



## MINUTES AND OVERVIEW PLAN

### CIBMTR WORKING COMMITTEE FOR HEALTH SERVICES AND INTERNATIONAL STUDIES

Orlando, FL

Saturday, February 22, 2020, 12:15 – 2:15 PM

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#### 1. Introduction

- a. Minutes and Overview Plan from February 2019 meeting (Attachment 1)
- b. Instructions for sign-in and voting

The meeting was called to order at 12:15 pm by Dr. Nandita Khera. Dr. Khera announced that Dr. Leslie Lehmann has been appointed as the co-Chair of the Health Service and International Studies Working Committee starting March 1st. Meanwhile Dr. Khera will be completing her 5-year term as co-Chair at the end of this month. On behalf of the committee, Dr. Saber thanked Dr. Khera for her leadership and service to the committee.

Then Dr. Khera described the goals, expectations, and limitations of the committee, and she gave an introduction of the data that are collected in CRF and TED database. She also explained the voting process, role of working committee members, rules of authorship and statistical hour allocation, and importance of the conference evaluations.

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

Dr. William A. Wood lead this section. Due to the full agenda, the accrual summary of registration and research cases between 2008 and 2019 were not presented to the committee but were available as part of the Working Committee attachments.

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

- a. **HS12-02** K Paulson, R Brazauskas, N Khera, N He, N Majhail, G Akpek, M Aljurf, D Buchbinder, L Burns, S Beattie, C Freytes, A Garcia, J Gajewski, T Hahn, J Knight, C LeMaistre, H Lazarus, D Szwajcer, M Seftel, B Wirk, W Wood, W Saber. Inferior Access to Allogeneic Transplant in Disadvantaged Populations: A CIBMTR Analysis. **Biology of Blood and Marrow Transplantation. 2019, June. DOI:10.1016/j.bbmt.2019.06.012**

- b. **HS14-01** S D. Arnold, R Brazauskas, N He, Y Li, M Hall, Y Atsuta, J Dalal, T Hahn, N Khera, C Bonfim, S Hashmi, S Parsons, W A. Wood, A Steinberg, C O. Freytes, C Dandoy, D I. Marks, H M. Lazarus, H Abdel-Azim, M Bitan, M Angel Diaz, R F. Olsson, U Gergis, A Seber, B Wirk, C. F LeMaistre, C Ustun, C Duncan, D Rizzieri, D Szwajcer, F Fagioli, H A. Frangoul, J M. Knight, P Mehta, R Schears, P Satwani, M Pulsipher, R Aplenc, W Saber The impact of donor type on outcomes and cost of allogeneic hematopoietic cell transplant for pediatric leukemia: a merged CIBMTR and PHIS analysis. **Submitted**
- c. **HS15-01** D Buchbinder, R Brazauskas, K Bo-Subait, K Ballen, S Parsons, T John, T Hahn, A Sharma, A Steinberg, A J. Kumar, A Yoshimi, B Wirk, B Shaw, C Freytes, C LeMaistre, C Bredeson, C Dandoy, D Almaguer, D I. Marks, D Szwajcer, G Hale, H Schouten, H Hashem, H Schoemans, H S. Murthy, H M. Lazarus, J Cerny, J Tay, J A. Yared, K Adekola, K R. Schultz, L Lehmann, L Burns, M Aljurf, M A Diaz, N Majhail, N Farhadfar, R Kamble, R Olsson, R Schears, S Seo, S Beattie, S Chhabra, B N. Savani, S Badawy, S Ganguly, S Ciurea, S Marino, U Gergis, Y Kuwatsuka, Y Inamoto, N Khera, S Hashmi, W Wood, W Saber. Predictors of Loss to Follow-Up Among Pediatric and Adult Hematopoietic Cell Transplantation Survivors: A Report from the Center for International Blood and Marrow Transplant Research. **Biology of Blood and Marrow Transplantation. 2019, November. doi: 10.1016/j.bbmt.2019.11.003.**
- d. **HS16-02** J Tay, R Brazauskas, N He, S Beattie, C Bredeson, J Dalal, S K. Hashmi, T E. Hahn, N Khera, W A. Wood, W Saber, et al. Pre-transplant Marital status and Hematopoietic Cell Transplantation Outcomes. **Submitted**
- e. **HS17-01** S Hong, R Brazauskas, K H. Herbert, S Ganguly, H Abdel-Azim, M Angel Diaz, S Beattie, S O. Ciurea, D Szwajcer, S M. Badawy, A A. Gratwohl, C LeMaistre, M D. S. M. Aljurf, R F. Olsson, N S. Bhatt, N Farhadfar, J A. Yared, A Yoshimi-Nöllke, S Seo, U Gergis, N Khera, S Hashmi, A M. Beitinjaneh, B Shaw, W Wood, T Hahn, S J. Lee, J. D Rizzo, N S. Majhail, W Saber. Community Health Status and Outcomes after Allogeneic Hematopoietic Cell Transplantation in the United States. **Submitted**

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

- a. **HS15-02** Impact of socioeconomic status on pediatric stem cell transplant outcomes (K Bona/ J Wolfe/ C Duncan/ L Lehmann) **Manuscript preparation**
- b. **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) **Protocol Development**
- c. **HS16-03** Relationship of Race/Ethnicity and Survival after Single and Double Umbilical Cord Blood Transplantation (K Ballen) **Protocol Development**
- d. **HS18-01** International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens (Y Arai/ Y Atsuta/ S Yano) **Protocol Development**
- e. **HS18-02** Racial differences in long term survivor outcomes after allogeneic transplants (B Blue/ N Majhail) **Protocol Development**
- f. **HS18-03** Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia (L Winestone/ R Aplenc/ K Getz) **Protocol Development**

#### 5. Future/proposed studies

- a. **PROP 1903-01** Access to Hematopoietic Stem Cell Transplantation in Pediatric Patients with Acute Lymphoblastic Leukemia and Acute Myeloid Leukemia (Tony H. Truong/ Wael Saber) (Attachment 4)

Dr. Truong presented this proposal. The specific aims of the study are to determine the prevalence of pediatric ALL and AML using SEER data and determine the transplant rate within the CIBMTR and evaluate factors that are associated with the likelihood of receiving HSCT. Dr. Truong explained he will use SEER data base to find out patients with indications for transplant then match the data with CIBMTR to identify people who received transplant. Regarding one question from meeting participant that if CIBMTR or SEERS has data on chemotherapy before they received transplant, Dr. Truong said this is one limitation for the registry studies. Dr. Khera also added that CIBMTR has lines of treatment for pre transplant but doesn't have very detailed data. One meeting participant pointed out that the SEER data base only covers 20% of the US population, Dr. Truong said this is also another limitation of the study. Regarding center effect, Dr. Truong explained he will look at the region difference, donor availability based on family size and the access to transplant rate among CAR. T cell centers and non-CAR.T cell centers.

- b. **PROP 1911-79** Resource Intensity of End-of-Life Care in Children After Hematopoietic Stem Cell Transplant for Acute Leukemia: Rates and Disparities (Emily E Johnston / Caitlin W. Elgarten / Lena Winestone/ Richard Aplenc) (Attachment 5)

Dr. Johnston presented this proposal. The specific aims of the study are three-fold: 1. Describe the resource utilization during the 30 days before death. 2. Determine the prevalence of patients with a resource intense phenotype in the last 30 days of life. 3. Determine the clinical and sociodemographic characteristics associated with a resource intense phenotype. Regarding discharge disposition code in PHIS data base, Dr. Johnston said in PHIS it's not very actually used but she will check it. In responding a participant questioning if PHIS data base has the date of cost to use for predicting mortality, Dr. Johnston explained that this study is not interested in prediction of mortality but tease out disparities in health care utilization. Dr. Saber added that the cost data in PHIS is reported by date. Regarding the differential utilization on relapse, Dr. Johnston said patient will be coded as relapse or no relapse for model building.

This proposal was accepted by the working committee and leadership, will be HS20-01.

- c. **PROP 1911-160** Predictors of Cost of Initial Hospitalization for Pediatric Allogeneic Hematopoietic Cell Transplantation. (Hemalatha Rangarajan / Prakash Satwani) (Attachment 6)

Dr. Rangarajan presented this proposal. The specific aims of the study are two-fold: 1. To determine the cost associated with first admission for children undergoing allogeneic HCT for malignant and non-malignant diseases from 2010-2019. 2. To validate and test a predictive model of cost for the transplant admission for patients  $\leq 21$  years of age undergoing allogeneic HCT for malignant and non-malignant disease. Dr. Wood suggested to test center effect in the model. Dr. Rizzo questioned why only looking at index of admission rather than certain period time to build a more robust model, Dr. Satwani said it's a good idea but the challenge in real world is the they don't know the transplant rate for each center. But this study could provide data to educate people whether to get transplant. Dr. Saber questioned the risk factors in the model for predicting cost, Dr. Rangarajan explained she will use post-transplant variables such as GVHD. Dr. Khera suggested to look at the cost distribution after building the model, examine the 10% of outliers then define that as cut off for the cost.

- d. **PROP 1911-215** Access to Allogeneic Hematopoietic Cell Transplant in the United States After Implementation of the Affordable Care Act (Neel S Bhatt/ Aks' cdhay Sharma/ Navneet Majhail/ Theresa Hahn) (Attachment 7)

Dr. Bhatt presented this proposal. The specific aims of the study are two-fold: 1. To assess the association between ACA Medicaid expansion and the rate of allogeneic HCT in females, racial

and ethnic minority populations and those living in high poverty areas. 2. To assess the association between ACA Medicaid expansion and the rates of uninsured patients undergoing allogeneic HCT. Dr. Khera questioned how to address other factors could influence the rate of transplant, Dr. Bhatt explained this is the limitation of the study and he can't address it yet. In response to the question that if the rate of renal transplant increased after implementation of the ACA, Dr. Bhatt replied he has looked at the oncology literature which shows transplant rate was increased but need to check solid organ transplant literature. Regarding how to catch patients diagnosed with cancer but didn't go to transplant, Dr. Bhatt replied he did think about using SEER data base before. Since SEER data base only cover 20% of US population until 2016 in some certain states so he did not use it at last. Dr. Brazauskas commented regardless policy changing, the rate of transplant keep going up. One meeting participant suggested that he can look at the population of the state as substitute data.

- e. **PROP 1911-253** Impact of seasons on outcomes of allogeneic hematopoietic cell transplantation (HCT) in North America (Pierre Teira) (Attachment 8)  
Dr. Teira presented this proposal. The specific aim of the study is to assess the impact of the season where the HSCT is done on cumulative incidence of Relapse, aGVHD, cGVHD, NRM, EFS and OS in HSCT in North America. Dr. Truong questioned how to identify the infection was due to seasonal virus or other virus, Dr. Teira said he doesn't have the data for this. Dr. Phelan suggested to look at non-malignant patients since hospitals do the transplant in summer on purpose to avoid viral infection. Dr. Rizzo questioned how to use the result, DR. Teira replied it depends on what he finds in the outcome and it may be used for guidelines.
- f. **PROP 1911-265** Assessing Top Barriers to Participate in Transplant Clinical Trials for Multiple Myeloma Patients (Ehsan Malek/ Leland Metheny) (Attachment 9)  
Dr. Metheny presented this proposal. The specific aims of the study are three-fold: 1. To assess the difference in age, renal function, performance status, socioeconomic characteristics between enrolled patients on STAMINA trial and patients in CIBMTR registry. 2. To determine the percentage of patients in the CIBMTR registry who do not meet eligibility criteria for BMT CTN 0702. 3. To assess the significance of each eligibility criteria in leading to potential exclusion to BMT CTN 0702. Dr. Saber commented the CIBMTR population are not general oncology patients but patients who passed the transplant screening tests and underwent transplants and there are other factors that center could not directly control for patients to enroll into a clinical trial. Dr. Khera suggested to include all clinical trials done for multiple myeloma and compare to the whole autologous transplant patients.
- g. **PROP 1912-06** Understanding the costs of cellular immunotherapy for cancer (Doug Rizzo) (Attachment 10)  
Dr. Rizzo presented this proposal. The specific aims of the study are four-fold: 1. Describe costs of care within 100d of cellular immunotherapy. 2. Evaluate patient, disease and transplant characteristics that affect costs of care. 3. Determine how post transplant complications, including CRS and ICANS impact costs of care. 4. Describe site of infusion (IP or OP) and impact on costs of care. Comments received on how to get centers' engagement. Dr. Rizzo also expressed the concerns of reliability of the billing from centers. Meeting participants also suggested to collaborate with Cellular Immunotherapy for Cancer committee since they received a similar proposal, Dr. Rizzo replied happy to collaborate.

## 6. Dropped proposed studies

- a. **PROP 1911-97** Evaluating the effect of delay in allogeneic stem cell transplantation due to donor unavailability on recipient stem cell transplantation outcomes. *Dropped due to feasibility and small sample size.*

**7. Study Presentation**

1. HS15-02 Analysis result update (K Bona)

Dr. Duncan briefly updated the committee on analysis result of the study. Meeting participants suggested that Dr. Duncan could look at the cause of death for the study population and Dr. Duncan agreed. Dr. Duncan explained that 20% cut off for poverty level is based on the poverty level that people who can get support for national poverty level and there are also different ways to look at it.

**Working Committee Overview Plan for 2020-2021**

Study number and title	Current status	Goal with date	Total hours to complete	Total hours to goal	Hours allocated to 6/30/2020	Hours allocated 7/1/2020-6/30/2021	Total Hours allocated
<b>HS14-01:</b> Investigating clinical outcomes and inpatient health care resource utilization of hematopoietic cell transplantation for children with acute leukemia	Submitted	Published – July 2021	10	10	10	0	10
<b>HS15-02:</b> Impact of Socioeconomic Status on Pediatric Stem Cell Transplant Outcomes	Submitted	Published – July 2021	20	20	10	10	20
<b>HS16-01:</b> Trends in Utilization and Outcomes of Autologous and Allogeneic Hematopoietic Cell Transplantation in Racial and Ethnic Minorities	Protocol Development	Submitted – July 2021	280	280	210	70	280
<b>HS16-02:</b> The Impact of Marital Status on Hematopoietic Stem Cell Transplant Recipient Outcomes: A surrogate for consistent caregiver	Submitted	Published – July 2020	10	10	10	0	10
<b>HS16-03:</b> Relationship of Race/Ethnicity and Survival after Single and Double Umbilical Cord Blood Transplantation	Protocol Development	Submitted – July 2021	250	250	180	70	250
<b>HS17-01:</b> Association of community health status and center survival for allogeneic hematopoietic cell transplantation	Submitted	Published – July 2020	10	10	10	0	10
<b>HS18-01:</b> International collaborative study to compare the prognosis for acute leukemia patients transplanted with intensified myeloablative regimens	Protocol Development	Submitted – July 2021	310	310	240	70	310
<b>HS18-02:</b> Racial differences in long term survivor outcomes after Allogeneic hematopoietic cell transplantation	Protocol Development	Manuscript Preparation – July 2021	310	240	100	140	240

<b>HS18-03:</b> Racial/ethnic disparities in receipt of hematopoietic cell transplantation and subsequent resource utilization in children with acute leukemia	Protocol Development	Analysis – July 2021	310	180	100	80	180
<b>HS19-01:</b> Factors associated with clinical trial participation among HSCT patients: a CIBMTR Analysis	Protocol Development	Manuscript Preparation – July 2021	330	260	0	260	260
<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	Data File Preparation – July 2021	330	100	0	100	100

<b>Oversight Assignments for Working Committee Leadership (March 2020)</b>	
William Wood	<b>HS14-01:</b> Investigating clinical outcomes and inpatient health care resource utilization of hematopoietic cell transplantation for children with acute leukemia
	<b>HS15-02:</b> Impact of Socioeconomic Status on Pediatric Stem Cell Transplant Outcomes
	<b>HS16-03:</b> Relationship of race/ethnicity and survival after single and double umbilical cord blood transplantation
	<b>HS17-01:</b> Association of community health status and center survival for allogeneic hematopoietic cell transplantation
	<b>HS19-01:</b> Factors associated with clinical trial participation among HSCT patients: a CIBMTR Analysis
Leslie Lehmann	<b>HS16-01:</b> Trends in utilization and outcomes of autologous and allogeneic hematopoietic cell transplantation in racial and ethnic minorities
	<b>HS16-02:</b> The impact of marital status on hematopoietic stem cell transplant recipient outcomes: a surrogate for consistent caregiver
	<b>HS20-01:</b> Resource Intensity of End-of-Life Care in children after hematopoietic stem cell transplant for Acute Leukemia: rates and disparities
Shahrukh Hashmi	<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