



## A G E N D A

### CIBMTR WORKING COMMITTEE FOR DONOR AND RECIPIENT HEALTH SERVICES WORKING COMMITTEE

San Antonio, TX

Wednesday, February 21, 2024, 1:00 – 3:00 PM CST

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:	Leslie Lehmann, MD; Dana Farber Cancer Institute, Boston, MA; Telephone: 617-632-4882; Email: leslie_lehmann@dfci.harvard.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
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Co-Chair:	Minoo Battiwalla, MD, MS; Sarah Cannon BMT Program, Nashville, TN; Telephone: 615-342-7644; E-mail: minoo.battiwalla@hcahealthcare.com Heather Stefanski, MD, PhD; CIBMTR Statistical Center, Minneapolis, MN; Telephone: 414-955-4153; E-mail: hstefans@nmdp.org
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WCTL Participant:	Megan Herr, PhD; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Telephone: 716-845-3557; Email: megan.herr@roswellpark.org

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### 1. Introduction

- a. Minutes from February 2023 DSWC and HSWC Tandem meeting sessions ([Attachment 1.1](#), [1.2](#))

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

### 3. Presentations, Published or Submitted papers

- a. **DS13-02** Guru Murthy GS, Logan BR, Bo-Subait S, Beitinjaneh A, Devine S, Farhadfar N, Gowda L, Hashmi S, Lazarus HM, 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. *American Journal of Hematology*. 2023 Apr 1; 98(4):608-619. doi:10.1002/ajh.26834. Epub 2023 Jan 6. Published.

**Not for publication or presentation**

- b. **DS19-02** Farhadfar N, Ahn KW, Bo-Subait S, Logan B, Stefanski H, Hsu J, Panch S, Confer D, Liu H, Badawy S, Beitinjaneh A, Diaz M, Hildebrandt G, Kelkar A, Lazarus H, Murthy H, Preussler JM, Schears R, Sharma A, Poel MV, Bruce J, Pulsipher M, Shaw B, Wingard J, Switzer G. 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):604.e1-603.e7. doi:10.1016/j.jtct.2022.05.042. Epub 2022 Jun 7. Published.
- c. **HS18-02** Blue BJ, Brazauskas R, Chen K, Patel J, Zeidan AM, Steinberg A, Ballen K, Kwok J, Rotz SJ, Perez MAD, Kelkar AH, Ganguly S, Wingard JR, Lad D, Sharma A, Badawy SM, Lazarus HM, Hashem H, Szwajcer D, Knight JM, Bhatt NS, Page K, Beattie S, Arai Y, Liu H, Arnold SD, Freytes CO, Abid MB, Beitinjaneh A, Farhadfar N, Wirk B, Winestone LE, Agrawal V, Preussler JM, Seo S, Hashmi S, Lehmann L, Wood WA, Rangarajan HG, Saber W, Majhail NS. Racial and Socioeconomic Disparities in Long-Term Outcomes in  $\geq 1$  Year Allogeneic Hematopoietic Cell Transplantation Survivors: A CIBMTR Analysis. *Transplantation and Cellular Therapy*. 2023 Nov 1; 29(11):709.e1-709.311. doi:10.1016/j.jtct.2023.07.013. Epub 2023 Jul 21. Published.
- d. **HS16-01a** Nandita Khera, Theresa Hahn, Sikander Ailawadhi, Wael Saber, Jinal Patel, Ruta Brazauskas. Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic Cell Transplantation in Racial and Ethnic Minorities. *Submission in-progress*.
- e. **HS16-03** Karen Ballen, Naya He, Tao Wang. Relationship of Race/Ethnicity and Survival After Single and Double Umbilical Cord Blood Transplantation. *Submission in-progress*.
- f. **HS18-01** Yasuyuki Arai, Yoshiko Atsuta, Shingo Yano, Naya He, Ruta Brazauskas. International Collaborative Study to Compare the Prognosis for Acute Leukemia Patients Transplanted with Intensified Myeloablative Regimens. *Submission in-progress*.

**4. Studies in progress (Attachment 3)**

- a. **DS20-01** Acute Toxicities of Bone Marrow Donation in Donors with Sickle Cell Trait (N Farhadfar/ J Wingard). **Analysis**.
- b. **DS23-01** Unrelated Donor Collection Efficiency and Adverse Events During the COVID-19 Pandemic (M Seftel). **Protocol Development**.
- c. **HS16-01b** Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic Cell Transplantation in Racial and Ethnic Minorities (N Khera/ T Hahn/ S Ailawadhi / W Saber). **Manuscript Preparation**.
- d. **HS19-01** Factors Associated with Clinical Trial Participation Among HCT Patients: A CIBMTR Analysis (TF Gray/ A El-Jawahri). **Datafile Preparation**.
- e. **HS19-03** Haploidentical Stem Cell Transplantation for Malignant and Non-malignant Hematological Diseases in Patients Without Sibling Donor: A Multicenter Prospective and Longitudinal Study of the Brazilian Bone Marrow Transplantation Study Group (SBTMO) (N Hamerschlak/ MN Kerbauy/AAF Ribeiro). **Data Collection**.
- f. **HS19-04** Outcomes After Allogeneic Stem Cell Transplants Performed in Brazil from HLA-matched Siblings, Unrelated and Mismatched Related Donors. Retrospective Study on Behalf of the Brazilian Bone Marrow Transplantation Society (SBTMO), GEDECo (Brazil-Seattle Transplant-related complications Consortium), Hospital Israelita Albert Einstein (AmigoH), Associação da Medula Óssea do Estado de São Paulo (Ameo), Programa Nacional de Apoio à Atenção Oncológica (Pronon), and CIBMTR (A Seber/ N Hamerschlak/ ME Flowers/ M Pasquini). **Datafile preparation/Analysis**.
- g. **HS20-01** Resource Intensity of End-of-Life Care in Children After Hematopoietic Stem Cell Transplant for Acute Leukemia: Rates and Disparities (EE Johnston/ CW Elgarten/ L Winestone/ R Aplenc/ K Getz/ V Huang/ Y Li). **Protocol Development**.

**5. Future/proposed studies**

- a. **PROP HS22-01** Health Care Utilization and Costs of haploidentical Allogeneic Stem Cell Transplants in a Contemporary Cohort Of Pediatric Patients With Acute Leukemia and Myelodysplastic Syndrome. (H Rangarajan / P Satwani)
- b. **PROP HS23-01** Community health status and long-term outcomes in 1-year survivors of autologous and allogeneic hematopoietic cell transplantation in the United States. (B Hamilton/ S Hong)
- c. **PROP 2302-01** Determining the Barriers Leading to Inferior Survival for Black and Hispanic Patients with Hodgkin lymphoma (E Mobley/ R Mailhot-Vega) ([Attachment 4](#))
- d. **PROP 2310-13; 2310-140; 2310-215; 2310-222; 2310-225; 2310-263** Racial and Ethnic Disparities in Safety and Efficacy of Chimeric Antigen Receptor T-cell Therapies in B-cell Acute Lymphoblastic Leukemia, Multiple Myeloma or Non-Hodgkin's Lymphoma (H Hashmi/ S Usmani/ J Ligon/ N Shah/ D Modi/ E Biltibo/ A Kassim/ L Gowda/ A Mirza) ([Attachment 5](#))
- e. **PROP 2310-44** Impact of Social Determinants of Health on Outcomes in Pediatric Patients Undergoing Haploidentical Stem Cell Transplantation for Acute Leukemia (L Davis/ P Satwani) ([Attachment 6](#))
- f. **PROP 2310-47** Outcomes for Medicaid Beneficiaries Following Allogeneic Hematopoietic Cell Transplantation: Exploring the Impact of Variable Medicaid Eligibility Criteria (P DeMartino/ N Majhail) ([Attachment 7](#))
- g. **PROP 2310-64** The Effect of Social Determinants of Health on Allogeneic Transplant Outcomes: A Study of the Impact of Social Vulnerability Index on Outcomes for Allogeneic Transplant for Acute Myeloid Leukemia (K Ballen/ I Varadarajan) ([Attachment 8](#))

***Proposed studies; not accepted for consideration at this time***

- h. **PROP 2310-74** Disparities in Multiple Myeloma Between Hispanics and non-Hispanics—Real World Outcomes. *Dropped - overlap with current study/publication.*
- i. **PROP 2310-79** Racial and Ethnic Discrepancies in Clinical Outcomes of Autologous Hematopoietic Cell Transplantation in Multiple Myeloma in non-Hispanic Black and Hispanic Populations as Compared to Caucasian Patients. *Dropped - low scientific impact.*
- j. **PROP 2310-133** Impact of Socioeconomic Factors on Allogeneic Stem Cell Transplant Outcomes. *Dropped - overlap with current study/publication.*
- k. **PROP 2310-149** Donor Race as a Determinant of Outcomes in Allogeneic Hematopoietic Stem Cell Transplantation for Myeloid Malignancies. *Dropped - supplemental data needed.*
- l. **PROP 2310-161** Longitudinal Investigation of Financial Toxicity and Association with Health-Related Quality of Life Indicators in Hematopoietic Stem Cell Transplant Recipients. *Dropped - small sample size.*

**6. Other business**

- a. HaploQol donor study



## MINUTES AND OVERVIEW PLAN

### CIBMTR WORKING COMMITTEE FOR DONOR HEALTH AND SAFETY

Orlando, FL

Wednesday, February 15, 2023, 1:00 – 3:00 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. 2022 Tandem DSWC session minutes (Attachment 1)

*The CIBMTR Donor Health and Safety Working Committee meeting was called to order by Dr. Galen Switzer at 1:10pm EST, on Wednesday, February 15<sup>th</sup>. The CIBMTR COI policy along with working committee leadership was introduced. Dr. Galen Switzer's departure was announced and Dr. Fotios (Frank) Michelis was appointed as the successor. Access to publicly available research datasets and the current patient reported outcome (PRO) protocol enrollment was illuminated. 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. **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)

*The studies in progress can be found in the materials which were linked to the online Tandem agenda.*

- 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)

*Dr. Jack Hsu introduced Lacey Williams, who gave an update on the review paper which aimed 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. The writing committee was considering the Journal of Clinical Oncology (JCO) for submission.*

#### 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)

*Matthew Seftel presented this proposal which aims to compare unrelated donor PBSC and BM collections prior to and during the COVID-19 pandemic era. The pandemic was hypothesized to*

*impact the target population by prompting higher cell dose requests, increased collection yields, and elevated incidences of donor adverse events. Results from this study may edify registries/collection centers on proper management of high cell dose requests, provide insight on donor counselling as cryopreservation continues, and optimize HPC dose targets with ongoing use of planned cryopreservation.*

*Concerns regarding the use of donor adverse event data were raised in consideration of the unfavorable data retention methods, though the importance of identifying potential trends of AEs justified the efforts required to retrieve data from spreadsheets. Isolating hospitalization from adverse events amongst donors was also advised. PIs were suggested to examine bone marrow transplants as a separate cohort and recognize COVID-19 as a potential confounder by stratifying on year of transplant. Acknowledgement of circumstances requiring donors to be prepped for fresh cell collection when cell count yield was too low from cryopreservation efforts would provide valuable insight for this protocol.*

***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

*Dr. Heather Stefanski introduced NMDP's new process for communicating genetic mutation findings identified in a patient's post-transplant appointment. Prior to the policy change enacted on 1/30/23, inconsistencies regarding donor disclosure and proper handling techniques were observed. Centers not being required to report genetic mutation findings raised concerns, but NMDP's efforts to encourage participation amongst centers will support this new research opportunity.*

*Dr. Galen Switzer introduced a new feasibility study for psychosocial, ethical, and clinical decisions regarding incidental diagnosis of clonal hematopoiesis among healthy, unrelated, hematopoietic stem cell donors. The qualitative examination of donors confirmed to have the CH+ genetic mutation will inform future research studies about study design feasibility and best practices of informing patients with incidental medical findings.*

<b>Working Committee Overview Plan for 2023-2024</b>		
<b>Study number and title</b>	<b>Current status</b>	<b>Chairs' priority</b>
DS20-01 Acute Toxicities of Bone Marrow Donation in Donors with Sickle Cell Trait	Data file preparation	1
DS23-01 Unrelated Donor Collection Efficiency and Adverse Events During the COVID-19 Pandemic	Protocol Pending	2

**MINUTES AND OVERVIEW PLAN****CIBMTR WORKING COMMITTEE FOR HEALTH SERVICES AND INTERNATIONAL STUDIES**

Orlando, FL

Friday, February 17, 2023, 12:00 – 2:00 pm

<b>Co-Chair:</b>	<b>Shahrukh Hashmi, MD, MPH, Mayo Clinic, Rochester, MN; Telephone: 507-284-3417; E-mail: hashmi.shahrukh@mayo.edu</b>
<b>Co-Chair:</b>	<b>Leslie Lehmann, MD, Dana Farber Cancer Institute, Boston, MA; Telephone: 617-632-4882; E-mail: leslie_lehmann@dfci.harvard.edu</b>
<b>Co-Chair:</b>	<b>Hemalatha Rangarajan, MD, Nationwide Children's Hospital, Columbus OH; Telephone: 740-953-0602 ; E-mail: hemalatha.rangarajan@nationwidechildrens.org</b>
<b>Scientific Director:</b>	<b>Wael Saber, MD, MS, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0677; E-mail: wsaber@mcw.edu</b>
<b>Scientific Director:</b>	<b>Rafeek Yusuf, MBBS, PHD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 614-355-1689; E-mail: ryusuf@nmdp.org</b>
<b>Statistical Director:</b>	<b>Ruta Brazauskas, PhD, CIBMTR Statistical Center; Milwaukee, WI ; Telephone: 414-955-8687; E-mail: ruta@mcw.edu</b>
<b>Statistician:</b>	<b>Jinalben Patel, BDS, MPH, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 469-571-3265; E-mail: jipatel@mcw.edu</b>

**1. Introduction**

The Health Services and International Studies Working Committee (HSWC) met on Friday, February 17, 2023, at 12:00 p.m. The chairs, scientific directors, and statisticians were all present at the meeting. Attendees were asked to have their name badges scanned at the front door to register physical attendance while those members attending the meeting virtually were counted as part of the committee membership roster. As chair of the HSWC, Dr. Shahrukh Hashmi welcomed the attendees on behalf of the working committee leadership and started the welcome presentation by introducing each member of the working committee leadership, acknowledging Dr. Saber for his contributions as the outgoing scientific director and introducing Dr. Yusuf as the new scientific director. Dr. Hashmi then explained how to enroll and maintain membership, the goals, and expectations of the working committee. Subsequently, Dr. Saber acknowledged and thanked Dr. Shahrukh for all his efforts and contributions as an outgoing co-chair and introduced Dr. Minoo Battiwalla as the newly appointed Chair for the Working Committee starting March 1, 2023.

Dr. Hashmi introduced the committee goals and expectations to the audience, then emphasized the scoring process and scoring guide. Dr. Hashmi discussed the rules of authorship and location of the publicly available datasets for secondary analysis on the CIBMTR webpage. He encouraged attendees to attend the Collaborative Study Proposal Session, where two proposals submitted to the Working Committee were selected for presentation. He then reviewed presentations, publications and submitted papers in 2022, and gave updates on the status of ongoing studies and their goals for 2023. Dr. Hashmi emphasized the productivity and engagement from the committee. He discussed important details about how the committee works, CIBMTR study development cycle, and explained the different sources of CIBMTR data collection. In addition, he discussed future priorities of the committee and clarified the voting process for submitted proposals to the audience and explained the PI's rule of conduct on the study cycle: timely completion of abstract, slides, and manuscript after the analysis is completed. If the PI does not write the first draft of the manuscript, after 3 requests, writing of the paper will be reassigned and the



investigator/member of the writing committee who writes the first draft will become the first author. The CIBMTR statistical resource was clarified to the audience. The average time to complete a study is 2-3 years dependent upon statistical hours allocation and other competing projects.

## 2. Accrual summary

The accrual summary was referenced by Dr. Hashmi for review but not formally presented due to a full agenda. The link to the full accrual summary was available online as part of the attachments. The accrual summary provides information about the number of patients available in the registration level (TED) and research level (CRF) for potential studies. Research level patients are subset of registration level. As of December 2022, 2,468,578 transplant cases were reported at the TED level only and 46,263 cases at the research level to the CIBMTR for first autologous transplant. For first allogeneic transplants, these numbers are 255,199 cases and 107,880 cases respectively.

## 3. Presentations, Published or Submitted Papers

Dr. Hashmi went through the abstracts presented at various conferences, mentioning that it was a very productive year. At the time three abstracts were presented or accepted for presentation.

These include:

- a. HS16-03 Karen K. Ballen, Tao Wang, Naya He, Shahrukh Hashmi, Leslie E. Lehmann, William A. Wood, Hemalatha G. Rangarajan, Wael Saber. Does Race/Ethnicity Impact Umbilical Cord Blood Transplant Outcomes in a Contemporary Era? **Oral presentation, ASH 2022 and Poster Presentation, 2023 Tandem Meetings.**
- b. HS18-01 Yasuyuki Arai, Yoshiko Atsuta, Ruta Brazauskas, Naya He, Shahrukh Hashmi, Leslie E. Lehmann, William A. Wood, Hemalatha G. Rangarajan, Shingo Yano, Shinichi Kako, Masamitsu Yanada, Yukiyasu Ozawa, Noriko Doki, Yoshinobu Kanda, Takahiro Fukuda, Yuta Katayama, Tatsuo Ichinohe<sup>18</sup>, Junji Tanaka, Junya Kanda, Takanori Teshima, Shinichiro Okamoto, Wael Saber; International Collaborative Study to Compare the Prognosis for Acute Leukemia Patients Transplanted with Intensified Myeloablative Regimens. **Poster presentation, ASH 2022.**
- c. HS16-01 Nandita Khera, Megan Herr, Ruta Brazauskas, Jinalben Patel, Benjamin Jacobs, Naya He, Leslie Lehmann, Shahrukh Hashmi, Hemalatha Rangarajan, Sikander Ailawadhi, Wael Saber, Theresa Hahn; Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic cell Transplantation in Racial and Ethnic Minorities. **Poster Presentation, 2023 Tandem Meetings.**

## 4. Studies in Progress

Dr. Hashmi presented the summary of studies in progress.

- a. HS16-01 Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic cell Transplantation in Racial and Ethnic Minorities (N Khera/ T Hahn/ S Ailawadhi / W Saber), Manuscript Preparation.
- b. HS16-03 Relationship of Race/Ethnicity and Survival after Single and Double Umbilical Cord Blood Transplantation (K Ballen), Manuscript Preparation.
- c. HS18-01 International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens (Y Arai/ Y Atsuta/ S Yano), Manuscript Preparation.
- d. HS18-02 Racial differences in long term survivor outcomes after allogeneic transplants (B Blue/ N Majhail), Manuscript Preparation.
- e. HS19-01 Factors Associated with Clinical Trial Participation among HCT Patients: A CIBMTR Analysis (T F Gray/ A El-Jawahri), Protocol Development.
- f. HS19-03 Haploidentical Stem Cell Transplantation for malignant and non-malignant hematological diseases in patients without sibling donor: A multicenter prospective and longitudinal study of the

Brazilian bone marrow transplantation study group (SBTMO) (N Hamerschlak/ M N Kerbauy/ A A F Ribeiro), Data Collection.

- g. HS19-04 Outcomes after allogeneic stem cell transplants performed in Brazil from HLA-matched siblings, unrelated and mismatched related donors. Retrospective study on behalf of the Brazilian Bone Marrow Transplantation Society (SBTMO), GEDECo (Brazil-Seattle Transplant-related complications Consortium), Hospital Israelita Albert Einstein (AmigoH), Associação da Medula Óssea do Estado de São Paulo (Ameo), Programa Nacional de Apoio à Atenção Oncológica (Pronon), and CIBMTR (A Seber/ N Hamerschlak/ M E Flowers/ M Pasquini), Analysis.
- h. HS20-01 Resource Intensity of End-of-Life Care in Children After Hematopoietic Stem Cell Transplant for Acute Leukemia: Rates and Disparities (E E Johnston/ C W. Elgarten/ L Winestone/ R Aplenc/ K Getz/ V Huang/ Y Li), Datafile Preparation.

## 5. Future/Proposed Studies/Study Updates

Dr. Shahrukh thanked the investigators whose proposals were submitted but not selected for presentation. This year, we had a record of 10 proposals received. Two were invited for presentation at the individual HSWC meeting and 2 (1 of which was a combination of 4 of the received proposals due to similar/complementary themes) were presented at the Collaborative Session. Dr. Shahrukh emphasized that the remaining were dropped due to overlaps with current studies and data availability issues; and reiterated the voting process. Dr. Leslie Lehmann introduced the presenters for the 2 proposals.

- a. **PROP 2209-20:** Impact of Ambient Air Pollution Exposure on Outcomes in Pediatric Bone Marrow Transplantation (Paul George; Staci Arnold)

It was a pre-recorded presentation by Dr. George on behalf of the group with Dr. Arnold attending in-person. This study hypothesizes that ambient air pollution exposure is a key biologic link between sociodemographic risk factors and poor health outcomes and therefore higher levels of neighborhood air pollution will be associated with worse overall survival and event free survival among pediatric BMT recipients. It further hypothesizes that these associations will be highest amongst socially vulnerable patients, including those living in high-poverty neighborhoods, minority patients, and those without private insurance. The primary exposure of interest will be neighborhood PM2.5 levels (continuous variable), and the primary outcomes of interest will be overall survival and event-free survival (binary variables). Covariates of interest will include age, gender, race, ethnicity, disease (malignant vs. non-malignant), neighborhood poverty, and primary insurance. Interactions between air pollution exposure and key sociodemographic factors will also be investigated as secondary outcomes, as it is hypothesized that air pollution exposure has increased harms amongst patients living in poverty. Time to-event analyses will also be performed as key secondary outcomes.

**Comments from the audience:** One of the attendees asked why the age is restricted to 21, will it not affect the older population? Dr. George answered that his area of interest is pediatric oncology, so his population of interest is pediatric population. Dr. Arnold added if the committee approves the study and is willing to extend the population and year that would be great. Another question was, how would the investigators tease out if low income/poverty not air pollution is the real cause of the outcomes under consideration? Dr. George commented that they will be accounting on neighborhood poverty data using US census data. And explained their hypothesis that these associations will be highest amongst socially vulnerable patients, including those living in high-poverty neighborhoods, minority patients, and those without private insurance, which would look for poverty. . Dr. Saber asked about hypothesis concerning autologous transplant and he stated it would be more corresponding to allogeneic transplant than autologous transplant. Dr. George agreed that pathology under allogeneic transplant would have higher impact and, also mentioned that sickle cell disease would have more pathophysiology undergoing transplant. He further explained that air pollution also damages endothelial layer and that was a justification that both auto- and allo-transplant would have overlapping pathophysiological impact. Also,

he added that with large sample size we would be able to see the impact. Dr. Battiwalla added that other covariates like pulmonary comorbidities should be considered. The audience was concerned about granularity of air pollution. Dr. George replied that it would be used on 1 km to 1 km grade by consolidating as CIBMTR data is zip code level. One of the attendees mentioned that gradient keep changing throughout measurement and what would be the cut point. Dr. George replied that yearly average would be considered. Dr. Rangarajan pointed out along with pre-transplant and ongoing transplant outcomes, the investigators should look for post-transplant outcome along with the lung outcomes.

- b. **PROP 2210-93:** Community health status and long-term outcomes in 1-year survivors of autologous and allogeneic hematopoietic cell transplantation in the United States (Betty Hamilton; Sanghee Hong)

Dr. Hong presented the proposal on behalf of the group. This study hypothesizes that poor community health factors (high community risk), measured using the County Health Rankings and Roadmaps (CHRR) database, (refs 1,2) are associated with inferior long-term outcomes in HCT recipients surviving at least 1 year after transplant. The primary objective of this proposal is to investigate the association between community health status based on patient's residence (Patient Community Score [PCS]) and both continuous and 5-year overall survival (OS) in long-term survivors ( $\geq 1$  year) of allogeneic and autologous HCT. The secondary objectives are to investigate the association between PCS and the following long-term transplant outcomes: non-relapse mortality (NRM), relapse, and chronic graft-versus-host disease (cGVHD) (measured by incidence and maximum grade, only for allogeneic HCT recipients). Investigate the association between PCS and other late effects of transplant and to identify associations between long-term outcomes (secondary aim 1) or late effects (secondary aim 2) and each of the four PCS subcategories: physical environment, social and economic factors, clinical care, and health behaviors.

**Comments from the audience:** Dr. Lehmann asked about poverty, how will it be adjusted for? Dr. Hong answered that one of the measures is socioeconomic status defined at county level will be used to adjust for it. Dr. Khera mentioned that patients might be moving out from the transplant zip code and that would be a limitation of the analysis. Dr. Hong agreed and added that survivors may have moved once, twice as many times as they want, and they could be impacted by the neighborhood they have been living. One of the attendees, mention that distance to transplant center should be considered to see how far they need to travel to get transplant. Dr. Hong mentioned that in a prior study, they did see a difference in late effects but a long-term survivor does not need to visit transplant center that often so that might be not as huge as we look in short term effects. Dr. Saber asked why the investigators were excluding patients who died within 1<sup>st</sup> year and wanted to know the rationale. Dr. Hong replied that we already know for short term outcome, and we need to know how the community is impacted by long term outcomes. Long term survivors would be more impacted by the infrastructure, set ups and neighborhoods they live in. Dr. Yusuf asked how the study would explain ecologic fallacy of using aggregate data to individual outcome. One of the attendees asked if all the covariates are continuous or categorical variables. Dr. Hong answered that this data is updated annually and some of the variables are updated 2-3 years. How would quality of life would be measured and if any metrics are available? Dr. Hong said they would consider admission rate, death rates, ED rates.

Dr. Hemalatha Rangarajan introduced the presenters for the 2 study updates.

- a. **HS16-01:** Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic cell Transplantation in Racial and Ethnic Minorities (N Khera/ T Hahn/ S Ailawadhi / W Saber)

Dr. Khera presented the study updates on behalf of the group. The main objectives of the study are to describe changes in the volume and rate of auto and alloHCT in different racial/ethnic groups from 2009

to 2018 and to examine trends in survival after auto and alloHCT within each racial/ethnic group from 2009 to 2018 (paper 1). AlloHCT in adult & pediatric patients (Acute Leukemias, Lymphoma and MDS/MPN) and autoHCT in adults (NHL, Hodgkin's lymphoma, and Multiple Myeloma). To examine trends in utilization of autoHCT for MM and Lymphomas and alloHCT for Acute Leukemias and MDS within each racial/ethnic group from 2009 to 2018, comparing two different methodologies (paper 2). Conclusion from the analysis was differences in the magnitude of rates though direction usually similar with the two methods. Significant increases in utilization of alloHCT, but not in autoHCT (except for Hispanics with MM) from 2009 to 2018 and disparities remain for alloHCT for most diseases for AAs.

**Comments from the audience:** Attendees appreciated the work and its affirmative to work on two methods and suggested to include sensitive analysis in the manuscript. Dr. Lehmann added that it is an amazing work no research to date has compared different methodologies. One of the attendees had concerns if there were any pattern for missing zip code data. Dr. Saber mentioned that CIBMTR started collecting data later so there was lag in reporting and till we get complete data.

- b. **HS19-01:** Factors Associated with Clinical Trial Participation among HCT Patients: A CIBMTR Analysis (T F Gray/ A El-Jawahri)

It was a pre-recorded study update presented by Dr. Gray on behalf of the group. This study hypothesizes that patients undergoing allogeneic HCT are more likely to participate in a clinical trial compared to those who undergo autologous HCT. Patients who are White, unmarried, younger, and those with private health insurance are more likely to participate in clinical trials. Patients with higher education and those with higher income are more likely to participate in clinical trials. Clinical trial participation will be associated with better OS and lower NRM among autologous and allogeneic HCT recipients. The specific aims of this study are to describe rates of clinical trial participation based on HCT type. To explore factors that are associated with clinical trial participation in patients with undergoing HCT. To assess the impact of clinical trial participation on overall survival (OS) and non-relapse mortality (NRM) in autologous and allogeneic HCT recipients.

**Comments from the audience:** Dr. Khara raised the question if there is data of those centers who never have clinical trials and will these centers be excluded. Dr. Gray agreed that we are going to look for that moving forward. One of the attendees mentioned that center effect would play a role as some centers are more motivated and active and get lots of patients' enrollment. Also, PI should look for number of open studies during the period and compare expected vs actual participation. Dr. Lehmann asked how the question is interpreted by the individual, is this question only for interventional study? PI mentioned that it would be a limitation of study, how the question is interpreted by the person.

**Three additional proposals were submitted but not presented as listed below:**

- a. **PROP 2210-85:** Outcomes of allogeneic hematopoietic stem cell transplantation based on access to care. Dropped-low scientific impact.
- b. **PROP 2210-162:** Socioeconomic Disparities Impacting Access to BCMA directed Chimeric Antigen Receptor T cell therapy and Clinical Outcomes. Dropped-supplemental data needed.
- c. **PROP 2210-258:** Geographic and Racial Disparities in Access to Chimeric Antigen Receptor-T Cells and Bispecific Antibodies. Dropped-low scientific impact.

The meeting was adjourned at **1:35** p.m. Dr. Saber asked the audience to give an applause and thanked them for actively participating in the meeting.

**6. Other Business**

The chairs of the working committee, scientific directors, and statisticians had a post-WC meeting afterwards. After the new proposals were presented, each attendee had the opportunity to vote for the proposals using the provided voting sheets. Based on the voting results, current scientific merit, and impact of the studies on the field, the following studies were decided to move forward as the committee’s research portfolio for the upcoming year:

- a. **PROP 2210-93:** Community health status and long-term outcomes in 1-year survivors of autologous and allogeneic hematopoietic cell transplantation in the United States (Betty Hamilton; Sanghee Hong)

<b>Working Committee Overview Plan for 2023-2024</b>		
<b>Study number and title</b>	<b>Current status</b>	<b>Chairs Priority</b>
<b>HS16-01</b> Trends in utilization and outcomes of autologous and allogeneic hematopoietic cell transplantation in racial and ethnic minorities.	Manuscript Preparation	1
<b>HS16-03</b> Relationship of Race/Ethnicity and Survival after Single and Double Umbilical Cord Blood Transplantation	Manuscript Preparation	2
<b>HS18-01</b> International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens	Manuscript Preparation	3
<b>HS18-02</b> Racial differences in long term survivor outcomes after Allogeneic hematopoietic cell transplantation	Manuscript Preparation	2
<b>HS18-03</b> Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia	Protocol Development	4
<b>HS19-01</b> Factors associated with clinical trial participation among hematopoietic stem cell transplant patients: A CIBMTR analysis.	Data File Preparation	5
<b>HS20-01</b> Resource Intensity of end-of-life care in children after hematopoietic stem cell transplant for acute leukemia: Rates and disparities.	Protocol Development	6
<b>HS22-01</b> Health care utilization and costs of haploidentical allogeneic stem cell transplants in a contemporary cohort of	Protocol Development	7

pediatric patients with acute leukemia and myelodysplastic syndrome.		
<b>HS23-01</b> Community health status and long-term outcomes in 1-year survivors of autologous and allogeneic hematopoietic cell transplantation in the United States.	Protocol Development	8

<b>Oversight Assignments for Working Committee Leadership (March 2023)</b>	
Leslie Lehmann	<b>HS16-01</b> Trends in utilization and outcomes of autologous and allogeneic hematopoietic cell transplantation in racial and ethnic minorities
	<b>HS20-01</b> Resource Intensity of end-of-life care in children after hematopoietic stem cell transplant for acute leukemia: Rates and disparities
	<b>HS22-01</b> Health care utilization and costs of haploidentical allogeneic stem cell transplants in a contemporary cohort of pediatric patients with acute leukemia and myelodysplastic syndrome.
Hemalatha Rangarajan	<b>HS16-03</b> Relationship of race/ethnicity and survival after single and double umbilical cord blood transplantation
	<b>HS19-01</b> Factors associated with clinical trial participation among HSCT patients: a CIBMTR Analysis
Mino Battiwalla	<b>HS18-01</b> International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens
	<b>HS18-02</b> Racial differences in long term survivor outcomes after Allogeneic hematopoietic cell transplantation
	<b>HS18-03</b> Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia
	<b>HS23-01</b> Community health status and long-term outcomes in 1-year survivors of autologous and allogeneic hematopoietic cell transplantation in the United States.

## Accrual Summary for the Donor and Recipient Health Services Working Committee

Table 1. Characteristics of domestic unrelated NMDP donors donating between 1988 and December 2022 <sup>a</sup>

Characteristic	Bone marrow	PBSC	Total
No. of patients	26498	43435	69933
<b>Characteristics</b>			
Donor age at collection - no. (%)			
Median (min-max)	33.7 (18.3-61.1)	30.3 (18.3-62.3)	31.7 (18.3-62.3)
18-29	9926 (37.5)	21141 (48.7)	31067 (44.4)
30-39	8800 (33.2)	11866 (27.3)	20666 (29.6)
40-49	6073 (22.9)	7417 (17.1)	13490 (19.3)
50+	1699 (6.4)	3011 (6.9)	4710 (6.7)
Donor sex - no. (%)			
Male	15893 (60.0)	27198 (62.6)	43091 (61.6)
Female	10605 (40.0)	16237 (37.4)	26842 (38.4)
Donor race/ethnicity - no. (%)			
Caucasian	18519 (69.9)	29073 (66.9)	47592 (68.1)
African/African-American	1505 (5.7)	1661 (3.8)	3166 (4.5)
Asian/Pacific Islander	1257 (4.7)	2311 (5.3)	3568 (5.1)
Hispanic	2404 (9.1)	3673 (8.5)	6077 (8.7)
Native American	285 (1.1)	288 (0.7)	573 (0.8)
Multiple/Other	1596 (6.0)	3521 (8.1)	5117 (7.3)
Missing	932 (3.5)	2908 (6.7)	3840 (5.5)
Donor CMV status - no. (%)			
Negative	14589 (55.1)	24163 (55.6)	38752 (55.4)
Positive	11564 (43.6)	18921 (43.6)	30485 (43.6)
Unknown/inconclusive	345 (1.3)	351 (0.8)	696 (1.0)
Year of donation - no. (%)			
1988	78 (0.3)	0 (0.0)	78 (0.1)
1989	176 (0.7)	0 (0.0)	176 (0.3)
1990	280 (1.1)	0 (0.0)	280 (0.4)
1991	433 (1.6)	0 (0.0)	433 (0.6)
1992	547 (2.1)	0 (0.0)	547 (0.8)
1993	639 (2.4)	0 (0.0)	639 (0.9)
1994	794 (3.0)	5 (0.0)	799 (1.1)

Characteristic	Bone marrow	PBSC	Total
1995	867 (3.3)	21 (0.0)	888 (1.3)
1996	1039 (3.9)	14 (0.0)	1053 (1.5)
1997	1164 (4.4)	17 (0.0)	1181 (1.7)
1998	1234 (4.7)	29 (0.1)	1263 (1.8)
1999	1222 (4.6)	71 (0.2)	1293 (1.8)
2000	1192 (4.5)	311 (0.7)	1503 (2.1)
2001	1063 (4.0)	454 (1.0)	1517 (2.2)
2002	1068 (4.0)	752 (1.7)	1820 (2.6)
2003	891 (3.4)	995 (2.3)	1886 (2.7)
2004	796 (3.0)	1091 (2.5)	1887 (2.7)
2005	646 (2.4)	1256 (2.9)	1902 (2.7)
2006	666 (2.5)	1385 (3.2)	2051 (2.9)
2007	643 (2.4)	1475 (3.4)	2118 (3.0)
2008	670 (2.5)	1719 (4.0)	2389 (3.4)
2009	672 (2.5)	1843 (4.2)	2515 (3.6)
2010	711 (2.7)	1964 (4.5)	2675 (3.8)
2011	753 (2.8)	2118 (4.9)	2871 (4.1)
2012	931 (3.5)	2515 (5.8)	3446 (4.9)
2013	924 (3.5)	2743 (6.3)	3667 (5.2)
2014	897 (3.4)	2647 (6.1)	3544 (5.1)
2015	805 (3.0)	2507 (5.8)	3312 (4.7)
2016	821 (3.1)	2308 (5.3)	3129 (4.5)
2017	812 (3.1)	2207 (5.1)	3019 (4.3)
2018	752 (2.8)	2260 (5.2)	3012 (4.3)
2019	662 (2.5)	2358 (5.4)	3020 (4.3)
2020	535 (2.0)	2470 (5.7)	3005 (4.3)
2021	552 (2.1)	2738 (6.3)	3290 (4.7)
2022	563 (2.1)	3162 (7.3)	3725 (5.3)
<b>Form completion</b>			
Baseline <sup>b,c</sup> - no./total no. (%)	10390/26498 (39.2)	33833/43435 (77.9)	44223/69933 (63.2)
Day of collection (BM donors) <sup>b,d</sup> - no./total no. (%)	9956/26498 (37.6)	0/43435 (0)	9956/69933 (14.2)
Day 1 of collection (PBSC donors) <sup>b,e</sup> - no./total no. (%)	0/26498 (0)	32734/43435 (75.4)	32734/69933 (46.8)



<b>Characteristic</b>	<b>Bone marrow</b>	<b>PBSC</b>	<b>Total</b>
Product (BM donors) <sup>b,f</sup> - no./total no. (%)	24291/26498 (91.7)	0/43435 (0)	24291/69933 (34.7)
First product (PBSC donors) <sup>b,g</sup> - no./total no. (%)	0/26498 (0)	32529/43435 (74.9)	32529/69933 (46.5)

<sup>a</sup> There have been 6439 bone marrow and 23950 PBSC international donors during this time frame.

<sup>b</sup> Completed with FormsNet1 or FormsNet2 (approximately 2004 and forward).

<sup>c</sup> Form 700 collects information related to vital signs, hematology, MTC, infection, pain, and venous access.

<sup>d</sup> Form 732 collects information related to MTC, infection, pain, vital signs, pre-collection hematology, post-collection hematology, and ABO typing.

<sup>e</sup> Form 730 collects information related to MTC, infection, pain, vital signs, pre-apheresis hematology, post-apheresis hematology, and ABO typing.

<sup>f</sup> Form 772 collects information related to marrow product analysis.

<sup>g</sup> 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 2022<sup>a</sup>**

<b>Characteristic</b>	<b>Bone marrow</b>	<b>PBSC</b>	<b>Total</b>
No. of patients	130	1061	1191
<b><u>Characteristics</u></b>			
Donor age at collection - no. (%)			
Median (min-max)	36.9 (18.0-60.5)	49.6 (18.2-63.0)	48.3 (18.0-63.0)
18-29	41 (31.5)	118 (11.1)	159 (13.4)
30-39	38 (29.2)	228 (21.5)	266 (22.3)
40-49	22 (16.9)	196 (18.5)	218 (18.3)
50+	29 (22.3)	519 (48.9)	548 (46.0)
Donor sex - no. (%)			
Male	80 (61.5)	639 (60.2)	719 (60.4)
Female	50 (38.5)	422 (39.8)	472 (39.6)
Donor race/ethnicity - no. (%)			
Caucasian	75 (57.7)	821 (77.4)	896 (75.2)
African/African-American	27 (20.8)	68 (6.4)	95 (8.0)
Asian/Pacific Islander	2 (1.5)	36 (3.4)	38 (3.2)
Hispanic	18 (13.8)	73 (6.9)	91 (7.6)
Multiple/Other	4 (3.1)	34 (3.2)	38 (3.2)
Missing	4 (3.1)	29 (2.7)	33 (2.8)
Donor CMV status - no. (%)			
Negative	67 (51.5)	534 (50.3)	601 (50.5)
Positive	63 (48.5)	521 (49.1)	584 (49.0)
Unknown/inconclusive	0 (0.0)	6 (0.6)	6 (0.5)
Year of donation - no. (%)			
2009	0 (0.0)	1 (0.1)	1 (0.1)
2012	0 (0.0)	1 (0.1)	1 (0.1)
2013	0 (0.0)	5 (0.5)	5 (0.4)
2014	1 (0.8)	2 (0.2)	3 (0.3)
2015	2 (1.5)	7 (0.7)	9 (0.8)
2016	6 (4.6)	17 (1.6)	23 (1.9)
2017	23 (17.7)	54 (5.1)	77 (6.5)
2018	18 (13.8)	92 (8.7)	110 (9.2)
2019	14 (10.8)	97 (9.1)	111 (9.3)

Characteristic	Bone marrow	PBSC	Total
2020	35 (26.9)	265 (25.0)	300 (25.2)
2021	18 (13.8)	317 (29.9)	335 (28.1)
2022	13 (10.0)	203 (19.1)	216 (18.1)
<b>Form completion</b>			
Baseline <sup>b,c</sup> - no./total no. (%)	130/130 (100)	1061/1061 (100)	1191/1191 (100)
Day of collection (BM donors) <sup>b,d</sup> - no./total no. (%)	129/130 (99.2)	0/1061 (0)	129/1191 (10.8)
Day 1 of collection (PBSC donors) <sup>b,d</sup> - no./total no. (%)	0/130 (0)	1059/1061 (99.8)	1059/1191 (88.9)
Product form (BM donors) <sup>b,d</sup> - no./total no. (%)	130/130 (100)	0/1061 (0)	130/1191 (10.9)
First product form (PBSC donors) <sup>b,d</sup> - no./total no. (%)	0/130 (0)	1057/1061 (99.6)	1057/1191 (88.7)

<sup>a</sup> There have been 31 bone marrow and 137 PBSC international donors during this time frame.

<sup>b</sup> Completed with FormsNet2 (approximately 2009 and forward). Similar data are collected prior to 2009.

<sup>c</sup> Form 700 collects information related to vital signs, hematology, MTC, infection, pain, and venous access.

<sup>d</sup> Form 732 collects information related to MTC, infection, pain, vital signs, pre-collection hematology, post-collection hematology, and ABO typing.

<sup>e</sup> Form 730 collects information related to MTC, infection, pain, vital signs, pre-apheresis hematology, post-apheresis hematology, and ABO typing.

<sup>f</sup> Form 772 collects information related to marrow product analysis.

<sup>g</sup> 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. 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	48612	21726	12745
Source of data			
CRF	25221 (52)	8369 (39)	5985 (47)
TED	23391 (48)	13357 (61)	6760 (53)
Number of centers	264	244	382
Disease at transplant			
AML	16913 (35)	8236 (38)	4255 (33)
ALL	7024 (14)	2775 (13)	2038 (16)
Other leukemia	1487 (3)	456 (2)	317 (2)
CML	3553 (7)	1171 (5)	1049 (8)
MDS	7232 (15)	3914 (18)	1638 (13)
Other acute leukemia	535 (1)	263 (1)	146 (1)
NHL	4284 (9)	1493 (7)	940 (7)
Hodgkin Lymphoma	962 (2)	277 (1)	216 (2)
Plasma Cell Disorders, MM	945 (2)	298 (1)	209 (2)
Other malignancies	60 (<1)	14 (<1)	22 (<1)
Breast cancer	7 (<1)	3 (<1)	1 (<1)
SAA	1557 (3)	671 (3)	561 (4)
Inherited abnormalities erythrocyte diff fxn	718 (1)	255 (1)	241 (2)
Inherited bone marrow failure syndromes	36 (<1)	51 (<1)	30 (<1)
Hemoglobinopathies	31 (<1)	31 (<1)	20 (<1)
Paroxysmal nocturnal hemoglobinuria	4 (<1)	10 (<1)	3 (<1)
SCIDs	842 (2)	367 (2)	401 (3)
Inherited abnormalities of platelets	42 (<1)	16 (<1)	12 (<1)
Inherited disorders of metabolism	306 (1)	93 (<1)	153 (1)
Histiocytic disorders	391 (1)	135 (1)	133 (1)
Autoimmune disorders	28 (<1)	19 (<1)	13 (<1)
MPN	1603 (3)	1160 (5)	323 (3)
Others	52 (<1)	18 (<1)	24 (<1)
AML Disease status at transplant			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CR1	9303 (55)	5250 (64)	2139 (50)
CR2	3208 (19)	1365 (17)	838 (20)
CR3+	341 (2)	116 (1)	98 (2)
Advanced or active disease	3877 (23)	1467 (18)	1033 (24)
Missing	184 (1)	38 (<1)	147 (3)
ALL Disease status at transplant			
CR1	3513 (50)	1625 (59)	870 (43)
CR2	1996 (28)	707 (25)	587 (29)
CR3+	581 (8)	180 (6)	191 (9)
Advanced or active disease	852 (12)	238 (9)	270 (13)
Missing	82 (1)	25 (1)	120 (6)
MDS Disease status at transplant			
Early	1535 (21)	712 (18)	370 (23)
Advanced	4722 (65)	2956 (76)	921 (56)
Missing	975 (13)	246 (6)	347 (21)
NHL Disease status at transplant			
CR1	613 (14)	290 (20)	133 (14)
CR2	800 (19)	296 (20)	153 (16)
CR3+	371 (9)	131 (9)	86 (9)
PR	449 (11)	111 (7)	94 (10)
Advanced	1959 (46)	637 (43)	440 (47)
Missing	72 (2)	20 (1)	31 (3)
Recipient age at transplant			
0-9 years	3999 (8)	1337 (6)	1694 (13)
10-17 years	3169 (7)	1049 (5)	1203 (9)
18-29 years	5825 (12)	2080 (10)	1687 (13)
30-39 years	5443 (11)	2021 (9)	1476 (12)
40-49 years	7259 (15)	2733 (13)	1823 (14)
50-59 years	9972 (21)	4217 (19)	2181 (17)
60-69 years	10440 (21)	6168 (28)	2185 (17)
70+ years	2505 (5)	2121 (10)	496 (4)
Median (Range)	48 (0-84)	55 (0-82)	42 (0-84)
Recipient race			
White	42622 (91)	19046 (91)	9527 (88)
Black or African American	2298 (5)	894 (4)	609 (6)
Asian	1235 (3)	664 (3)	553 (5)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Native Hawaiian or other Pacific Islander	70 (<1)	33 (<1)	40 (<1)
American Indian or Alaska Native	193 (<1)	96 (<1)	64 (1)
Other	49 (<1)	27 (<1)	28 (<1)
More than one race	285 (1)	129 (1)	62 (1)
Unknown	1860 (N/A)	837 (N/A)	1862 (N/A)
Recipient ethnicity			
Hispanic or Latino	4078 (10)	1642 (8)	1175 (11)
Non Hispanic or non-Latino	36772 (88)	17419 (90)	6776 (64)
Non-resident of the U.S.	882 (2)	297 (2)	2570 (24)
Unknown	6880 (N/A)	2368 (N/A)	2224 (N/A)
Recipient sex			
Male	28201 (58)	12741 (59)	7579 (59)
Female	20411 (42)	8985 (41)	5166 (41)
Karnofsky score			
10-80	17009 (35)	8589 (40)	4027 (32)
90-100	29824 (61)	12491 (57)	8060 (63)
Missing	1779 (4)	646 (3)	658 (5)
HLA-A B DRB1 groups - low resolution			
<=3/6	29 (<1)	97 (<1)	7 (<1)
4/6	265 (1)	112 (1)	60 (1)
5/6	6582 (14)	2447 (12)	1794 (15)
6/6	40711 (86)	17245 (87)	10049 (84)
Unknown	1025 (N/A)	1825 (N/A)	835 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	901 (2)	156 (1)	83 (1)
6/8	1833 (4)	194 (1)	262 (3)
7/8	9074 (19)	2726 (16)	1995 (22)
8/8	35275 (75)	14215 (82)	6922 (75)
Unknown	1529 (N/A)	4435 (N/A)	3483 (N/A)
HLA-DPB1 Match			
Double allele mismatch	11999 (29)	2830 (23)	1168 (25)
Single allele mismatch	22536 (54)	6397 (52)	2444 (52)
Full allele matched	7414 (18)	3115 (25)	1079 (23)
Unknown	6663 (N/A)	9384 (N/A)	8054 (N/A)
High resolution release score			
No	13343 (27)	21647 (>99)	12126 (95)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Yes	35269 (73)	79 (<1)	619 (5)
KIR typing available			
No	34811 (72)	21699 (>99)	12629 (99)
Yes	13801 (28)	27 (<1)	116 (1)
Graft type			
Marrow	16553 (34)	5318 (24)	4980 (39)
PBSC	31958 (66)	16179 (74)	7697 (60)
BM+PBSC	16 (<1)	20 (<1)	5 (<1)
PBSC+UCB	40 (<1)	186 (1)	10 (<1)
Others	45 (<1)	23 (<1)	53 (<1)
Conditioning regimen			
Myeloablative	29377 (60)	11114 (51)	7910 (62)
RIC/Nonmyeloablative	19007 (39)	10541 (49)	4668 (37)
TBD	228 (<1)	71 (<1)	167 (1)
Donor age at donation			
To Be Determined/NA	788 (2)	1002 (5)	302 (2)
0-9 years	4 (<1)	33 (<1)	1 (<1)
10-17 years	1 (<1)	14 (<1)	1 (<1)
18-29 years	23838 (49)	11625 (54)	5477 (43)
30-39 years	13560 (28)	5555 (26)	3778 (30)
40-49 years	7985 (16)	2666 (12)	2414 (19)
50+ years	2436 (5)	831 (4)	772 (6)
Median (Range)	30 (0-69)	29 (0-89)	32 (4-77)
Donor/Recipient CMV serostatus			
+/+	12113 (25)	6051 (28)	3314 (26)
+/-	5690 (12)	2775 (13)	1552 (12)
-/+	15778 (32)	6481 (30)	3842 (30)
-/-	13788 (28)	5611 (26)	3360 (26)
CB - recipient +	36 (<1)	150 (1)	9 (<1)
CB - recipient -	4 (<1)	44 (<1)	2 (<1)
CB - recipient CMV unknown	0	1 (<1)	0
Missing	1203 (2)	613 (3)	666 (5)
GvHD Prophylaxis			
No GvHD Prophylaxis	176 (<1)	93 (<1)	54 (<1)
TDEPLETION alone	123 (<1)	49 (<1)	64 (1)
TDEPLETION +- other	1101 (2)	304 (1)	392 (3)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CD34 select alone	290 (1)	159 (1)	103 (1)
CD34 select +- other	514 (1)	276 (1)	141 (1)
Cyclophosphamide alone	234 (<1)	88 (<1)	59 (<1)
Cyclophosphamide +- others	3834 (8)	3975 (18)	925 (7)
FK506 + MMF +- others	5440 (11)	2132 (10)	975 (8)
FK506 + MTX +- others(not MMF)	20699 (43)	9116 (42)	3590 (28)
FK506 +- others(not MMF,MTX)	2475 (5)	1310 (6)	486 (4)
FK506 alone	1186 (2)	509 (2)	227 (2)
CSA + MMF +- others(not FK506)	3093 (6)	966 (4)	1044 (8)
CSA + MTX +- others(not MMF,FK506)	6961 (14)	1934 (9)	3484 (27)
CSA +- others(not FK506,MMF,MTX)	1087 (2)	334 (2)	462 (4)
CSA alone	461 (1)	133 (1)	388 (3)
Other GVHD Prophylaxis	758 (2)	292 (1)	216 (2)
Missing	180 (<1)	56 (<1)	135 (1)
Donor/Recipient sex match			
Male-Male	19692 (41)	8442 (39)	4919 (39)
Male-Female	12055 (25)	5123 (24)	2796 (22)
Female-Male	8277 (17)	3895 (18)	2548 (20)
Female-Female	8162 (17)	3546 (16)	2282 (18)
CB - recipient M	18 (<1)	105 (<1)	3 (<1)
CB - recipient F	22 (<1)	90 (<1)	8 (<1)
Missing	386 (1)	525 (2)	189 (1)
Year of transplant			
1986-1990	346 (1)	48 (<1)	103 (1)
1991-1995	1838 (4)	439 (2)	745 (6)
1996-2000	3298 (7)	1184 (5)	1220 (10)
2001-2005	5304 (11)	1084 (5)	1907 (15)
2006-2010	9564 (20)	1926 (9)	1884 (15)
2011-2015	13304 (27)	3591 (17)	2668 (21)
2016-2020	10386 (21)	7188 (33)	2800 (22)
2021-2023	4572 (9)	6266 (29)	1418 (11)
Follow-up among survivors, Months			
N Eval	21810	12456	6004
Median (Range)	55 (0-384)	14 (0-362)	36 (0-385)



**Table 4. 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	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	6329	1790	2251
Source of data			
CRF	4553 (72)	1166 (65)	1090 (48)
TED	1776 (28)	624 (35)	1161 (52)
Number of centers	155	143	227
Disease at transplant			
AML	2405 (38)	618 (35)	733 (33)
ALL	1301 (21)	392 (22)	491 (22)
Other leukemia	98 (2)	30 (2)	37 (2)
CML	136 (2)	37 (2)	58 (3)
MDS	569 (9)	177 (10)	178 (8)
Other acute leukemia	100 (2)	24 (1)	48 (2)
NHL	410 (6)	107 (6)	134 (6)
Hodgkin Lymphoma	103 (2)	27 (2)	36 (2)
Plasma Cell Disorders, MM	38 (1)	12 (1)	13 (1)
Other malignancies	12 (<1)	1 (<1)	3 (<1)
SAA	95 (2)	33 (2)	51 (2)
Inherited abnormalities erythrocyte diff fxn	171 (3)	49 (3)	45 (2)
Inherited bone marrow failure syndromes	6 (<1)	5 (<1)	4 (<1)
Hemoglobinopathies	2 (<1)	1 (<1)	1 (<1)
SCIDs	284 (4)	92 (5)	174 (8)
Inherited abnormalities of platelets	21 (<1)	6 (<1)	10 (<1)
Inherited disorders of metabolism	398 (6)	130 (7)	145 (6)
Histiocytic disorders	108 (2)	30 (2)	53 (2)
Autoimmune disorders	9 (<1)	0	7 (<1)
MPN	53 (1)	16 (1)	20 (1)
Others	10 (<1)	3 (<1)	10 (<1)
AML Disease status at transplant			
CR1	1262 (52)	348 (56)	371 (51)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CR2	642 (27)	158 (26)	192 (26)
CR3+	66 (3)	11 (2)	26 (4)
Advanced or active disease	427 (18)	99 (16)	140 (19)
Missing	8 (<1)	2 (<1)	4 (1)
ALL Disease status at transplant			
CR1	584 (45)	166 (42)	212 (43)
CR2	490 (38)	149 (38)	177 (36)
CR3+	149 (11)	54 (14)	63 (13)
Advanced or active disease	77 (6)	22 (6)	38 (8)
Missing	1 (<1)	1 (<1)	1 (<1)
MDS Disease status at transplant			
Early	175 (31)	42 (24)	72 (40)
Advanced	341 (60)	120 (68)	84 (47)
Missing	53 (9)	15 (8)	22 (12)
NHL Disease status at transplant			
CR1	65 (16)	13 (12)	25 (19)
CR2	76 (19)	24 (22)	35 (26)
CR3+	45 (11)	11 (10)	12 (9)
PR	68 (17)	12 (11)	16 (12)
Advanced	153 (38)	45 (42)	42 (32)
Missing	0	2 (2)	3 (2)
Recipient age at transplant			
0-9 years	1903 (30)	642 (36)	803 (36)
10-17 years	667 (11)	162 (9)	265 (12)
18-29 years	757 (12)	161 (9)	242 (11)
30-39 years	609 (10)	162 (9)	217 (10)
40-49 years	673 (11)	174 (10)	214 (10)
50-59 years	868 (14)	221 (12)	287 (13)
60-69 years	733 (12)	230 (13)	207 (9)
70+ years	119 (2)	38 (2)	16 (1)
Median (Range)	27 (0-85)	24 (0-78)	20 (0-78)
Recipient race			
White	4442 (74)	1250 (74)	1372 (72)
Black or African American	937 (16)	249 (15)	281 (15)
Asian	381 (6)	128 (8)	173 (9)
Native Hawaiian or other Pacific Islander	36 (1)	4 (<1)	19 (1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
American Indian or Alaska Native	59 (1)	17 (1)	23 (1)
Other	1 (<1)	1 (<1)	1 (<1)
More than one race	130 (2)	39 (2)	38 (2)
Unknown	343 (N/A)	102 (N/A)	344 (N/A)
Recipient ethnicity			
Hispanic or Latino	1336 (22)	328 (19)	377 (17)
Non Hispanic or non-Latino	4793 (78)	1367 (80)	1347 (61)
Non-resident of the U.S.	53 (1)	24 (1)	469 (21)
Unknown	147 (N/A)	71 (N/A)	58 (N/A)
Recipient sex			
Male	3511 (55)	1018 (57)	1282 (57)
Female	2818 (45)	772 (43)	969 (43)
Karnofsky score			
10-80	1682 (27)	461 (26)	576 (26)
90-100	4431 (70)	1212 (68)	1479 (66)
Missing	216 (3)	117 (7)	196 (9)
HLA-A B DRB1 groups - low resolution			
<=3/6	167 (3)	93 (7)	63 (3)
4/6	2375 (41)	572 (40)	792 (39)
5/6	2549 (44)	564 (40)	840 (42)
6/6	757 (13)	196 (14)	313 (16)
Unknown	481 (N/A)	365 (N/A)	243 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	2990 (55)	651 (55)	929 (54)
6/8	1301 (24)	276 (23)	413 (24)
7/8	785 (14)	168 (14)	249 (14)
8/8	380 (7)	92 (8)	145 (8)
Unknown	873 (N/A)	603 (N/A)	515 (N/A)
HLA-DPB1 Match			
Double allele mismatch	872 (37)	140 (34)	199 (38)
Single allele mismatch	1244 (53)	231 (56)	278 (52)
Full allele matched	228 (10)	44 (11)	53 (10)
Unknown	3985 (N/A)	1375 (N/A)	1721 (N/A)
High resolution release score			
No	4853 (77)	1740 (97)	2226 (99)
Yes	1476 (23)	50 (3)	25 (1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
KIR typing available			
No	5056 (80)	1784 (>99)	2231 (99)
Yes	1273 (20)	6 (<1)	20 (1)
Graft type			
UCB	5940 (94)	1595 (89)	2112 (94)
BM+UCB	1 (<1)	0	0
PBSC+UCB	357 (6)	186 (10)	125 (6)
Others	31 (<1)	9 (1)	14 (1)
Number of cord units			
1	5293 (84)	0	1880 (84)
2	1034 (16)	0	370 (16)
3	1 (<1)	0	0
Unknown	1 (N/A)	1790 (N/A)	1 (N/A)
Conditioning regimen			
Myeloablative	4111 (65)	1137 (64)	1404 (62)
RIC/Nonmyeloablative	2201 (35)	646 (36)	827 (37)
TBD	17 (<1)	7 (<1)	20 (1)
Donor/Recipient CMV serostatus			
+/+	0	0	1 (<1)
+/-	1 (<1)	0	0
-/-	0	0	1 (<1)
CB - recipient +	3967 (63)	1088 (61)	1365 (61)
CB - recipient -	2259 (36)	638 (36)	812 (36)
CB - recipient CMV unknown	102 (2)	64 (4)	72 (3)
GvHD Prophylaxis			
No GvHD Prophylaxis	24 (<1)	9 (1)	15 (1)
TDEPLETION alone	1 (<1)	0	0
TDEPLETION +- other	27 (<1)	9 (1)	9 (<1)
CD34 select alone	0	2 (<1)	1 (<1)
CD34 select +- other	274 (4)	140 (8)	78 (3)
Cyclophosphamide alone	0	0	1 (<1)
Cyclophosphamide +- others	14 (<1)	10 (1)	12 (1)
FK506 + MMF +- others	1870 (30)	561 (31)	455 (20)
FK506 + MTX +- others(not MMF)	216 (3)	56 (3)	78 (3)
FK506 +- others(not MMF,MTX)	232 (4)	68 (4)	90 (4)
FK506 alone	145 (2)	44 (2)	27 (1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CSA + MMF +- others(not FK506)	2883 (46)	704 (39)	1083 (48)
CSA + MTX +- others(not MMF,FK506)	101 (2)	29 (2)	52 (2)
CSA +- others(not FK506,MMF,MTX)	342 (5)	116 (6)	228 (10)
CSA alone	51 (1)	18 (1)	68 (3)
Other GVHD Prophylaxis	137 (2)	21 (1)	43 (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	3511 (55)	1018 (57)	1280 (57)
CB - recipient F	2817 (45)	772 (43)	968 (43)
CB - recipient sex unknown	0	0	1 (<1)
Missing	1 (<1)	0	0
Year of transplant			
1996-2000	1 (<1)	2 (<1)	5 (<1)
2001-2005	112 (2)	85 (5)	34 (2)
2006-2010	1849 (29)	428 (24)	603 (27)
2011-2015	2682 (42)	510 (28)	841 (37)
2016-2020	1340 (21)	528 (29)	551 (24)
2021-2023	345 (5)	237 (13)	217 (10)
Follow-up among survivors, Months			
N Eval	3122	998	1185
Median (Range)	61 (0-196)	43 (0-213)	37 (0-240)

**Table 5. 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	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	11911	2051	1001
Source of data			
CRF	3933 (33)	566 (28)	332 (33)
TED	7978 (67)	1485 (72)	669 (67)
Number of centers	93	81	68
Disease at transplant			
AML	3939 (33)	666 (32)	340 (34)
ALL	1968 (17)	405 (20)	191 (19)
Other leukemia	224 (2)	42 (2)	19 (2)
CML	359 (3)	50 (2)	26 (3)
MDS	1600 (13)	249 (12)	130 (13)
Other acute leukemia	180 (2)	37 (2)	10 (1)
NHL	994 (8)	177 (9)	84 (8)
Hodgkin Lymphoma	214 (2)	41 (2)	27 (3)
Plasma Cell Disorders, MM	262 (2)	40 (2)	22 (2)
Other malignancies	24 (<1)	1 (<1)	1 (<1)
Breast cancer	1 (<1)	0	0
SAA	565 (5)	89 (4)	41 (4)
Inherited abnormalities erythrocyte diff fxn	488 (4)	72 (4)	22 (2)
Inherited bone marrow failure syndromes	26 (<1)	4 (<1)	4 (<1)
Hemoglobinopathies	185 (2)	36 (2)	18 (2)
Paroxysmal nocturnal hemoglobinuria	1 (<1)	1 (<1)	0
SCIDs	252 (2)	42 (2)	24 (2)
Inherited abnormalities of platelets	11 (<1)	0	0
Inherited disorders of metabolism	23 (<1)	6 (<1)	2 (<1)
Histiocytic disorders	67 (1)	10 (<1)	5 (<1)
Autoimmune disorders	11 (<1)	0	1 (<1)
MPN	498 (4)	82 (4)	34 (3)
Others	19 (<1)	1 (<1)	0
AML Disease status at transplant			
CR1	2615 (66)	463 (70)	219 (64)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CR2	600 (15)	89 (13)	42 (12)
CR3+	47 (1)	12 (2)	2 (1)
Advanced or active disease	669 (17)	97 (15)	77 (23)
Missing	8 (<1)	5 (1)	0
<b>ALL Disease status at transplant</b>			
CR1	1179 (60)	244 (60)	122 (64)
CR2	576 (29)	109 (27)	47 (25)
CR3+	124 (6)	26 (6)	10 (5)
Advanced or active disease	89 (5)	26 (6)	12 (6)
<b>MDS Disease status at transplant</b>			
Early	278 (17)	33 (13)	23 (18)
Advanced	1270 (79)	203 (82)	101 (78)
Missing	52 (3)	13 (5)	6 (5)
<b>NHL Disease status at transplant</b>			
CR1	197 (20)	41 (23)	18 (21)
CR2	188 (19)	35 (20)	11 (13)
CR3+	104 (11)	21 (12)	6 (7)
PR	69 (7)	13 (7)	6 (7)
Advanced	427 (43)	66 (38)	43 (51)
Missing	5 (1)	0	0
<b>Recipient age at transplant</b>			
0-9 years	1245 (10)	194 (9)	94 (9)
10-17 years	1177 (10)	168 (8)	79 (8)
18-29 years	1376 (12)	274 (13)	106 (11)
30-39 years	922 (8)	177 (9)	104 (10)
40-49 years	1424 (12)	249 (12)	112 (11)
50-59 years	2464 (21)	430 (21)	210 (21)
60-69 years	2761 (23)	472 (23)	252 (25)
70+ years	542 (5)	87 (4)	44 (4)
Median (Range)	49 (0-82)	49 (0-77)	51 (0-83)
<b>Recipient race</b>			
White	8882 (79)	1421 (75)	753 (80)
Black or African American	1569 (14)	277 (15)	112 (12)
Asian	566 (5)	155 (8)	55 (6)
Native Hawaiian or other Pacific Islander	45 (<1)	8 (<1)	2 (<1)
American Indian or Alaska Native	81 (1)	9 (<1)	5 (1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
More than one race	139 (1)	16 (1)	11 (1)
Unknown	629 (N/A)	165 (N/A)	63 (N/A)
Recipient ethnicity			
Hispanic or Latino	2227 (19)	481 (24)	215 (22)
Non Hispanic or non-Latino	9345 (80)	1492 (75)	751 (76)
Non-resident of the U.S.	124 (1)	26 (1)	17 (2)
Unknown	215 (N/A)	52 (N/A)	18 (N/A)
Recipient sex			
Male	6979 (59)	1202 (59)	585 (58)
Female	4932 (41)	849 (41)	416 (42)
Karnofsky score			
10-80	4292 (36)	833 (41)	423 (42)
90-100	7224 (61)	1155 (56)	527 (53)
Missing	395 (3)	63 (3)	51 (5)
HLA-A B DRB1 groups - low resolution			
<=3/6	2609 (24)	431 (24)	225 (29)
4/6	775 (7)	143 (8)	81 (10)
5/6	227 (2)	45 (3)	24 (3)
6/6	7279 (67)	1166 (65)	444 (57)
Unknown	1021 (N/A)	266 (N/A)	227 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	3245 (31)	533 (31)	269 (38)
6/8	145 (1)	33 (2)	13 (2)
7/8	164 (2)	29 (2)	18 (3)
8/8	7028 (66)	1098 (65)	405 (57)
Unknown	1329 (N/A)	358 (N/A)	296 (N/A)
HLA-DPB1 Match			
Double allele mismatch	11 (<1)	0	1 (<1)
Single allele mismatch	2722 (29)	315 (30)	173 (39)
Full allele matched	6752 (71)	741 (70)	265 (60)
Unknown	2426 (N/A)	995 (N/A)	562 (N/A)
High resolution release score			
No	5794 (49)	2025 (99)	975 (97)
Yes	6117 (51)	26 (1)	26 (3)
Graft type			
Marrow	3434 (29)	469 (23)	281 (28)



Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
PBSC	8370 (70)	1546 (75)	713 (71)
UCB (related)	2 (<1)	15 (1)	0
BM+PBSC	18 (<1)	4 (<1)	1 (<1)
BM+UCB	45 (<1)	12 (1)	2 (<1)
PBSC+UCB	1 (<1)	1 (<1)	4 (<1)
Others	41 (<1)	4 (<1)	0
Conditioning regimen			
Myeloablative	6607 (55)	1121 (55)	518 (52)
RIC/Nonmyeloablative	5242 (44)	915 (45)	464 (46)
TBD	62 (1)	15 (1)	19 (2)
Donor age at donation			
To Be Determined/NA	16 (<1)	5 (<1)	3 (<1)
0-9 years	828 (7)	129 (6)	47 (5)
10-17 years	928 (8)	148 (7)	66 (7)
18-29 years	2130 (18)	375 (18)	202 (20)
30-39 years	1812 (15)	356 (17)	185 (18)
40-49 years	1911 (16)	335 (16)	148 (15)
50+ years	4286 (36)	703 (34)	350 (35)
Median (Range)	41 (0-82)	40 (0-79)	40 (0-80)
Donor/Recipient CMV serostatus			
+/+	4848 (41)	906 (44)	394 (39)
+/-	1275 (11)	174 (8)	104 (10)
-/+	2998 (25)	494 (24)	260 (26)
-/-	2575 (22)	418 (20)	209 (21)
CB - recipient +	31 (<1)	16 (1)	5 (<1)
CB - recipient -	17 (<1)	12 (1)	1 (<1)
Missing	167 (1)	31 (2)	28 (3)
GvHD Prophylaxis			
No GvHD Prophylaxis	173 (1)	24 (1)	14 (1)
TDEPLETION alone	95 (1)	28 (1)	15 (1)
TDEPLETION +- other	99 (1)	23 (1)	7 (1)
CD34 select alone	83 (1)	23 (1)	11 (1)
CD34 select +- other	91 (1)	28 (1)	9 (1)
Cyclophosphamide alone	76 (1)	11 (1)	8 (1)
Cyclophosphamide +- others	4003 (34)	660 (32)	380 (38)
FK506 + MMF +- others	824 (7)	100 (5)	35 (3)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
FK506 + MTX +- others(not MMF)	4204 (35)	641 (31)	344 (34)
FK506 +- others(not MMF,MTX)	839 (7)	306 (15)	72 (7)
FK506 alone	109 (1)	17 (1)	6 (1)
CSA + MMF +- others(not FK506)	241 (2)	43 (2)	19 (2)
CSA + MTX +- others(not MMF,FK506)	731 (6)	95 (5)	53 (5)
CSA +- others(not FK506,MMF,MTX)	82 (1)	10 (<1)	3 (<1)
CSA alone	82 (1)	13 (1)	4 (<1)
Other GVHD Prophylaxis	166 (1)	21 (1)	21 (2)
Missing	13 (<1)	8 (<1)	0
Donor/Recipient sex match			
Male-Male	3957 (33)	728 (35)	338 (34)
Male-Female	2522 (21)	417 (20)	218 (22)
Female-Male	2987 (25)	456 (22)	244 (24)
Female-Female	2393 (20)	421 (21)	195 (19)
CB - recipient M	31 (<1)	17 (1)	3 (<1)
CB - recipient F	17 (<1)	11 (1)	3 (<1)
Missing	4 (<1)	1 (<1)	0
Year of transplant			
2006-2010	600 (5)	71 (3)	62 (6)
2011-2015	3668 (31)	508 (25)	229 (23)
2016-2020	5010 (42)	903 (44)	408 (41)
2021-2023	2633 (22)	569 (28)	302 (30)
Follow-up among survivors, Months			
N Eval	7728	1356	657
Median (Range)	25 (0-150)	24 (0-147)	17 (0-148)

**Table 6. Characteristics of recipients who underwent a first allogeneic transplant registered with the CIBMTR**

<b>Characteristic</b>	<b>TED N (%)</b>	<b>CRF N (%)</b>
No. of patients	273533	112940
No. of centers	676	589
Age at transplant, years - no. (%)		
Median (min-max)	37.7 (0.0-87.8)	33.1 (0.0-87.8)
0-9	38364 (14.0)	19173 (17.0)
10-19	34240 (12.5)	16364 (14.5)
20-29	35100 (12.8)	15831 (14.0)
30-39	38654 (14.1)	16653 (14.7)
40-49	43891 (16.0)	16878 (14.9)
50-59	44469 (16.3)	14797 (13.1)
60-69	33138 (12.1)	11079 (9.8)
70+	5677 (2.1)	2165 (1.9)
Recipient gender - no. (%)		
Male	160088 (58.5)	66394 (58.8)
Female	113445 (41.5)	46546 (41.2)
Recipient race - no. (%)		
Caucasian	184171 (67.3)	89060 (78.9)
African-American	13923 (5.1)	6933 (6.1)
Asian	20088 (7.3)	8821 (7.8)
Pacific islander	588 (0.2)	277 (0.2)
Native American	912 (0.3)	440 (0.4)
Other	8543 (3.1)	4031 (3.6)
Unknown	45308 (16.6)	3378 (3.0)
Disease - no. (%)		
Acute myelogenous leukemia	87769 (32.1)	31402 (27.8)
Acute lymphoblastic leukemia	46736 (17.1)	18445 (16.3)
Other leukemia	6703 (2.5)	2422 (2.1)
Chronic myelogenous leukemia	30427 (11.1)	15360 (13.6)
Myelodysplastic/myeloproliferative disorders	34402 (12.6)	15123 (13.4)
Other acute leukemia	3115 (1.1)	1069 (0.9)
Non-Hodgkin lymphoma	18339 (6.7)	6512 (5.8)
Hodgkin lymphoma	1767 (0.6)	660 (0.6)
Plasma cell disorder/Multiple Myeloma	3453 (1.3)	1421 (1.3)
Other Malignancies	1229 (0.4)	510 (0.5)

Characteristic	TED N (%)	CRF N (%)
Breast Cancer	183 (0.1)	93 (0.1)
Severe aplastic anemia	15327 (5.6)	7855 (7.0)
Inherited abnormalities erythrocyte differentiation or function	11455 (4.2)	5945 (5.3)
SCID and other immune system disorders	6982 (2.6)	3424 (3.0)
Inherited abnormalities of platelets	234 (0.1)	112 (0.1)
Inherited disorders of metabolism	2960 (1.1)	1650 (1.5)
Histiocytic disorders	1880 (0.7)	800 (0.7)
Autoimmune Diseases	164 (0.1)	50 (0.0)
Other diseases	408 (0.1)	87 (0.1)
Year of transplant - no. (%)		
<1985	4899 (1.8)	4507 (4.0)
1985-1989	10639 (3.9)	9507 (8.4)
1990-1994	23038 (8.4)	14871 (13.2)
1995-1999	36471 (13.3)	17192 (15.2)
2000-2004	41758 (15.3)	17722 (15.7)
2005-2009	42700 (15.6)	18974 (16.8)
2010-2014	51642 (18.9)	12042 (10.7)
2015-2019	54605 (20.0)	16893 (15.0)
2020-2022	7781 (2.8)	1232 (1.1)
Education - no. (%)	NA	
No primary education		69 (0.1)
Less than primary or elementary education		90 (0.1)
Primary of elementary education		767 (0.7)
Lower secondary education		876 (0.8)
Upper secondary education		11678 (10.3)
Post-secondary , non-tertiary education		4321 (3.8)
Tertiary education, Type A		8690 (7.7)
Tertiary education, Type B		1870 (1.7)
Advance research qualification		2236 (2.0)
Age<18 years old		32500 (28.8)
Missing		49843 (44.1)
Health insurance - no. (%)	NA	
No insurance		4587 (4.1)
Medicaid		9844 (8.7)
Medicare		6544 (5.8)
Disability insurance		772 (0.7)

Characteristic	TED N (%)	CRF N (%)
HMO		2539 (2.2)
Private health insurance		26161 (23.2)
National health insurance		16065 (14.2)
VA/Military		792 (0.7)
Other		3669 (3.2)
Missing		41967 (37.2)
Health insurance - no. (%)	NA	
No insurance		3600 (3.2)
Disability insurance +/-others		881 (0.8)
Private health insurance +/- others		31927 (28.3)
Medicaid +/-others		8718 (7.7)
Medicare +/-others		4035 (3.6)
Others		21812 (19.3)
Missing		41967 (37.2)
Occupation - no. (%)	NA	
Professional, technical, or related occupation		19906 (17.6)
Manager, administrator or proprietor		4105 (3.6)
Clerical or related occupation		2841 (2.5)
Sales occupation		2135 (1.9)
Service occupation		3476 (3.1)
Skilled crafts or related occupation		3438 (3.0)
Equipment/vehicle operator or related occupation		1617 (1.4)
Laborer		2225 (2.0)
Farmer		423 (0.4)
Member of military		362 (0.3)
Homemaker		1642 (1.5)
Student		11489 (10.2)
Under school age		2724 (2.4)
Not previously employed		2153 (1.9)
Other, specify		8090 (7.2)
Missing		46314 (41.0)

**Table 7. Characteristics of recipients who underwent a first autologous transplant registered with the CIBMTR**

<b>Characteristic</b>	<b>TED N (%)</b>	<b>CRF N (%)</b>
No. of patients	272409	49244
No. of centers	635	465
Age at transplant, years - no. (%)		
Median (min-max)	53.6 (0.0-86.4)	50.3 (0.0-83.2)
0-9	11519 (4.2)	2373 (4.8)
10-19	8270 (3.0)	1838 (3.7)
20-29	17700 (6.5)	3389 (6.9)
30-39	26827 (9.8)	6048 (12.3)
40-49	47864 (17.6)	10630 (21.6)
50-59	73941 (27.1)	13009 (26.4)
60-69	69942 (25.7)	10129 (20.6)
70+	16346 (6.0)	1828 (3.7)
Recipient gender - no. (%)		
Male	147757 (54.2)	24370 (49.5)
Female	124652 (45.8)	24874 (50.5)
Recipient race - no. (%)		
Caucasian	189096 (69.4)	38393 (78.0)
African-American	25695 (9.4)	6287 (12.8)
Asian	7095 (2.6)	1450 (2.9)
Pacific islander	356 (0.1)	60 (0.1)
Native American	823 (0.3)	232 (0.5)
Other	5620 (2.1)	1443 (2.9)
Unknown	43724 (16.1)	1379 (2.8)
Disease - no. (%)		
Acute myelogenous leukemia	8477 (3.1)	2504 (5.1)
Acute lymphoblastic leukemia	1657 (0.6)	485 (1.0)
Other leukemia	809 (0.3)	258 (0.5)
Chronic myelogenous leukemia	715 (0.3)	297 (0.6)
Myelodysplastic/myeloproliferative disorders	291 (0.1)	95 (0.2)
Other acute leukemia	165 (0.1)	31 (0.1)
Non-Hodgkin lymphoma	73249 (26.9)	11819 (24.0)
Hodgkin lymphoma	27495 (10.1)	4417 (9.0)
Plasma cell disorder/Multiple Myeloma	113141 (41.5)	16848 (34.2)

Characteristic	TED N (%)	CRF N (%)
Other Malignancies	21262 (7.8)	4486 (9.1)
Breast Cancer	22948 (8.4)	7773 (15.8)
Autoimmune Diseases	1560 (0.6)	142 (0.3)
Other diseases	640 (0.2)	89 (0.2)
Year of transplant - no. (%)		
<1985	31 (0.0)	5 (0.0)
1985-1989	2089 (0.8)	673 (1.4)
1990-1994	20048 (7.4)	7587 (15.4)
1995-1999	42023 (15.4)	13099 (26.6)
2000-2004	36630 (13.4)	6300 (12.8)
2005-2009	39539 (14.5)	8366 (17.0)
2010-2014	53702 (19.7)	4702 (9.5)
2015-2019	68088 (25.0)	8238 (16.7)
2020-2022	10259 (3.8)	274 (0.6)
Education - no. (%)	NA	
No primary education		18 (0.0)
Less than primary or elementary education		55 (0.1)
Primary of elementary education		356 (0.7)
Lower secondary education		429 (0.9)
Upper secondary education		7008 (14.2)
Post-secondary , non-tertiary education		2872 (5.8)
Tertiary education, Type A		5807 (11.8)
Tertiary education, Type B		1274 (2.6)
Advance research qualification		1783 (3.6)
Age<18 years old		3741 (7.6)
Missing		25901 (52.6)
Health insurance - no. (%)	NA	
No insurance		886 (1.8)
Medicaid		3823 (7.8)
Medicare		4788 (9.7)
Missing		39747 (80.7)
Heath insurance - no. (%)	NA	
No insurance		886 (1.8)
Medicaid +/-others		3823 (7.8)
Medicare +/-others		4788 (9.7)
Missing		39747 (80.7)

<b>Characteristic</b>	<b>TED N (%)</b>	<b>CRF N (%)</b>
Occupation - no. (%)	NA	
Professional, technical, or related occupation		17402 (35.3)
Manager, administrator or proprietor		1908 (3.9)
Clerical or related occupation		1353 (2.7)
Sales occupation		912 (1.9)
Service occupation		1787 (3.6)
Skilled crafts or related occupation		1622 (3.3)
Equipment/vehicle operator or related occupation		912 (1.9)
Laborer		1076 (2.2)
Farmer		232 (0.5)
Member of military		182 (0.4)
Homemaker		664 (1.3)
Student		1190 (2.4)
Under school age		381 (0.8)
Not previously employed		1100 (2.2)
Other, specify		3560 (7.2)
Missing		14963 (30.4)



**Table 8. Characteristics of recipients who received a first transplant from US centers reported to the CIBMTR, 2008 – 2022 (CRF)**

<b>Characteristic</b>	<b>Allogeneic N (%)</b>	<b>Autologous N (%)</b>
No. of patients	31417	15724
No. of centers	193	191
Age at transplant, years - no. (%)		
Median (min-max)	51.3 (0.0-87.8)	57.9 (0.2-82.4)
0-9	4012 (12.8)	589 (3.7)
10-19	2620 (8.3)	286 (1.8)
20-29	2450 (7.8)	687 (4.4)
30-39	2402 (7.6)	919 (5.8)
40-49	3589 (11.4)	2044 (13.0)
50-59	6237 (19.9)	4434 (28.2)
60-69	8143 (25.9)	5472 (34.8)
70+	1964 (6.3)	1293 (8.2)
Recipient gender - no. (%)		
Male	18352 (58.4)	9127 (58.0)
Female	13065 (41.6)	6597 (42.0)
Recipient race - no. (%)		
Caucasian	24786 (78.9)	10682 (67.9)
African-American	3590 (11.4)	3876 (24.7)
Asian	1576 (5.0)	622 (4.0)
Pacific islander	111 (0.4)	39 (0.2)
Native American	211 (0.7)	129 (0.8)
Unknown	1143 (3.6)	376 (2.4)
Disease - no. (%)		
Acute myelogenous leukemia	10306 (32.8)	183 (1.2)
Acute lymphoblastic leukemia	3960 (12.6)	18 (0.1)
Other leukemia	802 (2.6)	15 (0.1)
Chronic myelogenous leukemia	822 (2.6)	0 (0.0)
Myelodysplastic/myeloproliferative disorders	8357 (26.6)	3 (0.0)
Other acute leukemia	301 (1.0)	2 (0.0)
Non-Hodgkin lymphoma	1907 (6.1)	3647 (23.2)
Hodgkin lymphoma	182 (0.6)	1361 (8.7)
Plasma cell disorder/Multiple Myeloma	191 (0.6)	9518 (60.5)
Other Malignancies	23 (0.1)	878 (5.6)
Breast Cancer	0 (0.0)	2 (0.0)
Severe aplastic anemia	1460 (4.6)	2 (0.0)
Inherited abnormalities erythrocyte differentiation or function	1284 (4.1)	11 (0.1)

<b>Characteristic</b>	<b>Allogeneic N (%)</b>	<b>Autologous N (%)</b>
SCID and other immune system disorders	1074 (3.4)	44 (0.3)
Inherited abnormalities of platelets	37 (0.1)	0 (0.0)
Inherited disorders of metabolism	413 (1.3)	2 (0.0)
Histiocytic disorders	250 (0.8)	2 (0.0)
Autoimmune Diseases	20 (0.1)	32 (0.2)
Other diseases	28 (0.1)	4 (0.0)
Education - no. (%)		
No primary education	31 (0.1)	15 (0.1)
Less than primary or elementary education	55 (0.2)	28 (0.2)
Primary of elementary education	125 (0.4)	92 (0.6)
Lower secondary education	565 (1.8)	342 (2.2)
Upper secondary education	6361 (20.2)	3713 (23.6)
Post-secondary , non-tertiary education	2092 (6.7)	1260 (8.0)
Tertiary education, Type A	5704 (18.2)	3094 (19.7)
Tertiary education, Type B	1298 (4.1)	892 (5.7)
Advance research qualification	1111 (3.5)	594 (3.8)
Age<18 years old	6411 (20.4)	842 (5.4)
Missing	7664 (24.4)	4852 (30.9)
Health insurance - no. (%)		
No insurance	505 (1.6)	165 (1.0)
Medicaid	6186 (19.7)	2038 (13.0)
Medicare	5649 (18.0)	3325 (21.1)
Disability insurance	604 (1.9)	0 (0.0)
Private health insurance	16155 (51.4)	0 (0.0)
National health insurance	168 (0.5)	0 (0.0)
VA/Military	388 (1.2)	0 (0.0)
Other	578 (1.8)	0 (0.0)
Missing	1184 (3.8)	10196 (64.8)
Health insurance - no. (%)		
No insurance	379 (1.2)	165 (1.0)
Disability insurance +/-others	666 (2.1)	0 (0.0)
Private health insurance +/- others	19209 (61.1)	0 (0.0)
Medicaid +/-others	5421 (17.3)	2038 (13.0)
Medicare +/-others	3419 (10.9)	3325 (21.1)
Others	1139 (3.6)	0 (0.0)
Missing	1184 (3.8)	10196 (64.8)
Occupation - no. (%)		
Professional, technical, or related occupation	6183 (19.7)	3410 (21.7)
Manager, administrator or proprietor	2738 (8.7)	1478 (9.4)

<b>Characteristic</b>	<b>Allogeneic N (%)</b>	<b>Autologous N (%)</b>
Clerical or related occupation	1701 (5.4)	1013 (6.4)
Sales occupation	1344 (4.3)	674 (4.3)
Service occupation	2234 (7.1)	1410 (9.0)
Skilled crafts or related occupation	2161 (6.9)	1185 (7.5)
Equipment/vehicle operator or related occupation	1050 (3.3)	704 (4.5)
Laborer	1353 (4.3)	776 (4.9)
Farmer	222 (0.7)	145 (0.9)
Member of military	239 (0.8)	143 (0.9)
Homemaker	714 (2.3)	357 (2.3)
Student	5084 (16.2)	588 (3.7)
Under school age	1500 (4.8)	303 (1.9)
Not previously employed	708 (2.3)	416 (2.6)
Other, specify	1449 (4.6)	744 (4.7)
Missing	2737 (8.7)	2378 (15.1)
Recipient zip code - no. (%)		
Not Available	2533 (8.1)	1356 (8.6)
Available	28884 (91.9)	14368 (91.4)

**Table 9. Characteristics of recipients who received allogeneic transplants registered with the CIBMTR by WHO region, 2008 – 2022(HCT essential)**

Characteristic	Latin		Eastern		Southeastern		
	Africa	Americas	US / Canada	Mediterranean	Europe	Asia	Western Pacific
No. of patients	49	7694	114852	5553	16609	3485	10474
No. of centers	2	62	227	19	114	20	31
Age, in years - no. (%)							
<10	0 (0.0)	1476 (19.2)	11759 (10.2)	2309 (41.6)	1365 (8.2)	1263 (36.2)	1281 (12.2)
10-19	7 (14.3)	1465 (19.0)	9766 (8.5)	1289 (23.2)	1181 (7.1)	860 (24.7)	1187 (11.3)
20-29	6 (12.2)	1123 (14.6)	9640 (8.4)	946 (17.0)	1651 (9.9)	463 (13.3)	1069 (10.2)
30-39	2 (4.1)	1110 (14.4)	9898 (8.6)	538 (9.7)	1768 (10.6)	400 (11.5)	1215 (11.6)
40-49	11 (22.4)	1004 (13.0)	14243 (12.4)	289 (5.2)	2685 (16.2)	283 (8.1)	1737 (16.6)
50-59	14 (28.6)	914 (11.9)	24262 (21.1)	137 (2.5)	3748 (22.6)	191 (5.5)	2265 (21.6)
60-69	9 (18.4)	507 (6.6)	28402 (24.7)	44 (0.8)	3635 (21.9)	24 (0.7)	1618 (15.4)
>=70	0 (0.0)	95 (1.2)	6882 (6.0)	1 (0.0)	576 (3.5)	1 (0.0)	102 (1.0)
Gender - no. (%)							
Male	32 (65.3)	4503 (58.5)	66297 (57.7)	3266 (58.8)	9781 (58.9)	2290 (65.7)	6095 (58.2)
Female	17 (34.7)	3191 (41.5)	48555 (42.3)	2287 (41.2)	6828 (41.1)	1195 (34.3)	4379 (41.8)
Primary disease - no. (%)							
Acute myelogenous leukemia	18 (36.7)	2148 (27.9)	44228 (38.5)	942 (17.0)	6779 (40.8)	604 (17.3)	4153 (39.7)
Acute lymphoblastic leukemia	3 (6.1)	2097 (27.3)	18108 (15.8)	842 (15.2)	2586 (15.6)	412 (11.8)	2051 (19.6)
Chronic myelogenous leukemia	3 (6.1)	469 (6.1)	3617 (3.1)	150 (2.7)	563 (3.4)	115 (3.3)	275 (2.6)
Myelodysplastic disorders	11 (22.4)	891 (11.6)	21612 (18.8)	190 (3.4)	3125 (18.8)	221 (6.3)	1770 (16.9)
Non-Hodgkin lymphoma	4 (8.2)	195 (2.5)	8047 (7.0)	44 (0.8)	855 (5.1)	52 (1.5)	489 (4.7)

Characteristic	Latin		Eastern		Southeastern		
	Africa	Americas	US / Canada	Mediterranean	Europe	Asia	Western Pacific
Hodgkin lymphoma	0 (0.0)	71 (0.9)	572 (0.5)	19 (0.3)	106 (0.6)	22 (0.6)	38 (0.4)
Multiple myeloma	1 (2.0)	7 (0.1)	351 (0.3)	10 (0.2)	89 (0.5)	2 (0.1)	11 (0.1)
Other malignancies	1 (2.0)	182 (2.4)	4827 (4.2)	70 (1.3)	844 (5.1)	36 (1.0)	377 (3.6)
Severe aplastic anemia	5 (10.2)	851 (11.1)	4402 (3.8)	632 (11.4)	594 (3.6)	487 (14.0)	701 (6.7)
Other non-malignancies	3 (6.1)	783 (10.2)	9088 (7.9)	2654 (47.8)	1068 (6.4)	1534 (44.0)	609 (5.8)
Donor type - no. (%)							
HLA-identical sibling	20 (40.8)	3498 (45.5)	32792 (28.6)	4136 (74.5)	5051 (30.4)	2095 (60.1)	3729 (35.6)
Other Related donor	2 (4.1)	2049 (26.6)	17254 (15.0)	967 (17.4)	1053 (6.3)	986 (28.3)	1532 (14.6)
Unrelated donor	27 (55.1)	2145 (27.9)	64784 (56.4)	448 (8.1)	9703 (58.4)	404 (11.6)	5210 (49.7)
Missing	0 (0.0)	2 (0.0)	22 (0.0)	2 (0.0)	802 (4.8)	0 (0.0)	3 (0.0)
Graft type - no. (%)							
Bone Marrow	1 (2.0)	3622 (47.1)	24762 (21.6)	3022 (54.4)	3319 (20.0)	736 (21.1)	1684 (16.1)
Peripheral Blood	47 (95.9)	3811 (49.5)	80702 (70.3)	2227 (40.1)	12583 (75.8)	2722 (78.1)	8033 (76.7)
Cord Blood	1 (2.0)	258 (3.4)	9369 (8.2)	302 (5.4)	700 (4.2)	27 (0.8)	751 (7.2)
Missing	0 (0.0)	3 (0.0)	19 (0.0)	2 (0.0)	7 (0.0)	0 (0.0)	6 (0.1)
Year of transplant - no. (%)							
2008	5 (10.2)	196 (2.5)	5641 (4.9)	445 (8.0)	1728 (10.4)	84 (2.4)	526 (5.0)
2009	11 (22.4)	334 (4.3)	6011 (5.2)	466 (8.4)	1836 (11.1)	110 (3.2)	725 (6.9)
2010	8 (16.3)	407 (5.3)	6184 (5.4)	454 (8.2)	1861 (11.2)	120 (3.4)	830 (7.9)
2011	13 (26.5)	374 (4.9)	6733 (5.9)	222 (4.0)	1740 (10.5)	154 (4.4)	897 (8.6)
2012	7 (14.3)	434 (5.6)	6944 (6.0)	254 (4.6)	1721 (10.4)	164 (4.7)	866 (8.3)
2013	5 (10.2)	412 (5.4)	7451 (6.5)	258 (4.6)	1609 (9.7)	151 (4.3)	776 (7.4)

Characteristic	Latin		Eastern		Southeastern		
	Africa	Americas	US / Canada	Mediterranean	Europe	Asia	Western Pacific
2014	0 (0.0)	432 (5.6)	7610 (6.6)	275 (5.0)	1106 (6.7)	191 (5.5)	781 (7.5)
2015	0 (0.0)	421 (5.5)	7872 (6.9)	256 (4.6)	1035 (6.2)	224 (6.4)	624 (6.0)
2016	0 (0.0)	434 (5.6)	7937 (6.9)	285 (5.1)	888 (5.3)	296 (8.5)	813 (7.8)
2017	0 (0.0)	543 (7.1)	8330 (7.3)	359 (6.5)	1415 (8.5)	333 (9.6)	606 (5.8)
2018	0 (0.0)	688 (8.9)	8788 (7.7)	372 (6.7)	531 (3.2)	352 (10.1)	529 (5.1)
2019	0 (0.0)	769 (10.0)	8990 (7.8)	466 (8.4)	395 (2.4)	373 (10.7)	612 (5.8)
2020	0 (0.0)	644 (8.4)	8572 (7.5)	352 (6.3)	287 (1.7)	217 (6.2)	590 (5.6)
2021	0 (0.0)	672 (8.7)	8806 (7.7)	536 (9.7)	227 (1.4)	292 (8.4)	643 (6.1)
2022	0 (0.0)	934 (12.1)	8983 (7.8)	553 (10.0)	230 (1.4)	424 (12.2)	656 (6.3)

**Table 10. Allogeneic transplant recipients and centers by country registered with the CIBMTR,  
2008-2022(HCT essential)**

<b>Regions</b>	<b>N</b>	<b>Centers</b>
Africa		
South Africa	49	2
Americas		
United states	108E3	210
Argentina	669	7
Brazil	5909	38
Canada	7248	25
Chile	21	2
Venezuela	50	2
Mexico	633	5
Uruguay	77	3
Peru	121	2
Columbia	214	3
Eastern mediterranean		
Saudi Arabia	3756	9
Egypt	33	2
Iran	673	1
Kuwait	19	1
Pakistan	1072	6
Europe		
Austria	100	2
Belgium	1333	7
Denmark	1405	1
United kingdom	2318	17
Finland	407	2
France	1116	10
Germany	3057	19

Regions	N	Centers
Ireland	158	1
Israel	1105	7
Italy	576	7
Netherlands	765	9
Norway	117	1
Poland	390	4
Portugal	133	2
Spain	627	9
Sweden	859	4
Switzerland	880	3
Russia	91	1
Turkey	479	3
Greece	3	1
Czech republic	573	3
Slovak republic	117	1
Southeastern Asia		
India	3465	19
Thailand	20	1
Western pacific		
Australia	5065	18
South Korea	3088	3
New Zealand	1192	9
Taiwan	66	1
Hong Kong	112	1
Singapore	951	5



**Table 11. Number of patients who received a first allogeneic transplant registered with the CIBMTR between 2008 and 2022 by country**

Country	CRF		TED	
	Malignant disease	Non-malignant disease	Malignant disease	Non-malignant disease
Argentina	<100	<100	100-500	<100
Australia	501-999	100-500	>=1000	501-999
Austria	NA	NA	<100	<100
Belgium	<100	<100	>=1000	100-500
Brazil	501-999	100-500	>=1000	>=1000
Canada	100-500	100-500	>=1000	501-999
Chile	<100	<100	<100	<100
Colombia	<100	<100	100-500	<100
Czech Republic	<100	<100	100-500	<100
Denmark	100-500	<100	501-999	100-500
Ecuador	<100	<100	<100	<100
Egypt	NA	NA	<100	<100
Finland	NA	NA	100-500	<100
France	<100	<100	501-999	100-500
Germany	100-500	<100	>=1000	100-500
Greece	NA	NA	<100	<100
Hong Kong	<100	<100	<100	<100
India	100-500	501-999	>=1000	>=1000
Iran	<100	100-500	100-500	100-500
Ireland	<100	<100	100-500	<100
Israel	<100	<100	501-999	100-500
Italy	NA	NA	100-500	<100
Korea	501-999	100-500	>=1000	100-500
Kuwait	NA	NA	NA	<100
Mexico	<100	<100	100-500	100-500

Country	CRF		TED	
	Malignant disease	Non-malignant disease	Malignant disease	Non-malignant disease
Netherlands	<100	<100	501-999	100-500
New Zealand	100-500	<100	501-999	100-500
Nigeria	NA	NA	NA	<100
Norway	<100	<100	<100	<100
Pakistan	<100	100-500	100-500	100-500
Peru	<100	<100	<100	<100
Poland	<100	<100	100-500	<100
Portugal	NA	NA	<100	<100
Russia	NA	NA	<100	<100
Saudi Arabia	100-500	501-999	>=1000	>=1000
Singapore	100-500	<100	501-999	<100
Slovak Republic	NA	NA	<100	<100
South Africa	<100	<100	<100	<100
Spain	<100	<100	100-500	<100
Sweden	<100	<100	501-999	100-500
Switzerland	<100	<100	501-999	<100
Taiwan	<100	<100	<100	<100
Thailand	NA	NA	<100	NA
Turkey	<100	<100	100-500	<100
UK	100-500	100-500	>=1000	100-500
USA	>=1000	>=1000	>=1000	>=1000
Uruguay	<100	<100	<100	<100
Venezuela	<100	NA	<100	<100

Countries with <100 patients in both CRF and TED dataset are not included in this report.

**Table 12. Number of patients who received a first autologous transplant registered to the CIBMTR between 2008 and 2022 by country**

Country	CRF		TED	
	Malignant disease	Non-malignant disease	Malignant disease	Non-malignant disease
101	NA	NA	<100	NA
Argentina	100-500	NA	>=1000	<100
Australia	<100	<100	501-999	<100
Austria	NA	NA	<100	NA
Belgium	NA	NA	100-500	<100
Brazil	100-500	<100	>=1000	<100
Canada	100-500	<100	>=1000	100-500
Colombia	<100	NA	100-500	<100
Czech Republic	<100	NA	100-500	<100
Ecuador	<100	NA	<100	NA
Egypt	NA	NA	<100	NA
Finland	NA	NA	100-500	NA
France	NA	NA	501-999	<100
Germany	<100	NA	501-999	<100
Greece	NA	NA	<100	NA
Hong Kong	NA	NA	<100	NA
India	100-500	<100	501-999	<100
Iran	<100	<100	100-500	NA
Israel	<100	<100	501-999	<100
Italy	NA	NA	501-999	<100
Korea	100-500	NA	>=1000	<100
Kuwait	NA	NA	<100	NA
Mexico	<100	NA	100-500	501-999
Netherlands	NA	NA	100-500	<100

Country	CRF		TED	
	Malignant disease	Non-malignant disease	Malignant disease	Non-malignant disease
New Zealand	<100	NA	100-500	NA
Pakistan	<100	<100	100-500	<100
Peru	<100	NA	<100	<100
Poland	NA	NA	100-500	<100
Portugal	NA	NA	<100	NA
Russia	NA	NA	100-500	<100
Saudi Arabia	<100	NA	>=1000	<100
Singapore	100-500	<100	501-999	<100
Slovak Republic	NA	NA	<100	NA
South Africa	<100	NA	<100	NA
Spain	<100	NA	100-500	<100
Switzerland	NA	NA	100-500	<100
Taiwan	NA	NA	<100	NA
Thailand	NA	NA	<100	NA
Turkey	<100	NA	501-999	NA
UK	NA	NA	100-500	NA
USA	>=1000	100-500	>=1000	100-500
Uruguay	<100	NA	501-999	NA
Venezuela	<100	NA	100-500	NA

Countries with <100 patients in both CRF and TED dataset are not included in this report.



**TO:** Donor and Recipient Health Services Working Committee Members

**FROM:** Heather Stefanski, MD, PhD and Rafeek Yusuf, MBBS, PhD; Scientific Directors for the Donor and Recipient Health Services Working Committee

**RE:** Studies in Progress Summary

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**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 sickle cell trait on per-donation toxicity experienced by unrelated bone marrow donors. Secondary aims are to evaluate the impact of sickle cell trait 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 analysis, and we aim to submit the manuscript by July 2024.

**DS23-01 Unrelated Donor Collection Efficiency and Adverse Events During the COVID-19 Pandemic** (Mathew Seftel). This study primarily aims to analyze unrelated donor hematopoietic progenitor cell (HPC) cell dose requests, HPC cell yields, and unrelated donor adverse events comparing fresh vs cryopreserved HPC products since the onset of cryopreservation of HPC products during the COVID-19 pandemic. The study is currently in protocol development.

**HS16-01b Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic Cell Transplantation in Racial and Ethnic Minorities** (N. Khera/ T. Hahn/ S. Ailawadhi / W. Saber) This study will evaluate the trends in utilization and clinical outcomes of autologous and allogeneic HCT in patients of different race/ ethnicity utilizing data collected by the Center for International Blood and Marrow Transplant Research (CIBMTR). This study is in the manuscript preparation phase. The goal of this study is to have the manuscript submitted by June 2024.

**HS19-01 Factors Associated with Clinical Trial Participation among HCT Patients: A CIBMTR Analysis** (T. F. Gray/ A. El-Jawahri) The primary aims of this study are to: 1) Describe rates of clinical trial participation based on HCT type; 2) Explore factors that are associated with clinical trial participation in patients undergoing HCT; 3) Assess the impact of clinical trial participation on overall survival (OS) and non-relapse mortality (NRM) in autologous and allogeneic HCT recipients. This study is in the datafile preparation phase.

**HS19-03 Haploidentical Stem Cell Transplantation for malignant and non-malignant hematological diseases in patients without sibling donor: A multicenter prospective and longitudinal study of the Brazilian bone marrow transplantation study group (SBTMO)** (N. Hamerschlak/ M. N. Kerbaui/ A. A. F. Ribeiro). The primary objective of this study is determining if the 1 year overall survival after hematopoietic stem cell transplantation (HCT) plus post-Cy from haploidentical related donor (Haplo – HCT) for acute myeloid leukemia, acute lymphoblastic leukemia and Myelodysplastic / myelo-

proliferative disorders is not inferior compared to matched related or unrelated allogeneic HCT donor with 10/10 and 9/10 compatibility. This study is in the data collection phase.

**HS19-04 Outcomes after allogeneic stem cell transplants performed in Brazil from HLA-matched siblings, unrelated and mismatched related donors. Retrospective study on behalf of the Brazilian Bone Marrow Transplantation Society (SBTMO), GEDECo (Brazil-Seattle Transplant-related complications Consortium), Hospital Israelita Albert Einstein (AmigoH), Associação da Medula Óssea do Estado de São Paulo (Ameo), Programa Nacional de Apoio à Atenção Oncológica (Pronon), and CIBMTR (A. Seber/ N. Hamerschlak/ M. E. Flowers/ M. Pasquini).** The primary objective of this study is to compare 1-year overall survival after allogeneic HCT performed in Brazil from URD, Haplo and MSD. The secondary objective of this study is to compare the 100-day transplant-related mortality (TRM) and the 1-year event-free survival (EFS) after allogeneic HCT performed in Brazil from URD, Haplo and MSD. This study is in the analysis phase.

**HS20-01 Resource Intensity of End-of-Life Care in Children After Hematopoietic Stem Cell Transplant for Acute Leukemia: Rates and Disparities (E. E. Johnston/ C. W. Elgarten/ L. Winestone/ R. Aplenc/ K. Getz/ V. Huang/ Y. Li)** The primary aims of this study are to: 1) Describe the resource utilization during the 30 days before death among children who received a HSCT for a hematologic malignancy and then died within 5 years at the same PHIS hospital. 2) Determine the prevalence of patients with a resource intense phenotype in the last 30 days of life among children who received a HSCT for a hematologic malignancy and then died within 5 years at the same PHIS hospital. 3) Determine the clinical and sociodemographic characteristics associated with a resource intense phenotype among children who received a HSCT for a hematologic malignancy and then died within 5 years at the same PHIS hospital. This study is in the protocol development phase.

**Proposal: 2302-01**

**Title:**

Determining the barriers leading to inferior survival for Black and Hispanic patients with Hodgkin lymphoma

Erin Mobley, PhD, University of Florida

Raymond Mailhot-Vega, MD, MPH, University of Florida

**Hypothesis:**

We hypothesize that patients who lack access to adjuvant therapy (including stem cell transplant, SCT) will have decreased disease-specific survival and overall survival.

**Specific aims:**

Aim 1: Evaluate associations between race, ethnicity, social determinants of health, and receipt of adjuvant and salvage therapy (e.g., HCT), taking into consideration disease outcomes (e.g., survival, relapse) for HL patients of all ages.

Aim 2: Examine differences in access to SCT by state Medicaid expansion status using a novel data linkage of PCORnet to CIBMTR to take into consideration detailed aspects of treatment received that are not captured in the medical record or claims.

Exploratory Aim 3: Determine whether those infected with COVID experience differences in access to SCT and do those differences vary based on those from historically marginalized or underrepresented groups, as well as examine whether those with a prior COVID positive test were diagnosed at a later stage.

**Scientific impact:**

We propose establishing a novel data linkage using PCORnet and CIBMTR. PCORnet provides two key advantages heretofore not afforded by large population-level databases: (1) patient-level electronic health record data and (2) longitudinal data with patient-level encounters and administrative claims. One substantial gap still exists in the definition and coding of relapse and subsequent treatment, particularly receipt of autologous SCT. To address this gap, we propose a novel data linkage of PCORnet with CIBMTR to improve the validity and robustness of the analysis.

**Scientific justification:**

Although overall 5-year survival rates for Hodgkin lymphoma (HL) have improved to ~90%, Black and Hispanic patients have worse survival outcomes than White patients when diagnosed as children, young adults, and older adults (Henderson, 2017).<sup>1,2</sup> The bimodal age-distribution and generally high cure rates of HL offer a unique paradigm to study cancer survival disparities across the age spectrum, especially since each age group receives distinct initial and salvage therapy. HL survival outcomes are consistently worse for Black and Hispanic patients despite equivalent overall relapse rates of patients in trials, suggesting a role for mechanisms other than those that are biological in nature.<sup>3</sup> In that regard, discrete components of care in HL are associated with optimal outcomes including, but not limited to, receiving treatment at an NCI-designated comprehensive cancer center, participating in a therapeutic clinical trial, receiving combined-modality therapy (e.g., chemotherapy + radiation) initially, and undergoing stem cell transplantation at relapse – all of which we and others have reported are significantly less likely to occur for Black and Hispanic patients relative to White patients (2021).<sup>4-7</sup> We and others have also reported that compared to White patients, Black and Hispanic patients are significantly more likely to present with advanced stage and less likely to receive radiotherapy. Analyses

of trials and large databases that we and others have conducted have demonstrated an association between therapy receipt and inequities in social determinants of health (SDOH) such as socioeconomic status, marital status, rurality, and insurance status, with preliminary data noting each age group is influenced by particular and distinct SDOH factors. 8-10 Despite the knowledge gained about these inequities, a gap remains regarding the development of a comprehensive list of key SDOH characteristics (such as one defined by PROGRESS-Plus) at each age group associated with poor survival outcomes in Black and Hispanic HL patients.<sup>11</sup> Prior analyses with trial data and claims data were limited in part by incomplete determination of treatments received due to relapse and following relapse.<sup>1</sup> Our study will directly address these limitations bringing together novel data sources including longitudinal data from the PCORnet Research Data Network (providing patient-level data from regional PCORnet sites across the United States) coupled with access to comprehensive treatment data from the Center for International Blood and Marrow Transplantation Research (CIBMTR). There is, therefore, a critical need to identify SDOH predictors of worse survival reported in all age groups for Black and Hispanic patients with HL using these novel data linkages. Without such information, an evidence-based framework upon which to base the design of interventions to improve survival of HL across the lifespan will remain unlikely.

**Patient eligibility population:**

Inclusion criteria: All patients diagnosed with HL who received their first autologous SCT from 2010-2022.

Exclusion criteria: Patients whose primary residence is outside of the United States.

**Data requirements:**

Patient: DOB (2400: 1), sex (2400: 2), ethnicity (2400: 3), race (2400: 4-5), insurance, 9-digit zip code (2400: 11), all socioeconomic information (2000: 104-117), comorbid conditions (2400: 87-94) Disease: date of diagnosis (2018R6: 166-222), performance status (2400: 71-83; 2018R6:80), organ involvement (2018R6: 78), PET scan and subsequent positive result (2018R6: 69-70), b symptoms (2018R6: 79); all pre-HCT or pre-infusion therapy (2018R6: 166-222); any clinical trial data (2400: 16-21) SCT infusion: date, type (2400: 44), treatment facility location (9-digit zip code), adult or pediatric provider Post-SCT: vital status (2450R7rf: 1-2), response to treatment (2450R7rf: 75-97), subsequent SCTs (2450R7rf: 3-7), relapse or progression (2450R7rf:107-117), current disease status (2450R7rf: 118-120), new malignancy (2450R7rf: 56), socioeconomic information (2100: 331-335)

**Sample requirements:**

None

**Study design:**

None

**Non-CIBMTR data source:**

We propose linkage of CIBMTR data to PCORnet using Datavant. This linkage is required to answer the study aims detailed above, as neither dataset in isolation has all necessary components.

**Conflicts of interest:**

None



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**Demographics of patients with Hodgkin Lymphoma undergone allogenic transplant between 2010 to 2022 registered within CIBMTR.**

<b>Characteristic</b>	<b>N (%)</b>
No. of patients	9290
No. of centers	211
Recipient's age in years - no. (%)	
Median (min-max)	33.0 (4.0-84.0)
0-14	220 (2.4)
15-39	5595 (60.2)
40-64	2929 (31.5)
65+	546 (5.9)
Sex: (2400 Q942) - no. (%)	
Male	5202 (56.0)
Female	4088 (44.0)
Race - no. (%)	
White	7261 (78.2)
Black or African American	1202 (12.9)
Asian	257 (2.8)
Native Hawaiian or other Pacific Islander	27 (0.3)
American Indian or Alaska Native	49 (0.5)
Not Reported	494 (5.3)
Ethnicity (2400 Q957) - no. (%)	
Hispanic or Latino	1307 (14.1)
Non Hispanic or non-Latino	7720 (83.1)
Not Reported	253 (2.8)
Disease indication for Transplant - no. (%)	
HD	9290 (100)
Graft Source - no. (%)	
Bone Marrow	18 (0.2)
Peripheral blood	9271 (99.8)
Cord blood	1 (0.0)
GVHD prophylaxis - no. (%)	
None	9287 (100)
CD34 selection	3 (0.0)
Conditioning regimen - no. (%)	
MAC	162 (1.7)
RIC/NST	12 (0.1)
Not Reported	9116 (98.1)

Characteristic	N (%)
Time from diagnosis to transplant, months - no. (%)	
<3	50 (0.5)
3-5	158 (1.7)
6-8	425 (4.6)
9-11	1234 (13.3)
>12	7423 (79.9)
Zip code available - no. (%)	
No	2324 (25.0)
Yes	6966 (75.0)
Year of transplant - no. (%)	
2010	716 (7.7)
2011	777 (8.4)
2012	723 (7.8)
2013	709 (7.6)
2014	712 (7.7)
2015	732 (7.9)
2016	681 (7.3)
2017	703 (7.6)
2018	738 (7.9)
2019	731 (7.9)
2020	660 (7.1)
2021	671 (7.2)
2022	737 (7.9)
Follow-up of survivors - median (range)	52.7 (0.4-10897.2)

end of table

**Proposal: 2310-13; 2310-140; 2310-215; 2310-222; 2310-225; 2310-263**

**Title:**

Racial and Ethnic Disparities in Safety and Efficacy of Chimeric Antigen Receptor T-cell therapies in B-cell Acute Lymphoblastic Leukemia, Multiple Myeloma or Non-Hodgkin's Lymphoma

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Adetola Kassim, MD, MS, Vanderbilt University Medical Center

Lohith Gowda, MD, MRCP, Yale Cancer Center

Abu-Sayeed Mirza, MD, MPH, Moffitt Cancer Center

**Hypothesis:**

Race/ethnicity influences outcomes in recipients of CART for hematologic neoplasms.

**Specific aims:**

Primary: Racial and ethnic disparities in overall response (partial response or better), complete response, progression free survival, and overall survival in B-cell Acute Lymphoblastic Leukemia (B-ALL),

Multiple Myeloma (MM) or Non Hodgkin's Lymphoma (NHL) patients receiving CAR-T cell therapies

Secondary: Racial and ethnic differences in rates of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, cytopenias, infections, second primary malignancy, and non-relapse mortality in the same population

**Scientific impact:**

I. Racial and ethnic minorities are historically underrepresented in clinical trials, limiting understanding of safety and efficacy profiles of new treatment interventions in this unique population. This study will bridge this critical knowledge gap using real world data from the CIBMTR database.

II. The results of this study will motivate racial/ethnic minority patients and reassure providers to utilize CAR T-cell therapies in the treatment of B-ALL, MM or NHL patients within or outside of clinical trials.

III. Our study will identify patterns of CAR T-cell therapy associated adverse effects in this patient population allowing for anticipation, early detection, and treatment of potential side effects in the clinical setting.

**Scientific justification:**

Despite governmental and industry-sponsored efforts, clinical trial participation among racial and ethnic minorities remains low. The NIH Revitalization Act of 1993 directed the NIH to establish guidelines for inclusion of minorities in clinical research. In 2015, the Food and Drug Administration launched an action plan to improve the quality of demographic subgroup data collection, identify barriers to enrollment, employ strategies to increase participation, and promote transparency of related data. However subsequent studies showed no improvement in participation of racial minorities, including Blacks and Hispanics since this plan was enacted. Various complex system- and individual-based factors, including lack of clinical trial availability;

lack of diversity in the investigator work force; scant patient and provider awareness of clinical trials; lack of trust in the health care system; and issues with access to care—often driven by financial, geographic, or social constraints, and stringent eligibility criteria are deemed responsible. As the effort to racially diversify clinical trial participants continues, real world databases, like the CIBMTR database, become the only source of information to bridge the gap in the understanding of safety and efficacy of new interventions, including CAR T-cell therapies. A real-world data that looked at 215 relapsed/refractory MM patients (150 Non-Hispanic White, 36 Non-Hispanic Black, 21 Hispanic, and 8 Asian, Pacific Islander, American Indian, or Alaskan Native) who received ide-cel reported racial and ethnic differences in safety and PFS among RRMM patients treated with ide-cel CAR T-cell therapy in the SOC setting. When compared to Non-Hispanic White and Hispanic patients, Black patients were more likely to develop any grade CRS (84% vs. 76% vs. 97%, respectively;  $P=0.05$ ), have longer hospital stay (median of 9 vs. 8 vs. 12.5 days, respectively;  $P=0.01$ ), and experienced severe (i.e., grade  $\geq 3$ ) prolonged cytopenias ( $\geq 30$  days post infusion; 72% vs. 56% vs. 87%, respectively;  $P=0.07$ ). In terms of efficacy, although there was no difference in OS among the racial groups, when compared to Non-Hispanic Whites and Hispanics, Black patients had improved ORR rate (86% vs. 65% vs. 88%, respectively;  $P=0.08$ ). However, Hispanic, and Non-Hispanic Black patients combined had worse PFS, median PFS of 5.9 vs. 9.0 months in Non-Hispanic Whites ( $P=0.08$ ). While conveying important clinical information, this study is limited by the small number of patients from racial and ethnic minorities, and the short duration of follow up. None of the study patients received cilta-cel. We hope to alleviate these limitations by using the rich CIBMTR data repository to examine racial disparities in safety and efficacy of both commercially available CAR T-cell formulations, as well as other constructs being investigated in clinical trials, in the treatment of MM.

On the other hand, a retrospective study which examined the impact of race and ethnicity on efficacy and toxicity outcomes across five early-phase clinical CAR T-cell trials enrolling a total of 186 (139 B-ALL (used for primary analysis), 23 NHL, and 24 MM) patients at the National Cancer Institute, involving four CAR constructs reported that Hispanic patients were more likely to experience severe (grade  $\geq 3$ ) CRS and a non-statistically significant trend towards worse neurotoxicity. However, Hispanic patients were equally likely to achieve a complete remission and that this translated to comparable overall survival within our B- ALL Cohort. This suggests that CAR T-cells may be equally effective for Hispanic patients as they are for non-Hispanic patients. While this is promising early evidence that CAR T-cells may be equally effective for Hispanic patients, this is a single center experience and primarily in B-ALL. Performing this analysis through the CIBMTR would allow us to evaluate the effect of race and ethnicity more comprehensively on outcomes for patients receiving this novel treatment modality nationwide, as well as potentially among older patients and outside of B-ALL.

**Patient eligibility population:**

Inclusion Criteria:

All patients, including pediatric and adult age groups, who received CAR T-cell therapies for the treatment of B-cell Acute Lymphoblastic Leukemia, Multiple Myeloma or Non-Hodgkin's Lymphoma as standard of care or in clinical trials.

Race: Caucasians vs African Americans VS Asians vs Others

Ethnicity: Hispanic vs Non-Hispanic

Exclusion Criteria:

Exclude patients with missing racial/ethnic information.

**Data requirements:**

- 1) Patient variables from the Pre-Cellular Therapy Essential Data- Age, Ethnicity, Race, sex, Karnofsky score, comorbidities (HCT CI score)
- 2) Disease characteristics: (Lymphoma, ALL) -subtype (transformed FL, double-hit, triple-hit, MCL, Ph Positive B-ALL, Ph negative B-ALL, immunoglobulin subtype for MM), number of prior lines of therapy, prior CNS disease involvement, current active CNS involvement, time from prior autologous transplant, prior allogeneic stem cell transplantation (yes/no), time from prior allogeneic transplant, baseline organ dysfunction, cellular therapy comorbidity index (CT-CI) if available -baseline (pre-lymphodepletion chemotherapy) counts (ANC, WBC, ALC, HGB, PLT) -baseline marrow blast percentage (for B-ALL) -Baseline inflammatory markers and markers of cellular turnover (CRP, Ferritin, LDH) - Disease Burden  
Disease related variables from Multiple Myeloma/Plasma Cell Disorders Pre-Infusion: High risk(yes/no), plasma cell in bone marrow aspirate by morphologic assessment, specific cytogenetic abnormality, extramedullary plasmacytomas on PET, serum albumin, serum beta 2 microglobulin, LDH, number of lines of therapy, last hematologic response, prior BCMA-targeted therapy (Blenrep, teclistamab, other BCMA targeting CAR), prior autologous stem cell transplantation (yes/no)
- 3) Prior to CAR T-cell CAR T details: -product name -lymphodepletion chemotherapy -time from diagnosis -cell dose, viability, percent of genetically modified cells, and was target percent of genetically modified cells achieved (if available), bridging therapy yes/no, type of bridging therapy -disease status at the time of CAR (active disease or CR), Therapy given for the prevention of CRS, if any, Therapy given for prevention of neurotoxicity (ICANS), if any
- 4) variables from Pre-Cellular Therapy Baseline Data- Ferritin level; C-reactive protein level, creatinine level
- 5) Infusion related variables: Cellular Therapy  
Infusion Data: Total number of cells administered Post Cellular Therapy Essential data: Date of cellular therapy, Date of actual contact, alive/dead, Best response to cellular therapy, Date best response was established, Date ANC at 500 or above, Date platelet at or above 20,000, Date of relapse or progression, CRS diagnosis (yes or no), date of CRS diagnosis, Therapy given for CRS, Number of vasopressor required, any mechanical ventilator use for respiratory support, symptoms of CRS (to allow grading), date CRS resolved, any neurotoxicity, date of diagnosis of neurotoxicity, intervention to treat neurotoxicity, date of resolution of neurotoxicity, Any IVIG received, last immunoglobulin G level, other grade 3 or 4 toxicity with date of onset and date of resolution, any infection/organism
- 6) Other Outcomes details: -disease response (best) -disease response day 30 -relapse/progression -death/survival/last follow up -cause of death -Duration of hospitalization requirement (Form 4100 R8.0 #204-205)

**Sample requirements:**

None

**Study design:**

None

**Non-CIBMTR data source:**

N/A

**Conflicts of interest:**

Consultancy: JANSSEN; BMS Speakers Bureau: JANSSEN;

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**Racial and Ethnic Disparities in Safety and Efficacy of Chimeric Antigen Receptor T-cell therapies in B-cell Acute Lymphoblastic Leukemia, Multiple Myeloma or Non-Hodgkin’s Lymphoma**

Characteristic	Follicular					PCD	Total
	B cell-ALL	NHL	DLBCL	MCL	Other NHL		
No. of infusions	1143	538	5528	722	183	299	8413
No. of centers	158	92	152	99	79	67	210
CT infusion counting number - no. (%)							
1	995 (87.1)	531 (98.7)	5464 (98.8)	718 (99.4)	168 (91.8)	280 (93.6)	8156 (96.9)
2	131 (11.5)	5 (0.9)	55 (1.0)	4 (0.6)	13 (7.1)	15 (5.0)	223 (2.7)
3	12 (1.0)	1 (0.2)	7 (0.1)	0 (0.0)	2 (1.1)	4 (1.3)	26 (0.3)
4	5 (0.4)	1 (0.2)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)
5	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Age at infusion, by category - no.(%)							
Median (min-max)	19.3 (0.4-84.3)	62.1 (26.9-86.8)	63.1 (0.3-91.0)	67.5 (34.1-90.5)	52.4 (4.3-77.6)	60.8 (32.1-85.9)	61.5 (0.3-91.0)
- <10 years	251 (22.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	254 (3.0)
- 19 years	344 (30.1)	0 (0.0)	12 (0.2)	0 (0.0)	10 (5.5)	0 (0.0)	366 (4.4)
- 29 years	233 (20.4)	2 (0.4)	155 (2.8)	0 (0.0)	22 (12.0)	0 (0.0)	412 (4.9)
- 39 years	87 (7.6)	10 (1.9)	287 (5.2)	4 (0.6)	22 (12.0)	5 (1.7)	415 (4.9)
- 49 years	73 (6.4)	53 (9.9)	516 (9.3)	28 (3.9)	30 (16.4)	36 (12.0)	736 (8.7)
- 59 years	70 (6.1)	148 (27.5)	1203 (21.8)	107 (14.8)	35 (19.1)	86 (28.8)	1649 (19.6)
- 69 years	69 (6.0)	220 (40.9)	1973 (35.7)	318 (44.0)	40 (21.9)	119 (39.8)	2739 (32.6)
70+ years	16 (1.4)	105 (19.5)	1381 (25.0)	265 (36.7)	22 (12.0)	53 (17.7)	1842 (21.9)
Sex - no. (%)							
Male	698 (61.1)	329 (61.2)	3484 (63.0)	565 (78.3)	122 (66.7)	182 (60.9)	5380 (63.9)
Female	445 (38.9)	209 (38.8)	2043 (37.0)	156 (21.6)	61 (33.3)	117 (39.1)	3031 (36.0)
Not reported	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	2 (0.0)
Type of CT - no. (%)							
Commercial Car-T	1028 (89.9)	524 (97.4)	5475 (99.0)	717 (99.3)	95 (51.9)	186 (62.2)	8025 (95.4)
Other Cell Therapy	115 (10.1)	14 (2.6)	53 (1.0)	5 (0.7)	88 (48.1)	113 (37.8)	388 (4.6)



Characteristic	Follicular					PCD	Total
	B cell-ALL	NHL	DLBCL	MCL	Other NHL		
Recipient ethnicity - no. (%)							
Hispanic or Latino	388 (33.9)	56 (10.4)	595 (10.8)	57 (7.9)	19 (10.4)	23 (7.7)	1138 (13.5)
Not Hispanic or Latino	672 (58.8)	455 (84.6)	4573 (82.7)	638 (88.4)	147 (80.3)	271 (90.6)	6756 (80.3)
Non-resident of the U.S.	62 (5.4)	9 (1.7)	197 (3.6)	7 (1.0)	13 (7.1)	3 (1.0)	291 (3.5)
Unknown	21 (1.8)	18 (3.3)	163 (2.9)	20 (2.8)	4 (2.2)	2 (0.7)	228 (2.7)
Recipient race - no. (%)							
White	874 (76.5)	466 (86.6)	4561 (82.5)	641 (88.8)	139 (76.0)	246 (82.3)	6927 (82.3)
Black or African American	89 (7.8)	30 (5.6)	314 (5.7)	27 (3.7)	25 (13.7)	35 (11.7)	520 (6.2)
Asian	35 (3.1)	17 (3.2)	297 (5.4)	18 (2.5)	9 (4.9)	8 (2.7)	384 (4.6)
Native Hawaiian or other Pacific Islander	2 (0.2)	0 (0.0)	12 (0.2)	1 (0.1)	1 (0.5)	0 (0.0)	16 (0.2)
American Indian or Alaska Native	8 (0.7)	2 (0.4)	24 (0.4)	2 (0.3)	0 (0.0)	0 (0.0)	36 (0.4)
Other	30 (2.6)	0 (0.0)	24 (0.4)	3 (0.4)	1 (0.5)	2 (0.7)	60 (0.7)
More than one race	105 (9.2)	23 (4.3)	296 (5.4)	30 (4.2)	8 (4.4)	8 (2.7)	470 (5.6)
Age at infusion, by category #2 - no. (%)							
- 17	530 (46.4)	0 (0.0)	2 (0.0)	0 (0.0)	10 (5.5)	0 (0.0)	542 (6.4)
- 39	385 (33.7)	12 (2.2)	453 (8.2)	4 (0.6)	46 (25.1)	5 (1.7)	905 (10.8)
- 65	183 (16.0)	318 (59.1)	2690 (48.7)	283 (39.2)	84 (45.9)	179 (59.9)	3737 (44.4)
65+	45 (3.9)	208 (38.7)	2383 (43.1)	435 (60.2)	43 (23.5)	115 (38.5)	3229 (38.4)
Age at infusion, by category #3 - no. (%)							
- 64	1098 (96.1)	330 (61.3)	3145 (56.9)	287 (39.8)	140 (76.5)	184 (61.5)	5184 (61.6)
65+	45 (3.9)	208 (38.7)	2383 (43.1)	435 (60.2)	43 (23.5)	115 (38.5)	3229 (38.4)
Country - no. (%)							
US	1094 (95.7)	533 (99.1)	5349 (96.8)	716 (99.2)	169 (92.3)	295 (98.7)	8156 (96.9)
Other	49 (4.3)	5 (0.9)	179 (3.2)	6 (0.8)	14 (7.7)	4 (1.3)	257 (3.1)
Disease - no. (%)							

Characteristic	Follicular					PCD	Total
	B cell-ALL	NHL	DLBCL	MCL	Other NHL		
B-cell Acute lymphoblastic leukemia (ALL)	1143 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1143 (13.6)
Non-Hodgkin lymphoma (NHL)	0 (0.0)	538 (100)	5528 (100)	722 (100)	183 (100)	0 (0.0)	6971 (82.9)
Plasma cell disorder/Multiple myeloma (PCD/MM)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	299 (100)	299 (3.6)
Clinical trial - no. (%)							
No	1143 (100)	538 (100)	5528 (100)	722 (100)	183 (100)	299 (100)	8413 (100)
Product - no. (%)							
Kymriah	732 (64.0)	8 (1.5)	862 (15.6)	1 (0.1)	8 (4.4)	0 (0.0)	1611 (19.1)
Yescarta	0 (0.0)	514 (95.5)	4525 (81.9)	13 (1.8)	83 (45.4)	0 (0.0)	5135 (61.0)
Tecartus	296 (25.9)	0 (0.0)	4 (0.1)	703 (97.4)	3 (1.6)	0 (0.0)	1006 (12.0)
Breyanzi	0 (0.0)	2 (0.4)	84 (1.5)	0 (0.0)	1 (0.5)	0 (0.0)	87 (1.0)
Abecma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	186 (62.2)	186 (2.2)
Not Reported	115 (10.1)	14 (2.6)	53 (1.0)	5 (0.7)	88 (48.1)	113 (37.8)	388 (4.6)
Types of prior HCTs - no. (%)							
No prior HCT	700 (61.2)	442 (82.2)	4294 (77.7)	482 (66.8)	77 (42.1)	29 (9.7)	6024 (71.6)
Prior allo-HCT	16 (1.4)	0 (0.0)	3 (0.1)	0 (0.0)	1 (0.5)	0 (0.0)	20 (0.2)
Prior auto-HCT	1 (0.1)	4 (0.7)	100 (1.8)	12 (1.7)	0 (0.0)	4 (1.3)	121 (1.4)
Prior auto and allo-HCT	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)
Not Reported	426 (37.3)	92 (17.1)	1129 (20.4)	228 (31.6)	105 (57.4)	266 (89.0)	2246 (26.7)
Year of CT - no. (%)							
2016	1 (0.1)	0 (0.0)	2 (0.0)	1 (0.1)	7 (3.8)	13 (4.3)	24 (0.3)
2017	29 (2.5)	1 (0.2)	18 (0.3)	0 (0.0)	13 (7.1)	23 (7.7)	84 (1.0)
2018	179 (15.7)	13 (2.4)	469 (8.5)	3 (0.4)	20 (10.9)	30 (10.0)	714 (8.5)
2019	241 (21.1)	10 (1.9)	916 (16.6)	2 (0.3)	29 (15.8)	20 (6.7)	1218 (14.5)
2020	223 (19.5)	12 (2.2)	1035 (18.7)	70 (9.7)	28 (15.3)	12 (4.0)	1380 (16.4)
2021	181 (15.8)	165 (30.7)	998 (18.1)	238 (33.0)	30 (16.4)	193 (64.5)	1805 (21.5)
2022	169 (14.8)	188 (34.9)	1153 (20.9)	238 (33.0)	29 (15.8)	6 (2.0)	1783 (21.2)
2023	120 (10.5)	149 (27.7)	937 (17.0)	170 (23.5)	27 (14.8)	2 (0.7)	1405 (16.7)

Characteristic	Follicular					PCD	Total
	B cell-ALL	NHL	DLBCL	MCL	Other NHL		
Zip code available - no. (%)							
No	582 (50.9)	64 (11.9)	2498 (45.2)	67 (9.3)	91 (49.7)	105 (35.1)	3407 (40.5)
Yes	561 (49.1)	474 (88.1)	3030 (54.8)	655 (90.7)	92 (50.3)	194 (64.9)	5006 (59.5)
Time from receiving H4000 baseline form to infusion, days - median (min-max)	49.0 (-6.0-1638.0)	13.0 (-7.0-570.0)	23.0 (-33.0-1706.0)	19.0 (-7.0-1200.0)	126.0 (-4.0-1778.0)	27.0 (-2.0-1343.0)	25.0 (-33.0-1778.0)

**Proposal: 2310-44**

**Title:**

Impact of Social Determinants of Health on Outcomes in Pediatric Patients Undergoing Haploidentical Stem Cell Transplantation for Acute Leukemia

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**Hypothesis:**

Pediatric patients with leukemia of non-white ethnicity will have decreased overall survival (OS) and increased transplant related mortality (TRM) compared with patients of white ethnicity undergoing Haploidentical hematopoietic stem cell transplant (HCT).

**Specific aims:**

Primary Aim: Determine the impact of Social Determinants of Health (SDOH) on outcomes in pediatric AlloHCT patients for leukemia.

**Scientific impact:**

As the relative population of minority groups within the United States continues to grow, so will the need for pediatric patients of these minority groups to undergo HCT. Unfortunately, patients from diverse ethnic backgrounds are at a disadvantage when trying to find a suitable match within the bone marrow registries and are thus more reliant on alternative donor sources such as haploidentical donors [1]. This has been shown to be a viable alternative through randomized controlled trials which indicate that haploidentical HCT have similar OS compared to other donor types [2]. Unfortunately it has also been shown that patients of minority backgrounds have disparate outcomes post HCT [3]. Previous studies did not specifically analyze pediatric patients, which were often analyzed comingled with adult data, limiting the ability to apply results to pediatric populations. Therefore, we propose that the analysis of pediatric haploidentical HCT patient outcomes in relation to ethnic/racial background would elucidate any treatment related differences that could lead to changes in practice within this patient population.

**Scientific justification:**

In order to address, and potentially eliminate, racial disparities in any minority group they must first be identified to exist within at-risk patient populations [4]. Analysis of studies performed over the last 2 decades have shown disparity in outcomes in ethnic minority patients who underwent HCT in terms of overall survival, treatment related mortality, relapse and other measures [3]. A meta-analysis of available studies in adults and pediatric patients indicated an increase in overall mortality in Hispanic and African American patients compared to White patients [3]. There are a limited number of studies assessing the effect of ethnicity on HCT outcomes compared to other patient related factors, and even fewer in pediatric patient populations. These studies can vary in terms of finding significant differences between ethnic groups post-transplant [3, 5], which may highlight the limitations of smaller cohort studies. Ethnicity specific data can often be limited to adult patient populations, limiting the applicability of findings to pediatric HCT patient populations. It is known that patients with diverse ethnic backgrounds have limited availability to unrelated donors that can be accessed via donor registries [1]. In recent years patients with ethnically diverse backgrounds are increasingly receiving allogeneic HCT, which has been accompanied by an increase in the use of haploidentical donors and/or post-transplant Cytoxan (ptCy) as GVHD prophylaxis [6]. A phase 3 trial in patients older than 16yo has

shown that OS is not significantly different when compared to matched unrelated CIBMTR data, indicating that Haploidentical HCT with ptCy could be a viable alternative for patients without sufficient HLA match in unrelated donor registries [2]. Due to the limited number of studies investigating the outcomes of patients with minority ethnicity, specifically including pediatric populations, as well as the results having a range of significance in terms of outcome measures based on ethnicity, a larger study of pediatric patients including more recent data would allow for a more robust evaluation of outcomes. Identification of racial disparity among pediatric haploidentical HCT recipients is essential to developing patient specific interventions to attempt to ameliorate transplant related complications and give patients the best possible outcome post HCT.

**Patient eligibility population:**

Inclusion Criteria:

- Allogeneic Transplant
- Year-2012-2022
- Age 0-21 years at time of alloHCT
- Malignant and Non-Malignant Disease
- Peripheral blood stem cell or Bone Marrow
- Conditioning Intensity: Myeloablative

Exclusion Criteria:

- Embargoed centers and centers with 5-year completion index of <85%
- Graft manipulation (CD34 selection or alpha-beta depletion)
- Cord blood recipients – Secondary AML/ALL
- Conditioning Intensity: Reduced Intensity

**Data requirements:**

Patient Characteristics - Age - Gender - BMI - Ethnicity (Caucasian vs. Hispanic vs. African American vs. Other) - Indications: ALL and AML - HCT-CI score Performance Status (<90 vs 90-100) - Disease Status (1st and 2<sup>nd</sup> complete remission) - Pre-AlloHCT organ dysfunction (Liver, Cardiac, Lung, CNS, Renal, Other) – Insurance type - Zip code of residence at the time of AlloHCT - Distance of residence from the transplant center - Neighborhood poverty index Donor Characteristics - Age - Gender - Relationship with patient (sibling, parents or other) - Degree of HLA match Transplant Characteristics - Year of transplant: 2012-2022 - Total nucleated cells/kg infused - CD34 cell dose/kg infused - GCSF (yes v no) – GVHD prophylaxis used: ptCy/CNI/MMF Outcomes – Days to neutrophil engraftment - Days to platelet engraftment - Day 100 and day 365 survival – Transplant related mortality at 1 and 2 years - Overall survival at 1 and 2 years - Leukemia free survival at 1 and 2 years - GREFS at 1 year - Incidence of acute GVHD - Incidence of chronic GVHD - Incidence of VOD - Incidence of respiratory failure/mechanical ventilation - Incidence of TA-TMA - Incidence of bacterial/fungal infections - Incidence of dialysis/CRRT - Post-AlloHCT organ dysfunction (Liver, Cardiac, Lung, CNS, Renal, Other)

**Sample requirements:**

None

**Study design:**

None

**Non-CIBMTR data source:**

None

**Conflicts of interest:**

None

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**Demographics of patients aged less than 21 years undergone Haploidentical Stem Cell Transplantation for Acute Leukemia registered within CIBMTR from 2012-2022.**

<b>Characteristic</b>	<b>N (%)</b>
No. of patients	929
No. of centers	94
Recipient's age in years - no. (%)	
Median (min-max)	13.0 (0.0-20.0)
<5	173 (18.6)
5-10	209 (22.5)
11-15	260 (28.0)
16-<21	287 (30.9)
Sex: (2400 Q942) - no. (%)	
Male	562 (60.5)
Female	367 (39.5)
Race - no. (%)	
White	600 (64.6)
Black or African American	139 (15.0)
Asian	51 (5.5)
Native Hawaiian or other Pacific Islander	3 (0.3)
American Indian or Alaska Native	11 (1.2)
Not Reported	125 (13.5)
Ethnicity (2400 Q957) - no. (%)	
Hispanic or Latino	399 (42.9)
Non Hispanic or non-Latino	483 (52.0)
Non-resident of the U.S.	1 (0.1)
Not Reported	46 (4.9)
Disease indication for Transplant - no. (%)	
AML	399 (42.9)
ALL	530 (57.1)
Graft Source - no. (%)	
Bone Marrow	503 (54.1)
Peripheral blood	426 (45.9)
GVHD prophylaxis - no. (%)	
None	29 (3.1)
Ex-vivo T-cell depletion	152 (16.4)
CD34 selection	7 (0.8)
PtCy + other(s)	662 (71.3)
PtCy alone	1 (0.1)

<b>Characteristic</b>	<b>N (%)</b>
TAC + MMF +- other(s) (except PtCy)	52 (5.6)
TAC + MTX +- other(s) (except MMF, PtCy)	7 (0.8)
TAC alone	2 (0.2)
CSA + MMF +- other(s) (except PtCy,TAC)	5 (0.5)
CSA alone	2 (0.2)
Other(s)	2 (0.2)
Not Reported	8 (0.9)
Conditioning regimen - no. (%)	
MAC	929 (100)
Time from diagnosis to transplant - no. (%)	
<3	108 (11.6)
3-5	251 (27.0)
6-8	116 (12.5)
9-11	71 (7.6)
>12	383 (41.2)
Zip code available - no. (%)	
No	37 (4.0)
Yes	892 (96.0)
Year of transplant - no. (%)	
2012	12 (1.3)
2013	25 (2.7)
2014	14 (1.5)
2015	27 (2.9)
2016	60 (6.5)
2017	75 (8.1)
2018	86 (9.3)
2019	127 (13.7)
2020	189 (20.3)
2021	160 (17.2)
2022	154 (16.6)
Follow-up of survivors - median (range)	35.4 (2.5-120.9)

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**Proposal: 2310-47**

**Title:**

Outcomes for Medicaid beneficiaries following allogeneic hematopoietic cell transplantation: Exploring the impact of variable Medicaid eligibility criteria

Patrick DeMartino, MD,MPH, Oregon Health and Science University  
Navneet Majail, MD, MS, Sarah Cannon Cancer Institute

**Hypothesis:**

We hypothesize that heterogeneity in state Medicaid eligibility criteria influence the association between HCT outcomes and insurance status and that analyses describing inferior outcomes for Medicaid enrollees in aggregate (nationally) are of limited utility. We anticipate adult Medicaid enrollees from expansion versus non-expansion states undergoing HCT differ by demographics, pre-transplant comorbidities, and outcomes when compared to a commercially insured cohort. For pediatric HCT recipients, we expect the Medicaid income eligibility threshold influences the association between Medicaid enrollment and outcomes—specifically the strength of the association diminishes with higher income eligibility thresholds when comparing Medicaid enrollees to a commercially insured cohort.

**Specific aims:**

Primary objectives: i) To assess the association between insurance type and HCT outcomes for adult recipients from states with expansion of Medicaid compared to non-expansion states ii) To assess the association between insurance type and HCT outcomes for pediatric recipients from states with higher versus lower Medicaid income eligibility thresholds for children (combined upper income threshold of 255% of federal poverty limit, FPL) Secondary objectives: i) To compare the pre-transplant characteristics of adult Medicaid enrollees from states with Medicaid expansion versus non-expansion states ii) To compare the pre-transplant characteristics of pediatric Medicaid enrollees from states with higher versus lower Medicaid income eligibility thresholds

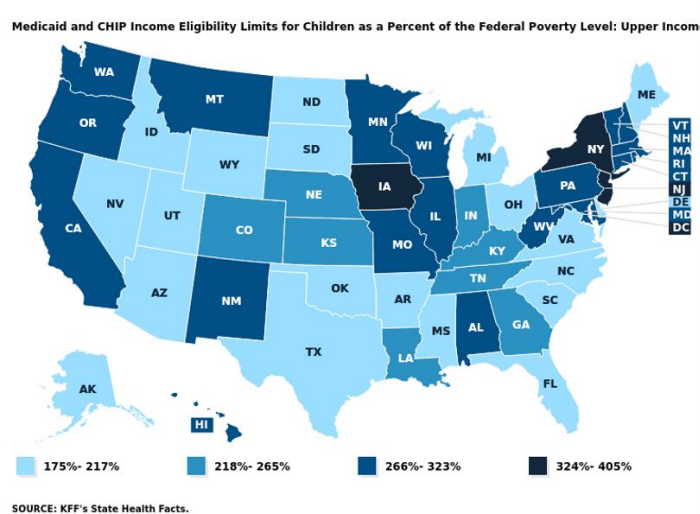
**Scientific impact:**

Evaluating the relationship between Medicaid eligibility thresholds and HCT outcomes may serve three purposes. First, it would support or call into question the utility of analyses using insurance status in aggregate at the national level. Second, it may inform the advocacy work of the ASTCT-NMDP ACCESS Initiative—possibly identifying states or policies for targeted advocacy efforts to address disparate outcomes. Lastly, this analysis would provide a more nuanced perspective of pre-transplant characteristics and HCT outcomes for Medicaid enrollees and possibly reduce some of the stigma associated with Medicaid enrollment. There are no published studies in transplant nor oncology exploring the impact of Medicaid eligibility thresholds on clinical outcomes at the state level.

**Scientific justification:**

Many studies have observed inferior access or outcomes for Medicaid enrollees undergoing HCT when compared to commercially insured individuals when analyzed in aggregate at the national level.<sup>1-5</sup> This association is likely resultant of a variety of socioeconomic forces associated with insurance status—including income, health literacy, race, or geography in addition to factors intrinsic to the insurance plan (e.g. benefit design or eligibility requirements). Medicaid is administered by the states within broad federal guidelines and there exists profound variability across state Medicaid plans in income eligibility requirements and benefit design. A recent analysis reported profound variation in Medicaid plan coverage for HCT and CAR-T.<sup>6</sup> As of September 2023, 11 states have not expanded Medicaid; providing

no pathway to coverage for low-income adults without children or disabilities. For children, income eligibility thresholds can range from 170% of the federal poverty limit (FPL) to 400% (for a family of four this corresponds to \$47,175 to \$110,000 annual income).<sup>7</sup> Additionally, the composition of Medicaid plans have changed substantially in the last decade, in part due to the Affordable Care Act and COVID-19 policies. An increasing proportion of HCT recipients are Medicaid beneficiaries and inter-state plan variability has historically limited our understanding of this population. A more nuanced perspective is needed for health services researchers and advocacy efforts. One limitation is the inability to identify individuals eligible for HCT but did not undergo the procedure—a critical issue for individuals of lower socioeconomic strata. The rate of uninsured adults is considerably higher in states without Medicaid expansion compared to expansion states.<sup>7</sup> Despite this limitation, the analysis should still provide actionable insight regarding the impact of eligibility thresholds on outcomes.



**Patient eligibility population:**

- a) Patients who underwent allogeneic HCT between July 1, 2014 and December 31, 2020 for acute leukemia in the United States
- b) Patients aged 1 to 64 years of age at time of transplant
- c) Insurance type: Medicaid/CHIP or private insurance, exclude Medicare dual enrollees
- i) Exclude patients residing in states that expanded Medicaid during the study period (#11): AK, ID, IN, LA, ME, MT, NC, NE, PA, UT, VA
- ii) Exclude states with inadequate number of residents undergoing transplant in a given year during the study period

**Data requirements:**

- a) Patient-related
  - i) Form: Pre-transplant essential data (1) Date of birth (2) Sex (3) Ethnicity and race (4) Country (US) and state of residence (5) Zipcode (6) Reason for current HCT (7) Clinical status prior to conditioning (#81-83, 95-116) (8) Conditioning regimen intensity (#122-123)
  - ii) Form: Recipient baseline data (1) Marital status (2) Work status and educational attainment (#106-110) (3) Insurance status (4) Combined gross annual income (5) Number living in the household and number under 18
- b) Disease-related (Disease classification form)
  - i) Date of diagnosis
  - ii) Primary disease
- c) Donor-related (Pre-TED form)
  - i) Donor type and product info (#44-52)
- d) Outcomes
  - i) Overall survival
  - ii) Disease free survival
  - iii) Non-relapse mortality
  - iv) Cause of death
  - v) aGVHD grade 2-4
  - vi) cGVHD any severity

**Sample requirements:**

None

**Study design:**

None

**Non-CIBMTR data source:**

Publicly available data from Medicaid and CHIP Payment and Access Commission for state income eligibility thresholds

**Conflicts of interest:**

None

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**Outcomes for Medicaid beneficiaries following allogeneic hematopoietic cell transplantation:  
Exploring the impact of variable Medicaid eligibility criteria**

<b>Characteristic</b>	<b>N (%)</b>
No. of patients	3786
No. of centers	138
Recipient's age in years - no. (%)	
Median (min-max)	44.0 (1.0-64.0)
0-9	330 (8.7)
10-19	375 (9.9)
20-29	487 (12.9)
30-39	462 (12.2)
40-49	585 (15.5)
50-59	885 (23.4)
60-69	662 (17.5)
Sex - no. (%)	
Male	2011 (53.1)
Female	1775 (46.9)
Race - no. (%)	
White	2739 (72.3)
Black or African American	473 (12.5)
Asian	325 (8.6)
Native Hawaiian or other Pacific Islander	19 (0.5)
American Indian or Alaska Native	34 (0.9)
Not Reported	196 (5.2)
Ethnicity - no. (%)	
Hispanic or Latino	688 (18.2)
Non Hispanic or non-Latino	3010 (79.5)
Not Reported	88 (2.3)
Disease indication for Transplant - no. (%)	
AML	2498 (66.0)
ALL	1288 (34.0)
Graft Source - no. (%)	
Bone Marrow	918 (24.2)
Peripheral blood	2127 (56.2)
Cord blood	741 (19.6)
GVHD prophylaxis - no. (%)	
None	13 (0.3)
Ex-vivo T-cell depletion	64 (1.7)
CD34 selection	144 (3.8)

Characteristic	N (%)
PtCy + other(s)	1030 (27.2)
PtCy alone	50 (1.3)
TAC + MMF +- other(s) (except PtCy)	480 (12.7)
TAC + MTX +- other(s) (except MMF, PtCy)	1192 (31.5)
TAC + other(s) (except MMF, MTX, PtCy)	139 (3.7)
TAC alone	82 (2.2)
CSA + MMF +- other(s) (except PtCy,TAC)	387 (10.2)
CSA + MTX +- other(s) (except PtCy,TAC,MMF)	155 (4.1)
CSA + other(s) (except PtCy,TAC,MMF,MTX)	9 (0.2)
CSA alone	11 (0.3)
Other(s)	30 (0.8)
Conditioning regimen - no. (%)	
MAC	2559 (67.6)
RIC/NST	1218 (32.2)
Not Reported	9 (0.2)
Donor type - no. (%)	
HLA-identical sibling	713 (18.8)
Other related	966 (25.5)
Well-matched unrelated (8/8)	1103 (29.1)
Partially-matched unrelated (7/8)	229 (6.0)
Mis-matched unrelated (<= 6/8)	25 (0.7)
Multi-donor	5 (0.1)
Unrelated (matching TBD)	4 (0.1)
Cord blood	741 (19.6)
Time from diagnosis to transplant, months - no. (%)	
<3	278 (7.3)
3-5	1701 (44.9)
6-8	618 (16.3)
9-11	277 (7.3)
>12	912 (24.1)
Zip code available - no. (%)	
No	13 (0.3)
Yes	3773 (99.7)
Year of transplant - no. (%)	
2014	474 (12.5)
2015	801 (21.2)
2016	711 (18.8)
2017	591 (15.6)

<b>Characteristic</b>	<b>N (%)</b>
2018	567 (15.0)
2019	455 (12.0)
2020	187 (4.9)
Follow-up of survivors, months - median (range)	61.2 (1.5-102.9)

**Proposal: 2310-64**

**Title:**

The effect of Social Determinants of Health on Allogeneic Transplant Outcomes: A study of the impact of Social Vulnerability Index on Outcomes for Allogeneic Transplant for Acute Myeloid Leukemia

Karen Ballen, MD, University of Virginia  
Indumathy Varadarajan, MBBS, University of Virginia

**Hypothesis:**

Hypothesis 1: Patients who live in counties with high social vulnerability index (above the median) will have lower 2 year overall survival compared to patients who live in counties with lower social vulnerability index. Hypothesis 2: Within the Social Vulnerability Index, the household composition and racial/ethnic subgroups will have the most impact on overall survival after HCT.

**Specific aims:**

Primary Outcome: Two year Overall Survival after HCT for AML Secondary Outcomes: Transplant related mortality at Day 100 Acute GVHD Grades II/IV Chronic GVHD at one year GVHD free, relapse free survival at one year and two years after transplant

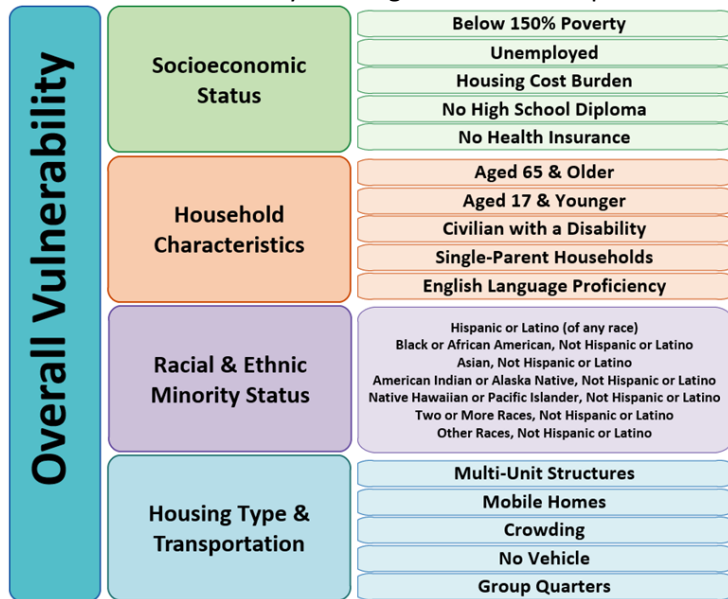
**Scientific impact:**

Social determinants of health affect both access to transplant care and outcomes after HCT. In this study, we use the social vulnerability index, identified by zip code, to determine how SVI affects overall survival after HCT for acute myeloid leukemia. In addition, the 16 subthemes of SVI can be assessed to determine which subthemes (household, race/ethnicity, transportation, socioeconomic status) are most impactful. This data can then be used to elicit attention and resources to the most important areas and implement strategy to affect change in the key areas.

**Scientific justification:**

Acute Myelogenous Leukemia (AML) is the most common form of acute leukemia in adults and the mean age at presentation is 65 years old. There are approximately 22,000 new cases of AML yearly in the United States. For most adults who are fit, induction chemotherapy with cytarabine in combination with an anthracycline or a hypomethylating agent based regimen remains the standard induction regimen. Induction treatment is then often followed by consolidation chemotherapy or hematopoietic cell transplantation (HCT). In general, HCT offers a higher chance of cure for patients with high risk features such as complex cytogenetics and presence of the FMS-like tyrosine kinase 3 (FLT-3) mutation. There are over 3000 HCT performed yearly in the US for AML, mostly in first complete remission, with matched unrelated donors (MUD) the most common donor type. 74% of transplants in the US are in White patients. According to data from the Center for International Blood and Marrow Transplant Research (CIBMTR), the estimated 3 year survival for AML adult patients in first remission undergoing unrelated HCT is 56% and 58% for those with HLA matched sibling donors. Several factors affect overall survival (OS) following HCT for AML. In this study, we examine the impact of social determinants of health, especially the local level social vulnerability, on 2 year OS for AML patients undergoing HCT. This study uses the Centers for Disease Control and Prevention (CDC) Social Vulnerability Index (SVI) to capture local levels of social vulnerability. The SVI can be determined by patient Zip Code. Composed of 16 social factors, SVI is a constantly evolving measure of a community's ability to respond to hazardous events and is traditionally used to help public health officials identify populations in most need of support after natural disaster. SVI is comprised of 16 social factors grouped into four related themes

(socioeconomic status; household characteristics; racial and ethnic minority status; and housing type and transportation). These individual components and themes comprise a composite SVI score that reflects a community’s overall vulnerability ranking. Areas with higher SVI values are at a higher risk during public health emergencies and are considered more socially vulnerable. SVI has traditionally been used for natural disaster outreach, but recently has been studied in cancer patients. Previous studies from our group examining acute myeloid leukemia (AML) patients have shown that patients living in high SVI areas are less likely to undergo allogeneic hematopoietic cell transplantation (HCT). Single center studies have documented worse survival outcomes after HCT for AML and autologous stem cell transplant for myeloma. However, to our knowledge, the impact of local level social vulnerability has not been studied extensively in a large series of AML patients undergoing HCT.



**Patient eligibility population:**

1. Diagnosis of Acute Myeloid Leukemia
2. Ages 18 to 75
3. Resident of US and transplant in US Transplant Center
4. Recipient of First Allogeneic Stem Cell Transplant
5. Received Allogeneic Stem Cell Transplant From January, 2015 to December 2020.
6. Zip Code information on recipient available
7. Recipient of any donor source, including matched related donor, cord blood, matched and mismatched unrelated donor, haploidentical donors
8. Recipient of any graft source including peripheral blood stem cells, bone marrow and cord blood.
9. Any GVHD prophylaxis including post-transplant cyclophosphamide and tacrolimus/methotrexate.

**Data requirements:**

Main effect: - SVI: Above and below median Patient-related Age: continuous; categorical by decade  
 Gender: male vs. female Race/Ethnicity: White, Black, Hispanic or Latinx, Other Karnofsky performance status prior to transplant &lt; 90% vs. 90-100% HCT-CI: 0 vs 1-2 vs 3-4 vs 5+ Recipient CMV status: positive vs. negative vs. unknown Insurance type: Public vs Private insurance Marital Status: Married vs Other Highest educational grade: College or above vs all others Employment status: Full time vs Part time vs Unemployed Distance from residence to transplant center: (&lt; 50 miles vs &gt; 50 miles) Disease-related Disease risk index: Low vs intermediate vs high vs very high Transplant-related Graft Source: Bone marrow vs peripheral blood stem cell vs cord blood Donor Source: Matched related donor vs haploidentical vs matched unrelated donor vs mismatched unrelated donor Conditioning regimen intensity: myeloablative-TBI vs. MAC-Chemo vs. nonmyeloablative/reduced intensity GVHD prophylaxis:



Post-CY + other(s) vs TAC + MTX vs other Post Transplant Maintenance: FLT 3 inhibitor vs other vs none All data is on CIBMTR forms. Social vulnerability index can be downloaded using zip code of residence. CDC/ATSDR Social Vulnerability Index (SVI) No additional data is required.

**Sample requirements:**

None

**Study design:**

None

**Non-CIBMTR data source:**

The SVI can be downloaded from the Zip Code on a public database, no additional information is required. CDC/ATSDR Social Vulnerability Index (SVI) 1. Socioeconomic status: Below 150% poverty Unemployed Housing Cost Burden No High School Diploma No Health Insurance 2. Household Characteristics Aged 65 and Older Aged 17 and Younger Civilian with a Disability Single Parent Households English Language Proficiency 3. Racial and Ethnic Minority Status Hispanic or Latino (of any race) Black or African American, Not Hispanic or Latino Asian, Not Hispanic or Latino American Indian or Alaska Native, Not Hispanic or Latino Native Hawaiian or Pacific Islander, Not Hispanic or Latino Two or More Races, Not Hispanic or Latino Other Races, Not Hispanic or Latino 4. Housing Type and Transportation Multi-Unit Structures Mobile Homes Crowding No Vehicle Group Quarters

**Conflicts of interest:**

None

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**Demographics of patients undergone first allogeneic transplant for Acute Myeloid Leukemia between 2015 to 2020 in USA registered within CIBMTR.**

<b>Characteristic</b>	<b>Total</b>
No. of patients	14962
No. of centers	170
Recipient's age in years - no. (%)	
Median (min-max)	57.0 (18.0-74.0)
18-28	1178 (7.9)
29-38	1384 (9.3)
39-48	1978 (13.2)
49-58	3457 (23.1)
59-68	5169 (34.5)
69-75	1796 (12.0)
Sex: (2400 Q942) - no. (%)	
Male	7972 (53.3)
Female	6990 (46.7)
Race - no. (%)	
White	12629 (84.4)
Black or African American	1014 (6.8)
Asian	688 (4.6)
Native Hawaiian or other Pacific Islander	35 (0.2)
American Indian or Alaska Native	49 (0.3)
Not Reported	547 (3.7)
Ethnicity (2400 Q957) - no. (%)	
Hispanic or Latino	1339 (8.9)
Non Hispanic or non-Latino	13237 (88.5)
Not Reported	386 (2.6)
Graft Source - no. (%)	
Bone Marrow	1927 (12.9)
Peripheral blood	12270 (82.0)
Cord blood	765 (5.1)
GVHD prophylaxis - no. (%)	
None	61 (0.4)
Ex-vivo T-cell depletion	100 (0.7)
CD34 selection	265 (1.8)
PtCy + other(s)	3969 (26.5)
PtCy alone	123 (0.8)
TAC + MMF +/- other(s) (except PtCy)	1642 (11.0)

Characteristic	Total
TAC + MTX +- other(s) (except MMF, PtCy)	6326 (42.3)
TAC + other(s) (except MMF, MTX, PtCy)	939 (6.3)
TAC alone	398 (2.7)
CSA + MMF +- other(s) (except PtCy,TAC)	620 (4.1)
CSA + MTX +- other(s) (except PtCy,TAC,MMF)	319 (2.1)
CSA + other(s) (except PtCy,TAC,MMF,MTX)	10 (0.1)
CSA alone	33 (0.2)
Other(s)	155 (1.0)
Not Reported	2 (0.0)
Conditioning regimen - no. (%)	
MAC	7634 (51.0)
RIC/NST	7306 (48.8)
Not Reported	22 (0.1)
Donor type - no. (%)	
HLA-identical sibling	3598 (24.0)
Other related	2807 (18.8)
Multi-donor	11 (0.1)
Unrelated (matching TBD)	7781 (52.0)
Cord blood	765 (5.1)
Time from diagnosis to transplant, months - no. (%)	
<3	1473 (9.8)
3-5	7819 (52.3)
6-8	2445 (16.3)
9-11	840 (5.6)
>12	2385 (15.9)
Year of transplant - no. (%)	
2015	2330 (15.6)
2016	2407 (16.1)
2017	2395 (16.0)
2018	2647 (17.7)
2019	2651 (17.7)
2020	2532 (16.9)
Follow-up of survivors, months - median (range)	49.1 (2.3-2199.5)

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