and how to report it.

- ii. **Review Proposal 2022-03** (Attachment 5) The safety of G-CSF (filgrastim) for mobilization in donors, both healthy donors or donors for autologous transplant. (Joseph Maakaron; Mark Juckett)

Joseph Maakaron presented his proposal aiming to examine the safety of G-CSF. Literature review produces a variety of case reports of developing adverse events after use of G-CSF. This proposal aims to review published information about donor health safety for healthy donors and describe the incidence and severity of autoimmune diseases, myeloid disorder, lung dysfunction, vascular complications and GVHD in recipients; to review published information on safety of G-CSF and biosimilars, and to compare incidence of the aforementioned adverse events to general population. The PIs will conclude with a recommendation regarding healthy donor eligibility.

Caution was expressed about overlap with current ongoing work within this specific area. Heather has a currently analysis but also the Notify project which is a WHO effort to collect AEs in donors – this group may be interested in producing a paper. The intent of this proposal is to summarize what we already know, rather than a prospective project on how to define a “risky” donation. It was felt that if this proposal proceeds, we should be careful with takeaway message, whether these AEs were directly associated with G-CSF versus something that occurred during the course of a person’s life and happened to occur at similar time with G-CSF administration. It was advised that the key thing would be to focus the efforts on definitive events and then focus on studies where there is a large control groups to get a sense of if this event is related. The aim would be strictly to advise on absolute donor exclusions.

b. Potential collaborations

- i. **Review Proposal 2022-01** (Attachment 6) What is the relationship between donor red blood cell characteristics and collection efficiency in peripheral blood stem cell donors? (Katie Cormier; Jenna Smith; Wolfgang Rennert; Catherine Broome)

Jenna Smith and Katie Cormier presented this collaboration proposal which aims to determine the correlation between CD34+ cell yield and red cell abnormalities by looking at linear and multivariate regression analysis to correlate CD34+ yields in HPCA product with donor MCV and peripherals CD34 levels; and to provide insight and guidance for collection centers to manage donors with lower MCV counts to successfully meet transplant centers HPC request.

The CIBMTR collection forms are likely not granular enough to capture the required information such as MCV. It was recommended that the PIs should join forces with other centers through the CIBMTR to evaluate this question as a center study. A question we should consider is, does this provide evidence that we should start collecting this data on a small subset of centers that do high volume of apheresis procedures to see if this is relevant.

- ii. **Significance of Red Blood Cell Alloimmunization in Hematopoietic Progenitor Cell Transplant Recipients** (Monica Pagano)

Monica Pagano presented this collaboration proposal which aims to evaluate the prevalence and incidence of red blood cell alloimmunization in the HSCT population and to analyze adverse events associated with red blood cell alloimmunization by focusing on outcomes of red blood cell transfusions and engraftment. She advises conducting a similar study with a larger population as she was limited by the number of patients in her own study and looking specifically at red blood cell transfusions in recipients. This proposal is similar to a study that is currently being conducted within the WC (DS13-02).

- c. **Additional business items** As needed and as time allows for discussion

Accrual Summary for the Donor Health and Safety Working Committee

Table 1. Characteristics of domestic unrelated NMDP donors donating between 1988 and December 2021 ^a

Characteristic	Bone marrow	PBSC	Total
No. of patients	25944	40114	66058
Characteristics			
Donor age at collection - no. (%)			
Median (min-max)	33.8 (18.3-61.1)	30.6 (18.3-62.3)	31.9 (18.3-62.3)
18-29	9605 (37)	19216 (48)	28821 (44)
30-39	8641 (33)	10888 (27)	19529 (30)
40-49	6010 (23)	7099 (18)	13109 (20)
50+	1688 (7)	2911 (7)	4599 (7)
Donor sex - no. (%)			
Male	15617 (60)	25353 (63)	40970 (62)
Female	10327 (40)	14761 (37)	25088 (38)
Donor race/ethnicity - no. (%)			
Caucasian	18265 (70)	27195 (68)	45460 (69)
African/African-American	1476 (6)	1547 (4)	3023 (5)
Asian/Pacific Islander	1230 (5)	2111 (5)	3341 (5)
Hispanic	2346 (9)	3356 (8)	5702 (9)
Native American	285 (1)	283 (1)	568 (1)
Multiple/Other	1498 (6)	3149 (8)	4647 (7)
Missing	844 (3)	2473 (6)	3317 (5)
Donor CMV status - no. (%)			
Negative	14336 (55)	22264 (56)	36600 (55)
Positive	11295 (44)	17551 (44)	28846 (44)
Unknown/inconclusive	313 (1)	299 (1)	612 (1)
Year of donation - no. (%)			
1988	78 (0)	0 (0)	78 (0)
1989	176 (1)	0 (0)	176 (0)
1990	280 (1)	0 (0)	280 (0)
1991	433 (2)	0 (0)	433 (1)
1992	547 (2)	0 (0)	547 (1)
1993	640 (2)	0 (0)	640 (1)
1994	794 (3)	5 (0)	799 (1)

Characteristic	Bone marrow	PBSC	Total
1995	867 (3)	21 (0)	888 (1)
1996	1039 (4)	14 (0)	1053 (2)
1997	1164 (4)	17 (0)	1181 (2)
1998	1234 (5)	29 (0)	1263 (2)
1999	1222 (5)	71 (0)	1293 (2)
2000	1192 (5)	311 (1)	1503 (2)
2001	1063 (4)	454 (1)	1517 (2)
2002	1068 (4)	749 (2)	1817 (3)
2003	891 (3)	988 (2)	1879 (3)
2004	796 (3)	1085 (3)	1881 (3)
2005	646 (2)	1254 (3)	1900 (3)
2006	666 (3)	1374 (3)	2040 (3)
2007	643 (2)	1470 (4)	2113 (3)
2008	670 (3)	1706 (4)	2376 (4)
2009	672 (3)	1836 (5)	2508 (4)
2010	711 (3)	1954 (5)	2665 (4)
2011	753 (3)	2109 (5)	2862 (4)
2012	933 (4)	2501 (6)	3434 (5)
2013	924 (4)	2733 (7)	3657 (6)
2014	897 (3)	2635 (7)	3532 (5)
2015	805 (3)	2497 (6)	3302 (5)
2016	821 (3)	2299 (6)	3120 (5)
2017	812 (3)	2202 (5)	3014 (5)
2018	759 (3)	2256 (6)	3015 (5)
2019	661 (3)	2344 (6)	3005 (5)
2020	535 (2)	2463 (6)	2998 (5)
2021	552 (2)	2737 (7)	3289 (5)

Form completion

Baseline ^{b,c} - no./total no. (%)	9835/25944 (38)	30559/40114 (76)	40394/66058 (61)
Day of collection (BM donors) ^{b,d} - no./total no. (%)	9402/25944 (36)	0/40114 (0)	9402/66058 (14)
Day 1 of collection (PBSC donors) ^{b,e} - no./total no. (%)	0/25944 (0)	0/40114 (0)	0/66058 (0)
Product (BM donors) ^{b,f} - no./total no. (%)	23739/25944 (92)	0/40114 (0)	23739/66058 (36)
First product (PBSC donors) ^{b,g} - no./total no. (%)	0/25944 (0)	29267/40114 (73)	29267/66058 (44)

^a There have been 6187 bone marrow and 21618 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.

Table 2. Characteristics of domestic related NMDP donors donating between 1988 and December 2021^a

Characteristic	Bone marrow	PBSC	Total
No. of patients	117	856	973
<u>Characteristics</u>			
Donor age at collection - no. (%)			
Median (min-max)	38.0 (18.0-60.5)	49.1 (18.2-63.0)	47.5 (18.0-63.0)
18-29	33 (28)	103 (12)	136 (14)
30-39	36 (31)	186 (22)	222 (23)
40-49	21 (18)	159 (19)	180 (18)
50+	27 (23)	408 (48)	435 (45)
Donor sex - no. (%)			
Male	73 (62)	512 (60)	585 (60)
Female	44 (38)	344 (40)	388 (40)
Donor race/ethnicity - no. (%)			
Caucasian	67 (57)	643 (75)	710 (73)
African/African-American	22 (19)	56 (7)	78 (8)
Asian/Pacific Islander	2 (2)	33 (4)	35 (4)
Hispanic	18 (15)	67 (8)	85 (9)
Multiple/Other	4 (3)	31 (4)	35 (4)
Missing	4 (3)	26 (3)	30 (3)
Donor CMV status - no. (%)			
Negative	63 (54)	444 (52)	507 (52)
Positive	54 (46)	404 (47)	458 (47)
Unknown/inconclusive	0 (0)	8 (1)	8 (1)
Year of donation - no. (%)			
2009	0 (0)	1 (0)	1 (0)
2012	0 (0)	1 (0)	1 (0)
2013	0 (0)	5 (1)	5 (1)
2014	1 (1)	2 (0)	3 (0)
2015	2 (2)	7 (1)	9 (1)
2016	6 (5)	17 (2)	23 (2)
2017	23 (20)	54 (6)	77 (8)
2018	18 (15)	92 (11)	110 (11)
2019	14 (12)	97 (11)	111 (11)

Characteristic	Bone marrow	PBSC	Total
2020	35 (30)	264 (31)	299 (31)
2021	18 (15)	316 (37)	334 (34)
Form completion			
Baseline ^{b,c} - no./total no. (%)	117/117 (100)	856/856 (100)	973/973 (100)
Day of collection (BM donors) ^{b,d} - no./total no. (%)	116/117 (99)	0/856 (0)	116/973 (12)
Day 1 of collection (PBSC donors) ^{b,d} - no./total no. (%)	0/117 (0)	0/856 (0)	0/973 (0)
Product form (BM donors) ^{b,d} - no./total no. (%)	117/117 (100)	0/856 (0)	117/973 (12)
First product form (PBSC donors) ^{b,d} - no./total no. (%)	0/117 (0)	852/856 (100)	852/973 (88)

^a There have been 22 bone marrow and 114 PBSC international donors during this time frame.

^b Completed with FormsNet2 (approximately 2009 and forward). Similar data are collected prior to 2009.

^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.

Table 3. Characteristics of Related Donors from the RCI-BMT 06-DON (RDSafe) Study

Variable	<u>GMARROW^a</u>	<u>MARROW</u>	<u>PBSC</u>	<u>Total</u>
	N (%)	N (%)	N (%)	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

Table 4. 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	<u>Samples</u>		
	<u>Available for</u>	<u>Samples</u>	<u>Samples</u>
	<u>Recipient and</u>	<u>Available for</u>	<u>Available for</u>
	<u>Donor</u>	<u>Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Number of patients	47323	19111	12053
Source of data			
CRF	24443 (52)	7079 (37)	5666 (47)
TED	22880 (48)	12032 (63)	6387 (53)
Number of centers	264	241	378
Disease at transplant			
AML	16388 (35)	7160 (37)	3977 (33)
ALL	6871 (15)	2478 (13)	1928 (16)
Other leukemia	1469 (3)	423 (2)	310 (3)
CML	3528 (7)	1111 (6)	1028 (9)
MDS	6936 (15)	3307 (17)	1526 (13)
Other acute leukemia	501 (1)	230 (1)	142 (1)
NHL	4211 (9)	1361 (7)	904 (8)
Hodgkin Lymphoma	947 (2)	258 (1)	212 (2)
Plasma Cell Disorders, MM	940 (2)	292 (2)	206 (2)
Other malignancies	58 (<1)	14 (<1)	22 (<1)
Breast cancer	7 (<1)	3 (<1)	1 (<1)
SAA	1519 (3)	594 (3)	510 (4)
Inherited abnormalities erythrocyte diff fxn	728 (2)	255 (1)	231 (2)
Inherited bone marrow failure syndromes	26 (<1)	32 (<1)	20 (<1)
Hemoglobinopathies	22 (<1)	22 (<1)	15 (<1)
Paroxysmal nocturnal hemoglobinuria	4 (<1)	7 (<1)	2 (<1)
SCIDs	827 (2)	328 (2)	370 (3)
Inherited abnormalities of platelets	40 (<1)	16 (<1)	12 (<1)
Inherited disorders of metabolism	301 (1)	89 (<1)	143 (1)
Histiocytic disorders	387 (1)	125 (1)	129 (1)
Autoimmune disorders	27 (<1)	14 (<1)	11 (<1)
Other	53 (<1)	18 (<1)	25 (<1)

Variable	<u>Samples</u>		
	<u>Available for Recipient and Donor</u> N (%)	<u>Samples Available for Recipient Only</u> N (%)	<u>Samples Available for Donor Only</u> N (%)
MPN	1507 (3)	947 (5)	297 (2)
Disease missing	26 (<1)	27 (<1)	32 (<1)
AML Disease status at transplant			
CR1	8855 (54)	4408 (62)	1974 (50)
CR2	3149 (19)	1237 (17)	782 (20)
CR3+	337 (2)	108 (2)	92 (2)
Advanced or active disease	3862 (24)	1364 (19)	984 (25)
Missing	185 (1)	43 (1)	145 (4)
ALL Disease status at transplant			
CR1	3403 (50)	1426 (58)	814 (42)
CR2	1956 (28)	631 (25)	557 (29)
CR3+	570 (8)	167 (7)	180 (9)
Advanced or active disease	860 (13)	230 (9)	257 (13)
Missing	82 (1)	24 (1)	120 (6)
MDS Disease status at transplant			
Early	1480 (21)	609 (18)	351 (23)
Advanced	4487 (65)	2464 (75)	836 (55)
Missing	969 (14)	234 (7)	339 (22)
NHL Disease status at transplant			
CR1	598 (14)	262 (19)	125 (14)
CR2	781 (19)	259 (19)	145 (16)
CR3+	365 (9)	114 (8)	80 (9)
PR	448 (11)	112 (8)	95 (11)
Advanced	1928 (46)	588 (43)	424 (47)
Missing	71 (2)	18 (1)	32 (4)
Recipient age at transplant			
0-9 years	3974 (8)	1246 (7)	1582 (13)
10-17 years	3152 (7)	969 (5)	1122 (9)
18-29 years	5720 (12)	1928 (10)	1607 (13)
30-39 years	5327 (11)	1851 (10)	1428 (12)
40-49 years	7110 (15)	2503 (13)	1748 (15)
50-59 years	9750 (21)	3711 (19)	2071 (17)
60-69 years	10023 (21)	5257 (28)	2052 (17)
70+ years	2267 (5)	1646 (9)	443 (4)
Median (Range)	48 (0-84)	53 (0-82)	42 (0-84)

Variable	<u>Samples</u>	<u>Samples</u>	<u>Samples</u>
	<u>Available for</u> <u>Recipient and</u> <u>Donor</u> N (%)	<u>Available for</u> <u>Recipient Only</u> N (%)	<u>Available for</u> <u>Donor Only</u> N (%)
Recipient race/ethnicity			
White	39105 (83)	15871 (83)	8419 (70)
Black or African American	2150 (5)	753 (4)	555 (5)
Asian	1167 (2)	602 (3)	520 (4)
Native Hawaiian or other Pacific Islander	59 (<1)	31 (<1)	32 (<1)
American Indian or Alaska Native	172 (<1)	73 (<1)	49 (<1)
Hispanic	2873 (6)	1076 (6)	718 (6)
Missing	1797 (4)	705 (4)	1760 (15)
Recipient sex			
Male	27519 (58)	11189 (59)	7161 (59)
Female	19804 (42)	7922 (41)	4892 (41)
Karnofsky score			
10-80	16419 (35)	7366 (39)	3802 (32)
90-100	29141 (62)	11142 (58)	7620 (63)
Missing	1763 (4)	603 (3)	631 (5)
HLA-A B DRB1 groups - low resolution			
<=3/6	31 (<1)	54 (<1)	5 (<1)
4/6	246 (1)	98 (1)	58 (1)
5/6	6320 (14)	1956 (12)	1680 (15)
6/6	39021 (86)	13671 (87)	9199 (84)
Unknown	1705 (N/A)	3332 (N/A)	1111 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	907 (2)	104 (1)	82 (1)
6/8	1783 (4)	159 (1)	224 (3)
7/8	8777 (20)	2047 (16)	1797 (23)
8/8	33290 (74)	10596 (82)	5866 (74)
Unknown	2566 (N/A)	6205 (N/A)	4084 (N/A)
HLA-DPB1 Match			
Double allele mismatch	11284 (29)	1543 (23)	914 (26)
Single allele mismatch	20903 (54)	3374 (51)	1832 (52)
Full allele matched	6608 (17)	1716 (26)	787 (22)
Unknown	8528 (N/A)	12478 (N/A)	8520 (N/A)
High resolution release score			
No	11606 (25)	19036 (>99)	11519 (96)
Yes	35717 (75)	75 (<1)	534 (4)

Variable	Samples		
	<u>Available for Recipient and Donor</u> N (%)	<u>Samples Available for Recipient Only</u> N (%)	<u>Samples Available for Donor Only</u> N (%)
KIR typing available			
No	33478 (71)	19085 (>99)	11980 (99)
Yes	13845 (29)	26 (<1)	73 (1)
Graft type			
Marrow	16451 (35)	5091 (27)	4800 (40)
PBSC	30790 (65)	13824 (72)	7191 (60)
BM+PBSC	10 (<1)	6 (<1)	1 (<1)
PBSC+UCB	38 (<1)	170 (1)	10 (<1)
Others	34 (<1)	20 (<1)	51 (<1)
Conditioning regimen			
Myeloablative	28854 (61)	10141 (53)	7518 (62)
RIC/Nonmyeloablative	18244 (39)	8909 (47)	4372 (36)
TBD	225 (<1)	61 (<1)	163 (1)
Donor age at donation			
To Be Determined/NA	396 (1)	563 (3)	147 (1)
0-9 years	5 (<1)	37 (<1)	4 (<1)
10-17 years	2 (<1)	13 (<1)	1 (<1)
18-29 years	23149 (49)	9900 (52)	5152 (43)
30-39 years	13299 (28)	4964 (26)	3623 (30)
40-49 years	7988 (17)	2533 (13)	2357 (20)
50+ years	2484 (5)	1101 (6)	769 (6)
Median (Range)	30 (0-123)	29 (0-121)	32 (0-123)
Donor/Recipient CMV serostatus			
+/+	11583 (24)	4767 (25)	3042 (25)
+/-	5466 (12)	2181 (11)	1479 (12)
-/+	15215 (32)	5254 (27)	3593 (30)
-/-	13359 (28)	4498 (24)	3132 (26)
CB - recipient +	34 (<1)	136 (1)	9 (<1)
CB - recipient -	4 (<1)	42 (<1)	2 (<1)
CB - recipient CMV unknown	0	1 (<1)	0
Missing	1662 (4)	2232 (12)	796 (7)
GvHD Prophylaxis			
No GVHD prophylaxis	200 (<1)	94 (<1)	67 (1)
Ex vivo T-cell depletion	1160 (2)	319 (2)	408 (3)
CD34 selection	720 (2)	339 (2)	194 (2)

Variable	<u>Samples</u>		
	<u>Available for Recipient and Donor</u> N (%)	<u>Samples Available for Recipient Only</u> N (%)	<u>Samples Available for Donor Only</u> N (%)
Post-CY + other(s)	3020 (6)	2569 (13)	743 (6)
Post-CY alone	228 (<1)	109 (1)	58 (<1)
Tacrolimus + MMF +- others	5383 (11)	1947 (10)	920 (8)
Tacrolimus + MTX +- others (except MMF)	20389 (43)	8407 (44)	3390 (28)
Tacrolimus + others (except MTX, MMF)	2432 (5)	1220 (6)	469 (4)
Tacrolimus alone	1182 (2)	484 (3)	216 (2)
CSA + MMF +- others (except Tacrolimus)	3083 (7)	909 (5)	1017 (8)
CSA + MTX +- others (except Tacrolimus, MMF)	6993 (15)	1899 (10)	3358 (28)
CSA + others (except Tacrolimus, MTX, MMF)	1089 (2)	335 (2)	452 (4)
CSA alone	482 (1)	136 (1)	402 (3)
Other GVHD prophylaxis	752 (2)	270 (1)	208 (2)
Missing	210 (<1)	74 (<1)	151 (1)
Donor/Recipient sex match			
Male-Male	19283 (41)	7409 (39)	4699 (39)
Male-Female	11786 (25)	4525 (24)	2668 (22)
Female-Male	8013 (17)	3384 (18)	2383 (20)
Female-Female	7842 (17)	3072 (16)	2157 (18)
CB - recipient M	18 (<1)	96 (1)	3 (<1)
CB - recipient F	20 (<1)	83 (<1)	8 (<1)
Missing	361 (1)	542 (3)	135 (1)
Year of transplant			
1986-1990	350 (1)	46 (<1)	106 (1)
1991-1995	1839 (4)	439 (2)	748 (6)
1996-2000	3305 (7)	1185 (6)	1215 (10)
2001-2005	5345 (11)	1074 (6)	1880 (16)
2006-2010	9622 (20)	1923 (10)	1829 (15)
2011-2015	13414 (28)	3587 (19)	2563 (21)
2016-2020	10431 (22)	7184 (38)	2758 (23)
2021-2022	3017 (6)	3673 (19)	954 (8)
Follow-up among survivors, Months			
N Eval	20064	9350	5352
Median (Range)	60 (0-385)	24 (0-362)	40 (0-372)

Table 5. Unrelated Cord 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	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Number of patients	6214	1700	2170
Source of data			
CRF	4494 (72)	1137 (67)	1068 (49)
TED	1720 (28)	563 (33)	1102 (51)
Number of centers	154	142	223
Disease at transplant			
AML	2354 (38)	580 (34)	706 (33)
ALL	1279 (21)	373 (22)	468 (22)
Other leukemia	98 (2)	30 (2)	37 (2)
CML	132 (2)	36 (2)	57 (3)
MDS	559 (9)	168 (10)	172 (8)
Other acute leukemia	96 (2)	24 (1)	44 (2)
NHL	403 (6)	98 (6)	134 (6)
Hodgkin Lymphoma	103 (2)	27 (2)	36 (2)
Plasma Cell Disorders, MM	38 (1)	12 (1)	13 (1)
Other malignancies	11 (<1)	1 (<1)	3 (<1)
SAA	97 (2)	32 (2)	49 (2)
Inherited abnormalities erythrocyte diff fxn	171 (3)	51 (3)	45 (2)
Inherited bone marrow failure syndromes	4 (<1)	3 (<1)	3 (<1)
Hemoglobinopathies	2 (<1)	1 (<1)	0
SCIDs	278 (4)	91 (5)	165 (8)
Inherited abnormalities of platelets	20 (<1)	5 (<1)	10 (<1)
Inherited disorders of metabolism	387 (6)	118 (7)	142 (7)
Histiocytic disorders	107 (2)	29 (2)	51 (2)
Autoimmune disorders	9 (<1)	0	6 (<1)
Other	10 (<1)	2 (<1)	9 (<1)
Disease missing	4 (<1)	3 (<1)	0
MPN	52 (1)	16 (1)	20 (1)
AML Disease status at transplant			

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
CR1	1222 (52)	324 (56)	350 (50)
CR2	636 (27)	149 (26)	188 (27)
CR3+	66 (3)	9 (2)	26 (4)
Advanced or active disease	422 (18)	96 (17)	138 (20)
Missing	8 (<1)	2 (<1)	4 (1)
ALL Disease status at transplant			
CR1	574 (45)	159 (43)	202 (43)
CR2	480 (38)	137 (37)	166 (35)
CR3+	148 (12)	54 (14)	61 (13)
Advanced or active disease	76 (6)	22 (6)	38 (8)
Missing	1 (<1)	1 (<1)	1 (<1)
MDS Disease status at transplant			
Early	173 (31)	41 (24)	72 (42)
Advanced	337 (60)	113 (67)	78 (45)
Missing	49 (9)	14 (8)	22 (13)
NHL Disease status at transplant			
CR1	63 (16)	9 (9)	25 (19)
CR2	75 (19)	22 (22)	35 (26)
CR3+	45 (11)	11 (11)	12 (9)
PR	68 (17)	12 (12)	16 (12)
Advanced	149 (37)	43 (44)	42 (32)
Missing	0	1 (1)	3 (2)
Recipient age at transplant			
0-9 years	1868 (30)	612 (36)	771 (36)
10-19 years	655 (11)	158 (9)	255 (12)
20-29 years	745 (12)	152 (9)	234 (11)
30-39 years	599 (10)	150 (9)	210 (10)
40-49 years	655 (11)	172 (10)	203 (9)
50-59 years	856 (14)	210 (12)	280 (13)
60-69 years	722 (12)	212 (12)	201 (9)
70+ years	114 (2)	34 (2)	16 (1)
Median (Range)	27 (0-83)	24 (0-78)	20 (0-78)
Recipient race/ethnicity			
White	3432 (55)	996 (59)	1090 (50)
Black or African American	893 (14)	221 (13)	263 (12)
Asian	366 (6)	120 (7)	163 (8)

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Native Hawaiian or other Pacific Islander	32 (1)	3 (<1)	17 (1)
American Indian or Alaska Native	45 (1)	10 (1)	19 (1)
Hispanic	1108 (18)	253 (15)	297 (14)
Missing	338 (5)	97 (6)	321 (15)
Recipient sex			
Male	3439 (55)	968 (57)	1241 (57)
Female	2775 (45)	732 (43)	929 (43)
Karnofsky score			
10-80	1647 (27)	437 (26)	556 (26)
90-100	4361 (70)	1157 (68)	1433 (66)
Missing	206 (3)	106 (6)	181 (8)
HLA-A B DRB1 groups - low resolution			
<=3/6	101 (2)	57 (4)	32 (2)
4/6	2448 (41)	557 (40)	789 (40)
5/6	2664 (45)	596 (43)	854 (43)
6/6	750 (13)	184 (13)	294 (15)
Unknown	251 (N/A)	306 (N/A)	201 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	2891 (55)	569 (55)	881 (55)
6/8	1271 (24)	248 (24)	370 (23)
7/8	730 (14)	141 (14)	221 (14)
8/8	349 (7)	70 (7)	123 (8)
Unknown	973 (N/A)	672 (N/A)	575 (N/A)
HLA-DPB1 Match			
Double allele mismatch	859 (39)	99 (38)	164 (40)
Single allele mismatch	1117 (51)	136 (52)	209 (51)
Full allele matched	202 (9)	25 (10)	33 (8)
Unknown	4036 (N/A)	1440 (N/A)	1764 (N/A)
High resolution release score			
No	4674 (75)	1650 (97)	2145 (99)
Yes	1540 (25)	50 (3)	25 (1)
KIR typing available			
No	4941 (80)	1694 (>99)	2150 (99)
Yes	1273 (20)	6 (<1)	20 (1)
Graft type			
UCB	5836 (94)	1521 (89)	2034 (94)

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
BM+UCB	1 (<1)	0	0
PBSC+UCB	347 (6)	170 (10)	122 (6)
Others	30 (<1)	9 (1)	14 (1)
Number of cord units			
1	5200 (84)	0	1809 (83)
2	1012 (16)	0	360 (17)
3	1 (<1)	0	0
Unknown	1 (N/A)	1700 (N/A)	1 (N/A)
Conditioning regimen			
Myeloablative	4030 (65)	1076 (63)	1346 (62)
RIC/Nonmyeloablative	2168 (35)	619 (36)	807 (37)
TBD	16 (<1)	5 (<1)	17 (1)
Donor age at donation			
To Be Determined/NA	4858 (78)	646 (38)	1741 (80)
0-9 years	1081 (17)	844 (50)	348 (16)
10-19 years	58 (1)	88 (5)	17 (1)
20-29 years	65 (1)	37 (2)	15 (1)
30-39 years	57 (1)	38 (2)	21 (1)
40-49 years	46 (1)	21 (1)	11 (1)
50+ years	49 (1)	26 (2)	17 (1)
Median (Range)	4 (0-112)	5 (0-73)	4 (0-119)
Donor/Recipient CMV serostatus			
+/+	0	0	1 (<1)
-/-	0	0	1 (<1)
CB - recipient +	3888 (63)	1027 (60)	1306 (60)
CB - recipient -	2227 (36)	613 (36)	790 (36)
CB - recipient CMV unknown	99 (2)	60 (4)	72 (3)
GvHD Prophylaxis			
No GVHD prophylaxis (forms under review)	23 (<1)	8 (<1)	14 (1)
Ex vivo T-cell depletion	25 (<1)	9 (1)	8 (<1)
CD34 selection	213 (3)	100 (6)	61 (3)
Post-CY + other(s)	12 (<1)	9 (1)	13 (1)
Post-CY alone	0	0	1 (<1)
Tacrolimus + MMF +/- others	1857 (30)	539 (32)	446 (21)
Tacrolimus + MTX +/- others (except MMF)	216 (3)	56 (3)	78 (4)
Tacrolimus + others (except MTX, MMF)	225 (4)	64 (4)	84 (4)

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Tacrolimus alone	153 (2)	45 (3)	30 (1)
CSA + MMF +- others (except Tacrolimus)	2847 (46)	683 (40)	1039 (48)
CSA + MTX +- others (except Tacrolimus, MMF)	101 (2)	29 (2)	50 (2)
CSA + others (except Tacrolimus, MTX, MMF)	341 (5)	117 (7)	223 (10)
CSA alone	52 (1)	18 (1)	70 (3)
Other GVHD prophylaxis	137 (2)	20 (1)	42 (2)
Missing	12 (<1)	3 (<1)	11 (1)
Donor/Recipient sex match			
Male-Female	0	0	1 (<1)
Female-Male	0	0	1 (<1)
CB - recipient M	3439 (55)	968 (57)	1239 (57)
CB - recipient F	2775 (45)	732 (43)	928 (43)
CB - recipient sex unknown	0	0	1 (<1)
Year of transplant			
1996-2000	1 (<1)	2 (<1)	5 (<1)
2001-2005	112 (2)	86 (5)	34 (2)
2006-2010	1850 (30)	426 (25)	601 (28)
2011-2015	2682 (43)	510 (30)	839 (39)
2016-2020	1341 (22)	528 (31)	547 (25)
2021-2022	228 (4)	148 (9)	144 (7)
Follow-up among survivors, Months			
N Eval	2964	887	1105
Median (Range)	64 (0-196)	49 (0-213)	43 (0-240)

Table 6. 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 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	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and Samples Available</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Number of patients	11071	1859	851
Source of data			
CRF	3500 (32)	454 (24)	281 (33)
TED	7571 (68)	1405 (76)	570 (67)
Number of centers	93	78	63
Disease at transplant			
AML	3667 (33)	605 (33)	285 (33)
ALL	1843 (17)	362 (19)	163 (19)
Other leukemia	205 (2)	41 (2)	19 (2)
CML	337 (3)	45 (2)	24 (3)
MDS	1483 (13)	226 (12)	111 (13)
Other acute leukemia	164 (1)	33 (2)	11 (1)
NHL	936 (8)	168 (9)	76 (9)
Hodgkin Lymphoma	204 (2)	40 (2)	23 (3)
Plasma Cell Disorders, MM	257 (2)	39 (2)	23 (3)
Other malignancies	24 (<1)	0	1 (<1)
Breast cancer	1 (<1)	0	0
SAA	516 (5)	81 (4)	29 (3)
Inherited abnormalities erythrocyte diff fxn	494 (4)	72 (4)	20 (2)
Inherited bone marrow failure syndromes	16 (<1)	2 (<1)	4 (<1)
Hemoglobinopathies	111 (1)	22 (1)	8 (1)
Paroxysmal nocturnal hemoglobinuria	2 (<1)	0	0
SCIDs	228 (2)	36 (2)	16 (2)
Inherited abnormalities of platelets	10 (<1)	0	0
Inherited disorders of metabolism	16 (<1)	5 (<1)	2 (<1)
Histiocytic disorders	63 (1)	9 (<1)	5 (1)
Autoimmune disorders	11 (<1)	0	1 (<1)
Other	16 (<1)	0	0
Disease missing	10 (<1)	4 (<1)	1 (<1)
MPN	457 (4)	69 (4)	29 (3)

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
AML Disease status at transplant			
CR1	2403 (66)	411 (68)	186 (65)
CR2	562 (15)	86 (14)	36 (13)
CR3+	44 (1)	14 (2)	1 (<1)
Advanced or active disease	651 (18)	90 (15)	62 (22)
Missing	7 (<1)	4 (1)	0
ALL Disease status at transplant			
CR1	1119 (61)	226 (62)	103 (63)
CR2	522 (28)	91 (25)	40 (25)
CR3+	114 (6)	19 (5)	11 (7)
Advanced or active disease	86 (5)	26 (7)	9 (6)
Missing	2 (<1)	0	0
MDS Disease status at transplant			
Early	253 (17)	31 (14)	20 (18)
Advanced	1177 (79)	183 (81)	85 (77)
Missing	53 (4)	12 (5)	6 (5)
NHL Disease status at transplant			
CR1	174 (19)	39 (23)	16 (21)
CR2	176 (19)	34 (20)	10 (13)
CR3+	100 (11)	18 (11)	4 (5)
PR	68 (7)	13 (8)	7 (9)
Advanced	409 (44)	63 (38)	39 (51)
Missing	5 (1)	0	0
Recipient age at transplant			
0-9 years	1123 (10)	180 (10)	68 (8)
10-19 years	1071 (10)	139 (7)	63 (7)
20-29 years	1257 (11)	250 (13)	90 (11)
30-39 years	865 (8)	166 (9)	88 (10)
40-49 years	1356 (12)	218 (12)	99 (12)
50-59 years	2336 (21)	401 (22)	185 (22)
60-69 years	2583 (23)	431 (23)	226 (27)
70+ years	480 (4)	74 (4)	32 (4)
Median (Range)	49 (0-82)	49 (0-76)	51 (0-83)
Recipient race/ethnicity			
White	6869 (62)	977 (53)	514 (60)
Black or African American	1373 (12)	240 (13)	81 (10)

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Asian	518 (5)	138 (7)	43 (5)
Native Hawaiian or other Pacific Islander	34 (<1)	5 (<1)	2 (<1)
American Indian or Alaska Native	47 (<1)	4 (<1)	4 (<1)
Hispanic	1677 (15)	357 (19)	151 (18)
Missing	553 (5)	138 (7)	56 (7)
Recipient sex			
Male	6513 (59)	1084 (58)	496 (58)
Female	4558 (41)	775 (42)	355 (42)
Karnofsky score			
10-80	3971 (36)	745 (40)	349 (41)
90-100	6760 (61)	1052 (57)	454 (53)
Missing	340 (3)	62 (3)	48 (6)
HLA-A B DRB1 groups - low resolution			
<=3/6	2161 (23)	346 (26)	166 (28)
4/6	636 (7)	112 (8)	65 (11)
5/6	204 (2)	37 (3)	21 (4)
6/6	6481 (68)	861 (63)	333 (57)
Unknown	1589 (N/A)	503 (N/A)	266 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	2647 (29)	416 (33)	200 (38)
6/8	118 (1)	26 (2)	14 (3)
7/8	143 (2)	26 (2)	15 (3)
8/8	6262 (68)	798 (63)	296 (56)
Unknown	1901 (N/A)	593 (N/A)	326 (N/A)
HLA-DPB1 Match			
Double allele mismatch	9 (<1)	0	0
Single allele mismatch	725 (26)	8 (18)	6 (25)
Full allele matched	2072 (74)	37 (82)	18 (75)
Unknown	8265 (N/A)	1814 (N/A)	827 (N/A)
High resolution release score			
No	4655 (42)	1830 (98)	835 (98)
Yes	6416 (58)	29 (2)	16 (2)
Graft type			
Marrow	3187 (29)	431 (23)	238 (28)
PBSC	7789 (70)	1395 (75)	599 (70)
UCB	2 (<1)	14 (1)	0

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
BM+PBSC	8 (<1)	4 (<1)	1 (<1)
BM+UCB	30 (<1)	9 (<1)	2 (<1)
PBSC+UCB	0	0	11 (1)
Others	55 (<1)	6 (<1)	0
Conditioning regimen			
Myeloablative	6168 (56)	1021 (55)	439 (52)
RIC/Nonmyeloablative	4849 (44)	825 (44)	395 (46)
TBD	54 (<1)	13 (1)	17 (2)
Donor age at donation			
To Be Determined/NA	15 (<1)	3 (<1)	8 (1)
0-9 years	761 (7)	119 (6)	32 (4)
10-19 years	843 (8)	139 (7)	52 (6)
20-29 years	1915 (17)	319 (17)	167 (20)
30-39 years	1633 (15)	323 (17)	161 (19)
40-49 years	1796 (16)	300 (16)	115 (14)
50+ years	4108 (37)	656 (35)	316 (37)
Median (Range)	42 (0-122)	41 (0-118)	41 (0-121)
Donor/Recipient CMV serostatus			
+/+	4485 (41)	812 (44)	288 (34)
+/-	1187 (11)	151 (8)	72 (8)
-/+	2766 (25)	443 (24)	198 (23)
-/-	2371 (21)	381 (20)	162 (19)
CB - recipient +	24 (<1)	14 (1)	7 (1)
CB - recipient -	8 (<1)	9 (<1)	6 (1)
Missing	230 (2)	49 (3)	118 (14)
GvHD Prophylaxis			
No GVHD prophylaxis (forms under review)	156 (1)	35 (2)	16 (2)
Ex vivo T-cell depletion	114 (1)	31 (2)	11 (1)
CD34 selection	119 (1)	33 (2)	13 (2)
Post-CY + other(s)	3488 (32)	547 (29)	309 (36)
Post-CY alone	76 (1)	11 (1)	8 (1)
Tacrolimus + MMF +- others	794 (7)	93 (5)	26 (3)
Tacrolimus + MTX +- others (except MMF)	4050 (37)	606 (33)	309 (36)
Tacrolimus + others (except MTX, MMF)	815 (7)	292 (16)	67 (8)
Tacrolimus alone	108 (1)	22 (1)	7 (1)
CSA + MMF +- others (except Tacrolimus)	243 (2)	38 (2)	15 (2)

Variable	<u>Samples Available</u>		<u>Samples</u>
	<u>for Recipient and</u>		<u>Available for</u>
	<u>Donor</u>	<u>for Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
CSA + MTX +- others (except Tacrolimus, MMF)	719 (6)	95 (5)	43 (5)
CSA + others (except Tacrolimus, MTX, MMF)	81 (1)	11 (1)	3 (<1)
CSA alone	85 (1)	12 (1)	4 (<1)
Other GVHD prophylaxis	148 (1)	19 (1)	15 (2)
Missing	75 (1)	14 (1)	5 (1)
Donor/Recipient sex match			
Male-Male	3666 (33)	646 (35)	285 (33)
Male-Female	2322 (21)	388 (21)	182 (21)
Female-Male	2791 (25)	415 (22)	196 (23)
Female-Female	2200 (20)	374 (20)	164 (19)
CB - recipient M	21 (<1)	16 (1)	8 (1)
CB - recipient F	11 (<1)	7 (<1)	5 (1)
Missing	60 (1)	13 (1)	11 (1)
Year of transplant			
2006-2010	601 (5)	71 (4)	61 (7)
2011-2015	3701 (33)	503 (27)	203 (24)
2016-2020	5028 (45)	894 (48)	399 (47)
2021-2022	1741 (16)	391 (21)	188 (22)
Follow-up among survivors, Months			
N Eval	6629	1113	510
Median (Range)	35 (0-150)	24 (0-124)	24 (0-148)



TO: Donor Health and Safety Working Committee Members

FROM: Heather Stefanski, MD, PhD; Scientific Director for the Donor Health and Safety Working Committee

RE: Studies in Progress Summary

DS20-01 Acute toxicities of bone marrow donation in donors with sickle cell trait (Nosha Farhadfar; John Wingard). This study primarily aims to evaluate the impact of present of sickle cell trait on per-donation toxicity experienced by unrelated bone marrow donors. Secondary aims are to evaluate the impact of sickle cell rail on time to complete recovery from donation-associated symptoms and to compare the BM collected yield between unrelated donors with and without sickle cell trait. This study is in data file preparation, and we aim to submit the manuscript by July 2023.

Proposal: 2210-205**Title:**

Unrelated donor collection efficiency and adverse events during the COVID-19 pandemic

Matthew Seftel MD MPH, University of British Columbia

Hypothesis:

Since the onset of the COVID-19 pandemic, have unrelated donor (UD) hematopoietic progenitor yields increased, and have UDs experienced more adverse or unplanned events?

Specific aims:

The primary objective of this study is to collate and analyse unrelated donor HPC cell dose requests (if available), HPC cell yields, adverse events and unplanned events (>1 day collections and central line placements) in unrelated donors comparing the pre-pandemic and pandemic eras.

Scientific impact:

The results of this study would have implications on the optimal HPC dose targets with ongoing use of planned HPC cryopreservation, and on how donors should be counselled and managed as cryopreservation of UD HPC products continues.

Scientific justification:

Since the onset of the COVID-19 pandemic there has been widespread use of cryopreservation of unrelated donor HPC products (Hsu et al TCT 2021, Devine et al, ASH 2021). While there are published data about transplant-related outcomes during the COVID-19 pandemic era, much less is known about donor outcomes and the donor experience during the pandemic era. Our preliminary analysis of the Canadian Blood Services Stem Cell Registry suggests that planned cryopreservation of unrelated donor HPC products has resulted in higher cell dose requests by transplant centers in anticipation of progenitor cell loss during cryopreservation. This in turn resulted in higher HPC yields from UD and higher than expected numbers of adverse events including multi-day collections and central line placements in these UDs. We propose that we confirm these findings in a much larger sample size harnessing data reported to CIBMTR. We plan to collate and analyse unrelated donor HPC cell dose requests (if available), HPC cell yields, and adverse/unplanned events in unrelated donors comparing the pre-pandemic and pandemic eras. The results of this study would have implications on the optimal HPC dose targets during the cryopreservation era, and on how donors should be counselled and managed as cryopreservation of UD HPC products continues.

Patient eligibility population:

1st unrelated donor HPC collection from peripheral blood apheresis or bone marrow as reported to the CIBMTR for the 2 years prior to the COVID19 pandemic (January 1, 2018 to December 31, 2019) and 2 years after the pandemic onset (March 12 2020 to March 11 2022).

Data requirements:

Data from CIBMTR form 2066 R6.0 (Infusion variables):

Donor variables: Donor registry (name); Age; Sex; Ethnicity; Type of growth factor used.

Donor outcome: Donor hospitalized? (Y/N); Transfused? (autologous vs allogeneic); Life threatening complications?

Central line placement? Death? (Y/N, cause if Y); Days of collection (1 vs >1)

Product variables: PBSC or BM; Cryopreservation used? (Y/N); TNC total and per kg recipient weight; CD34 total and /kg recipient weight; entire product thawed?(Y/N); incidence or product complaints during processing or thawing of product? (Y/N); product manipulation prior to infusion?(Y/N and type of manipulation if any); Positive culture obtained from product? (Y/N and type if any)

Sample requirements:

None

Study design:

None

Non-CIBMTR data source:

If possible, the requested cell dose for by transplant centres, as reported to NMDP for each donor would be added to the dataset.

Conflicts of interest:

None

References:

1. Hsu JW, Farhadfar N, Murthy H, et al. The Effect of Donor Graft Cryopreservation on Allogeneic Hematopoietic Cell Transplantation Outcomes: A Center for International Blood and Marrow Transplant Research Analysis. Implications during the COVID-19 Pandemic. *Transplant Cell Ther* 2021;27(6):507–16.
2. Devine S, Kuxhausen M, Spellman SR, et al. Cryopreservation of Allogeneic Hematopoietic Cell Grafts Did Not Adversely Affect Early Post-Transplant Survival during the First Six Months of the COVID-19 Pandemic. *Blood [Internet]* 2021;138:2846.

Table 1. Characteristics of unrelated NMDP donors donating between March 1st 2018 and July 31st 2022

Characteristic	2018	2019	2020	2021	2022	Total
No. of patients	3080	3806	4442	4765	2753	18846
Donor age at collection - no. (%)						
Median (min-max)	27.5 (18.1-60.8)	27.2 (18.2-60.9)	27.3 (18.3-60.8)	27.5 (17.7-60.9)	27.1 (18.2-60.8)	27.4 (17.7-60.9)
18-29	1982 (64)	2526 (66)	2953 (66)	3141 (66)	1861 (68)	12463 (66)
30-39	743 (24)	868 (23)	1023 (23)	1203 (25)	661 (24)	4498 (24)
40-49	276 (9)	309 (8)	361 (8)	302 (6)	166 (6)	1414 (8)
50+	79 (3)	103 (3)	105 (2)	118 (2)	65 (2)	470 (2)
Missing	0 (0)	0 (0)	0 (0)	1 (0)	0 (0)	1 (0)
Donor sex - no. (%)						
Male	2059 (67)	2548 (67)	2820 (63)	2905 (61)	1658 (60)	11990 (64)
Female	1021 (33)	1258 (33)	1622 (37)	1860 (39)	1095 (40)	6856 (36)
Disease - no. (%)						
AML/ANLL	1262 (41)	1539 (40)	1785 (40)	1943 (41)	1117 (41)	7646 (41)
ALL	387 (13)	471 (12)	571 (13)	541 (11)	334 (12)	2304 (12)
Other acute leukemia	26 (1)	65 (2)	42 (1)	71 (1)	38 (1)	242 (1)
CML	88 (3)	105 (3)	146 (3)	115 (2)	66 (2)	520 (3)
Other leukemia	50 (2)	40 (1)	58 (1)	50 (1)	28 (1)	226 (1)
MDS	601 (20)	794 (21)	901 (20)	985 (21)	612 (22)	3893 (21)
MPN	190 (6)	262 (7)	285 (6)	378 (8)	190 (7)	1305 (7)
NHL	181 (6)	209 (5)	259 (6)	226 (5)	172 (6)	1047 (6)
HD	28 (1)	41 (1)	52 (1)	32 (1)	38 (1)	191 (1)
PCD	39 (1)	32 (1)	46 (1)	51 (1)	10 (0)	178 (1)
Solid tumor	0 (0)	1 (0)	0 (0)	0 (0)	1 (0)	2 (0)
Non-malignant	223 (7)	240 (6)	294 (7)	340 (7)	127 (5)	1224 (6)
Other disease	2 (0)	4 (0)	2 (0)	11 (0)	4 (0)	23 (0)
Missing	3 (0)	3 (0)	1 (0)	22 (0)	16 (1)	45 (0)
Product - no. (%)						
Bone marrow	403 (13)	457 (12)	399 (9)	428 (9)	179 (7)	1866 (10)
PBSC	2677 (87)	3349 (88)	4043 (91)	4337 (91)	2574 (93)	16980 (90)

Characteristic	2018	2019	2020	2021	2022	Total
Cell dose as requested by center available - no. (%)						
No	186 (6)	240 (6)	281 (6)	310 (7)	149 (5)	1166 (6)
Yes	2894 (94)	3566 (94)	4161 (94)	4455 (93)	2604 (95)	17680 (94)
Number of donors where recipient data is available - no. (%)						
Yes	1865 (61)	2733 (72)	4114 (93)	4499 (94)	2664 (97)	15875 (84)
Cryopreservation of product - no. (%)						
No	1769 (95)	2565 (94)	1123 (27)	1448 (32)	758 (28)	7663 (48)
Yes	83 (4)	150 (5)	2986 (73)	3051 (68)	1906 (72)	8176 (52)
Missing	13 (1)	18 (1)	5 (0)	0 (0)	0 (0)	36 (0)
Cell dose infused/recipient kg available - no. (%)						
No	31 (2)	57 (2)	128 (3)	91 (2)	59 (2)	366 (2)
Yes	1834 (98)	2676 (98)	3986 (97)	4408 (98)	2605 (98)	15509 (98)