Not for publication or presentation

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR HEALTH SERVICES AND INTERNATIONAL STUDIES
Salt Lake City, UT
Saturday, April 23, 2022, 12:15 – 1:45 PM MDT

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1. **Introduction**
   a. *Minutes and Overview Plan from April 2022 meeting (Attachment 1)*
   b. *Instructions for sign-in and voting*

   The meeting was called to order at 1:15 pm by Dr. Shahrukh K. Hashmi. He announced leadership changes welcoming Hemalatha Rangarajan as incoming chair and William Wood as outgoing chair. He described the COI, Working Committees Membership, goals, expectations, and limitations of the committee, and he gave an introduction of the data that are collected in CRF and TED database, sources of cellular therapy data. He also explained the voting process, the role of working committee members, the rules of authorship, and the new collaborative study proposals session. He describes the two abstracts selected at ASH, HS16-01, and HS18-02 as clinically important papers and were already presented at ASH 2021. He encouraged audiences to submit proposals at TCT 2023, also for international research.

   Dr. Wael Saber then gratified Naya for her work and welcomed Jinal as a new statistician.

2. **Accrual summary** (Attachment 2)
   Due to the full agenda, the accrual summary of registration and research cases between 2008 and 2018 were not presented to the committee but were available as part of the Working Committee attachments.

3. **Presentations, published or submitted papers**

The progress of the ongoing studies during the past year were presented.

a. **HS16-01:** Trends in Volume and Outcomes of Autologous and Allogeneic Hematopoietic Cell Transplantation in Racial/Ethnic Minorities (Nandita Khera)**. *Analysis.***

b. **SC21-02:** Impact of Center Specific Analysis (CSA) on HCT Center Volumes (Akshay Sharma/Brent Logan/Leslie E Lehmann/ Hemalatha G Rangarajan/ Jaime Preussler/ Jesse D Troy/ Luke P Akard/ Neel S Bhatt/ Tony H Truong/ Willliam A Wood/ W Saber)**. Manuscript preparation.**

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

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). ***Analysis.***

b. **HS16-03** Relationship of Race/Ethnicity and Survival after Single and Double Umbilical Cord Blood Transplantation (K Ballen). ***Analysis.***

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). ***Analysis.***

d. **HS18-02:** Racial differences in long term survivor outcomes after allogeneic transplants (B Blue/ N Majhail). ***Manuscript preparation.***

e. **HS18-03:** Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia.

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

g. **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.***

h. **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). ***Data file preparation.***

i. **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). **Protocol development.**

5. Future/proposed studies

Dr. Leslie Lehmann and Dr. William A. Wood led this section.

a. **PROP 2109-18:** Health Care Utilization and costs of haploidentical allogeneic stem cell transplants in a contemporary cohort of pediatric patients with acute leukemia and myelodysplastic syndrome. (Hema Rangarajan/ Prakash Satwani) (Attachment 4)

Dr. Rangarajan presented this study. The specific aims of this study are two-fold: 1. Determine cost & HCU associated with HaploHCT (PTCY +_ Ex-vivo) for pediatric patients (<=21 years) with acute leukemia (ALL, AML) and MDS from 2010-2020. 2. Compare costs & HCU HaploHCT with that of MSD, MUD, MMURD and UCB. If feasible compare costs & HCU: T replete (PTCY) vs T deplete (Ex-Vivo) approaches. Comments received on the inclusion criteria and how much proportion would be in PHIS. Dr. Rangarajan said that she would like to add data after 2019 and added that all the centers were in PHIS as its PHIS restricted and it would be US based. One participant asked if the cost before transplant is available in PHIS. Dr. Rangarajan replied these data were not available. A brief explanation of what is PHIS by Dr. Rangarajan. Graft equitation as a limitation of the study stated by Dr. Rangarajan.

b. **PROP 2110-28:** Utilization of chimeric antigen receptor (CAR) T-cells differs by race and ethnicity compared to autologous hematopoietic cell transplant (autoHCT) for NHL (Megan Herr/ Christine Ho/ Theresa Hahn) (Attachment 5)

Dr. Herr presented this study. The specific aims of this study are two folds: 1. Compare the proportion of race and ethnicity for first autoHCT vs first CAR T. 2. Describe therapy choices after a failed autologous HCT for NHL by race and ethnicity (including 2nd autoHCT, 1st allHCT, CAR T-cell, other, and no therapy). Comment received on restriction of population selection to the centers that perform the procedure and Dr. Herr responded that it would be restricted and also mentioned about considering the factor, how this patient is being treated as insurance coverage (Medicare, Medicaid). Study would focus only on US or US vs other country as sensitive analysis. Enough power considering the small sample size. One of the meeting participants noted concern that if the CIBMTR best database to answer the question and Dr. Herr said it is the best as CIBMTR have access to CAR-T follow up data.

c. **PROP 2110-164:** Changes in international Hematopoietic Cell Transplantation (HCT) Practices since publication of "Choosing Wisely BMT". (Matthew Seftel /Sita Bhella) (Attachment 6)

Dr. Seftel presented this study. The specific aims of this study are three-fold: 1. To measure BM vs. PBSC for MUD HCT after MA conditioning in pts with hematological malignancies. 2. To measure BM vs. PBSC for HCT in pts with aplastic anemia. 3. To measure Single vs. Double cord blood units for cord blood transplantation (CBT). Comments received on the definition on number of cord blood as adequate dose. Dr. Seftel said they are looking for cell doses reported in the data to decide if it was chosen wisely or not and added that size of cord blood availability should not be changed in pre and post years. One of the meeting participants noted concern that confounding factors can be center effect, covid. Dr. Seftel said to overcome the effect we would select the population broadly and considering covid impact there would data for 2 calendar years or do a sensitivity analysis to see drop after March.

d. **PROP 2110-229:** The Impact of Ethnicity, Race, and Socio-Economic Status (SES) in Mismatched Unrelated Donor (MMUD) Allogeneic Hematopoietic Cell Transplantation (HCT). (Trent Wang / Antonio Jimenez) (Attachment 7)

Dr. Wang presented this study. The specific aims of this study are three-fold: 1. To describe the racial/ethnic and SES composition of MMUD recipients. 2. To compare MMUD HCT outcomes among recipients of varying backgrounds in ethnicity/race and SES. 3. To evaluate the impact of GVHD prophylaxis regimes relative to ethnicity/race and SES. Comments were received on mismatched unrelated donor utilization has gone down significantly so if that would have impact on long term results of study. Meeting participants expressed concern regarding how much impact this study would have in future and if this is the right time to perform this study or wait for some time to get more data. One meeting participant suggested to breakdown race and ethnicity, Dr.Wang agreed.

e. **PROP 2110-31:** Characterizing differences in the clinical outcomes of and access to commercial CAR T-cells for relapsed/ refractory large B-cell lymphoma, based on patient race/ ethnicity, sex, and socioeconomic status

Dropped proposed studies

a. **PROP 2110-41:** Association of Racial and ethnic disparities and outcomes of acute leukemia patients receiving a haploidentical stem cell transplant. ***Dropped-overlap with recent study.***

b. **PROP 2110-140:** Trend in Survival in Patients Undergoing Allogeneic Hematopoietic Stem Cell Transplantation. ***Dropped overlap with recent study.***

c. **PROP 2110-226:** Comparing demographic characteristics of pediatric and young adult patients receiving cellular therapy versus hematopoietic stem cell transplantation for relapsed/refractory acute lymphoblastic leukemia. ***Dropped-low scientific impact.***

d. **PROP 2110-247:** Characterizing Changes in the Transplant and Cellular Therapy Workforce and Associations with Race-Ethnic Treatment Equity. ***Dropped-supplemental data needed.***

e. **PROP 2110-297:** Evaluation of Allogeneic Hematopoietic Cell Transplantation Outcomes in Underrepresented Minorities in the Era of Haploidentical Donor Transplant with Post-Transplant Cyclophosphamide. ***Dropped-overlap with recent study.***

6. CIBMTR strategic initiative: Fostering international collaboration

7. Other Business

Working Committee Overview Plan for 2022-2023

Study Number and Title	Current Status	Chairs Priority
HS16-01: Trends in utilization and outcomes of autologous and allogeneic hematopoietic cell transplantation in racial and ethnic minorities	Datafile preparation	2
HS16-03: Relationship of race/ethnicity and survival after single and double umbilical cord blood transplantation	Manuscript preparation	2
HS18-01: International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens	Manuscript preparation	2
HS18-02: Racial differences in long term survivor outcomes after Allogeneic hematopoietic cell transplantation	Manuscript preparation	2
HS18-03: Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia	Deferred	3
HS19-01: Factors associated with clinical trial participation among HSCT patients: a CIBMTR Analysis	Protocol Development	4
HS19-03: Haploidentical stem cell transplantation for malignant and non-malignant hematological diseases in patients without sibling donor: a multicenter prospective longitudinal study of the Brazilian bone marrow transplantation study group.	Data collection	4
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)	Datafile preparation	4
HS20-01: Resource Intensity of end-of-life care in children after hematopoietic stem cell transplant for acute leukemia: Rates and disparities	Protocol pending	4

Working Assignments Assignments for Working Committee Leadership (May 2022)

Leslie Lehmann	**HS16-01:** Trends in utilization and outcomes of autologous and allogeneic hematopoietic cell transplantation in racial and ethnic minorities
	HS20-01: Resource Intensity of end-of-life care in children after hematopoietic stem cell transplant for acute leukemia: Rates and disparities
Hemalatha Rangarajan	**HS16-03:** Relationship of race/ethnicity and survival after single and double umbilical cord blood transplantation
	HS19-01: Factors associated with clinical trial participation among HSCT patients: a CIBMTR Analysis
Shahrukh Hashmi	**HS18-01:** International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens
	HS18-02: Racial differences in long term survivor outcomes after Allogeneic hematopoietic cell transplantation
	HS18-03: Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia
	HS19-03: Haploidentical stem cell transplantation for malignant and non-malignant hematological diseases in patients without sibling donor: a multicenter prospective longitudinal study of the Brazilian bone marrow transplantation study group
	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)