Not for publication or presentation

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR MORBIDITY, RECOVERY, AND SURVIVORSHIP
San Antonio, TX
Friday, February 23, 2024, 1:00 – 3:00 PM CT

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1. Introduction

a. Minutes and Overview Plan from February 2023 meeting

The CIBMTR Morbidity Recovery and Survivorship Working Committee (MRSWC) meeting was called to order at 1:00 CT on Friday, February 23, 2024 by Dr. Bipin Savani. He began by welcoming all the in-person and virtual attendees and providing the CIBMTR's Industry Funding Disclosure. Then, he introduced all the committee's leadership listed above, including Dr. Michelle Schoettler as our Working Committee Training and Leadership representative, Rebecca Higgins and Brandon Nuechterlein as our CAC representatives, and Dr. Amy Moskop (Co-Scientific Director) and Dr. Sairah Ahmed (Chair) joining us from the Cellular Immunotherapy WC. After reviewing the committee's COI disclosures, Dr. Savani explained that everyone attending this session has

been added to MRSWC membership! If you are unable to participate in a research study this year, we invite you to utilize the publicly available datasets on our website (cibmtr.org/datasets).

Dr. Hélène Schoemans then explained the scoring process for the proposals on a 1-9 (highest to lowest) scale based on scientific impact. Each presentation will be about 5 minutes with a 5-minute Q&A. We hope to select studies moving forward in one month. If your study is selected, anyone is welcome to have authorship given that they provide contributions to every stage of the study's lifecycle. Dr. Schoemans then explained our Transplant Essential Data (TED), which all patients contribute to, and our Comprehensive Report Forms, which only a subset of patients receives to contribute to more in-depth transplant research. Cellular therapy patients receive a different set of forms. CIBMTR has also begun collecting Patient-Reported Outcome (PRO) data across different physical, mental, and social health topics. For investigators that are early in your career, we invite you to participate in our WC's Training and Leadership Program, which will get you more involved in our committee's activities and statistical meetings.

2. Accrual Summary

3. Presentations, published or submitted papers

Dr. Rachel Phelan then introduced the studies in progress. Currently, we have 5 in protocol development, 5 in data file preparation, 1 in analysis, 4 in manuscript preparation, and 1 waiting to be published. She then gave a brief synopsis of each of these studies and their stage in the process.

a. **RT18-01a:** Broglie L, Friend BD, Chhabra S, Logan BR, Bupp C, Schiller G, Savani BN, Stadtmauer E, Abraham AA, Aljurf M, Badawy SM, Perez MAD, Guinan EC, Hashem H, Krem MM, Lazarus HM, Rotz SJ, Wirk B, Yared JA, Pasquini M, Thakar MS, Sorror ML. Expanded HCT-CI definitions capture comorbidity better for younger patients of allogeneic HCT for nonmalignant diseases. ***Transplantation and Cellular Therapy. 2023 Feb 1; 29(2):125.e1-125.e9. doi:10.1016/j.jtct.2022.11.020. Epub 2022 Nov 25. PMC9911359.***

b. **RT18-01b:** Friend BD, Broglie L, Logan BR, Chhabra S, Bupp C, Schiller G, Beitinjaneh A, Perez MAD, Guilcher G, Hashem H, Hildebrandt GC, Krem MM, Lazarus HM, Nishihori T, Nusrat R, Rotz SJ, Wirk B, Wieduwilt M, Pasquini M, Savani BN, Stadtmauer EA, Sorror ML, Thakar MS. Adapting the HCT-CI definitions for children, adolescents, and young adults with hematologic malignancies undergoing allogeneic hematopoietic cell transplantation. ***Transplantation and Cellular Therapy. 2023 Feb 1; 29(2):123.e1-123.e10. doi:10.1016/j.jtct.2022.11.019. Epub 2022 Nov 26. PMC9911376.***

c. **LE19-01a:** Zinter M, Brazauskas R, Strom J, Chen S, Bo-Subait S, Sharma A, Beitinjaneh A, Dimitrova D, Guilcher G, Preussler J, Myers K, Bhatt N, Ringden O, Hematti P, Hayashi R, Patel S, De Oliveira S, Rotz S, Badawy S, Nishihori T, Buchbinder D, Hamilton B, Savani B, Schoemans H, Sorror M, Winestone L, Duncan C, Phelan R, Dvorak C. Intensive care risk and long-term outcomes in pediatric allogeneic hematopoietic cell transplant recipients. ***Blood Advances. doi:10.1182/bloodadvances.2023011002. Epub 2023 Dec 21.***

d. **LE20-02:** Taylor MR, Cole SW, Strom J, Brazauskas R, Baker KS, Phelan R, Buchbinder D, Hamilton B, Schoemans H, Shaw BE, Sharma A, Bhatt NS, Badawy SM, Winestone LE, Preussler JM, Mayo S, Jamani K, Nishihori T, Lee MA, Knight JM. Unfavorable transcriptome profiles and social disadvantage in hematopoietic cell transplantation: A CIBMTR analysis. ***Blood Advances. 2023 Nov 28; 7(22):6830-6838. doi:10.1182/bloodadvances.2023010746. Epub 2023 Sep 29.***

e. **LE16-02b** Late effects after AlloHCT for pediatric patients with non-malignant diseases. (J Kahn/ P Satwani) ***Submitted.***

4. Studies in progress

a. **LE12-03a:** Outcomes for patients undergoing hematopoietic cell transplantation followed by solid organ transplants (M Gupta/ PL Abt/ M Levine) **Manuscript Preparation.**
b. **LE12-03b:** Outcomes for patients undergoing solid organ transplants followed by hematopoietic cell transplantation (M Gupta/ PL Abt/ M Levine) **Manuscript Preparation.**
c. **LE17-01a:** Late effects after hematopoietic stem cell transplantation for sickle cell disease. (E Stenger/ R Phelan/ S Shenoy/ L Krishnamurti) **Manuscript Preparation.**
d. **LE17-01b:** Comparison of survival between transplanted and non-transplanted SCD patients. (E Stenger/ R Phelan/ S Shenoy/ L Krishnamurti) **Data File Preparation.**
e. **LE18-01:** Trends in late mortality amongst two-year survivors of pediatric allogeneic hematopoietic cell transplantation for hematologic malignancies. (L Broglie/ P Satwani) **Manuscript Preparation.**
f. **LE19-01b:** POP TA-DAH! - Predictors of Pediatric Transplant Associated Diffuse Alveolar Hemorrhage (M Zinter/ C Dvorak/ C Duncan) **Data File preparation.**
g. **LE19-02:** Incidence and predictors of long-term toxicities and late side effects in elderly patients (≥60 years) receiving allogeneic hematopoietic cell transplantation for hematological malignancies. (M Veeraputhiran/ S Pingali/ A Mukherjee/ L Muffly) **Analysis.**
h. **LE20-01:** Cardiometabolic risk after total body irradiation during childhood. (D Novetsky Friedman/ E Chow) **Protocol Development.**
i. **LE21-01:** Risk of subsequent neoplasms in patients with post-transplant cyclophosphamide use for graft-versus-host disease prophylaxis. (A Tomas/ I Muhsen/ L Yanez San Segundo/ S K. Hashmi/ M- Angel Perales/ A Kansagra) **Data File Preparation.**
j. **RT19-01:** Analysis of comorbidity-associated toxicity at a regimen-based level (R Shouval/ B Savani/ A Nagler) **Data File Preparation.**
k. **RT19-02:** Hemorrhagic cystitis as a complication of hematopoietic stem cell transplantation in the post-transplant cyclophosphamide graft-versus-host disease prophylaxis era compared to other allogeneic stem cell transplants (K Adekola/ N Ali/ O Frankfurt/ L Metheny/ J Moreira/ M de Lima) **Protocol Development.**
l. **RT20-01:** Toxicities of older adults receiving allogeneic hematopoietic cell transplant compared to younger patients (R Jayani/ H Murff) **Data File Preparation.**
m. **MRS22-01:** Racial/ethnic disparities and role of poverty in long-term health outcomes among survivors of allogeneic hematopoietic cell transplant performed in childhood (N Bhatt/ A Sharma/ C Duncan/ L Jimenez-Kurlander) **Protocol Development.**
n. **MRS22-02:** Post-transplant cyclophosphamide related cardiomyopathy; incidence, risk factors and outcome: A retrospective review from CIBMTR database (K Poonsombudlert/ C Strouse) **Protocol Development.**
o. **MRS23-01:** Updated Analysis of Long-Term Survival and Late Deaths after Allogeneic Hematopoietic Cell Transplantation for Hematologic Malignancies and Severe Aplastic Anemia (U Rao/ M Battiwalla) **Protocol Pending.**

5. Future/Proposed Studies

a. **PROP 2305-05/2310-55:** Defibrotide prophylaxis for hepatic sinusoidal obstructive syndrome in hematopoietic cellular therapy recipients: real-world outcomes and health care utilization implications (M Pamukcuoglu/ M Schoettler/ K Williams)

Dr. Betty Hamilton introduced Dr. Michelle Schoettler. This proposal is a case-control study with a pediatric and adult arm. The primary aim is to determine the difference in cumulative incidence of severe SOS in patients who received defibrotide prophylaxis for SOS vs. a matched cohort who did not receive defibrotide prophylaxis. This will be done for both the pediatric and adult arms separately. CIBMTR identified 215 adult patients with defibrotide prophylaxis and 86539 patients without that are eligible for the study in the TED retrieval (2009-2020). CIBMTR also identified 517 pediatric patients with defibrotide prophylaxis and 11788 without defibrotide prophylaxis that are eligible.

After the presentation, Dr. Phelan clarified that we hope to have more data available up until the present day as we continue to update our new database (HCT Essentials).

The first question from the audience noted that there is an increase in the utilization of defibrotide prophylaxis after 2015. This makes sense since defibrotide was approved by the FDA in March 2016. He was wondering if it would be worth amending the proposal to start at the FDA approval date instead of 2019. Dr. Schoettler said that they would use the timepoint in which they received defibrotide prophylaxis.

The second question noted that there may be a bit of bias in matching the patients across centers; they should figure out if the centers have set some scoring criteria to select defibrotide prophylaxis or classify VOD. Dr. Schoettler said that the study is limited by what is reported for SOS to the CIBMTR. In terms of severity, they can pull data from the forms and PHIS to collect data on renal failure.

The next question asked how the older patients at transplant in the pediatric group will be classified once they reach 18 years of age. They will need to look closer at the distribution of ages if the study progresses. It may be a good idea to combine the pediatric and adult cohorts together to avoid the center bias.

The fourth question asked if the PIs would compare defibrotide to those that did not receive prophylaxis or those that received a different type of prophylaxis. Dr. Schoettler said there should exist data on how other prophylaxis types perform. The intention is that the cohorts will be whether you got defibrotide, regardless of other prophylaxis.

The last question noted that there is a higher frequency of VOD on the prophylaxis arm. Since patients that got defibrotide may be a higher risk of VOD, they may need to take this into consideration as a confounder. They may do propensity score matching to address this. Also, it was asked if we have data on the dose of defibrotide or when it was stopped, which we do not.

b. **PROP 2310-28:** Toxicity profile and survival of patients with BMI >30 undergoing allogeneic stem cell transplantation (N Tijaro Ovalle/ A Jakubowski)

Dr. Hamilton introduced Dr. Natalia Tijaro Ovalle, who gave a virtual presentation. The primary aim of this proposal is to determine if increasing obesity impacts post-transplant toxicities in allogeneic transplant patients. Among the adult first allo-HCT patients for AML and MDS/MPN, CIBMTR identified 9887 eligible patients with BMI 25-29, 7174 patients with BMI 30-39, and 1226 patients with BMI 40+ from the CRF retrieval (2000-2020).

The first question noted that this study will have a lot of value in the BMI 40+ group. He asked if it would be reasonable to even further subdivide the BMI 40+ group. Dr. Tijaro Ovalle said that it would be interesting to look into these BMIs further and see if this is a possibility.

The second question asked if we have information on if the chemotherapy was adjusted and how much it was adjusted. Sometimes (especially with very high BMIS), physicians will make up a little more adjustment or not be sure what to do. She said that it will be very important for toxicity and relapse risk. Dr. Tijaro Ovalle replied that the old version of the 2000 form does ask about dose adjustments by weight. However, there are other ways to infer if there is any adjustment since we know the weight at transplant. She has reached out to Andy Peterson (Statistician for MRS) and confirmed that we can calculate adjusted weights in the SAS code.

The last question recommended looking at the cell dose because there is a discrepancy between the weight of the donor and the patient. Dr. Tijaro Ovalle said that this is something that she plans to include in the multivariate analysis.

c. **PROP 2310-35/2310-210:** Incidence, risk factors, and characteristics of subsequent neoplasms in CAR-T recipients and its impact on survival (M Shah/ V Irizarry Gatell/ R Faramand)

Dr. Hamilton introduced Dr. Vivian Irizarry Gatell. The primary aim of this proposal is to define the incidence, risk factors, and pattern of subsequent neoplasms and second hematological malignancies following CAR-T for adults with NHL or MM. Among the adult CAR-T patients that achieved remission at day 100, CIBMTR identified 3783 patients with NHL and 926 patients with MM that are eligible (This data will become available in 2 years, or with company approval, after the end of the data embargo. With this embargo applied, we currently have 3312 NHL patients and 128 MM/PCD patients eligible).

The first question asked why the PIs selected a landmark of 100 days. Dr. Irizarry Gatell said they want to make sure that they are not capturing patients who relapsed within the first 100 days. In the inclusion criteria, they select patients that achieved complete CR up until day 100. She also asked if we are confident that the cases of NHL and ALL defined as second malignancies are not relapse. Dr. Irizarry Gatell responded that since there are only a couple in which this is the case, they will go back to the path reports to confirm. Dr. Moskop said that some of these path reports have queries out, and some are still under review and actively being updated.

The second question alluded to a publication that came out a day before this meeting. This publication showed a model that is associated with myeloid neoplasms. He asked if there is an added benefit of this study compared to the publication. Dr. Irizarry Gatell added that they are not only looking at myeloid neoplasms, but also other solid tumors. We would hope to characterize T-cell lymphomas as well. He also asked about the baseline features that they want to explore. The PIs are interested in treatment related features, like whether they had a stem cell transplant and other therapies. They are also interested in the amount of inflammation that happens, so it would be good to look at the presence of CRS.

The next question was a suggestion that there may be a benefit to having a control group of patients that did not undergo CAR-T, or perhaps having a cohort of transplant patients. Dr. Irizarry Gatell acknowledged that this is a great suggestion and was initially not included in

case there were not enough patients. However, as they continue to look into the data, this may be a great option.

The last question asked why the PIs decided to exclude pediatric patients. Since they are stratifying by indication for CAR-T, they are unsure if they had enough patients. However, they are very happy to include pediatrics and ALL patients given that they have the numbers to power the analysis.

In the interest of time, we made this the last question for this proposal.

d. **PROP 2310-45:** The impact of obesity and body weight on immune mediated toxicities and outcomes of patients with relapsed/refractory large B cell lymphoma treated with CD19 CAR T cells (K Wudhikarn)

Dr. Hamilton introduced Dr. Kitsada Wudhikarn. The primary aim of this proposal is to explore if obesity affects toxicities and outcomes after CAR-T for large B-cell lymphoma patients. Amongst the adult CAR-T cell patients with large B-cell lymphoma, CIBMTR identified 1495 patients with BMI < 25, 1384 patients with BMI 25-29, and 1169 patients with BMI 30+ that are eligible for this study (This data will become available in 2 years, or with company approval, after the end of the data embargo. With this embargo applied, we currently have 1107 BMI < 25 patients, 1045 BMI 25-29 patients, and 922 BMI 30+ patients eligible).

The first question asked if we plan to stratify by disease burden for comparing outcomes. Dr. Wudhikarn said that this would be a great baseline characteristic for multivariate analysis, but the primary question will have us stratify by BMI.

The second question mentioned that it may be hard to explore interesting aspects of body habitus using CIBMTR data. She noted a paper that looks at visceral fat, which had a different impact compared to BMI. Dr. Wudhikarn notes that this may be a limitation of this study, and perhaps it would be something captured by another study in the future. She also asked why the PIs decided to stratify based on 100 kg. Dr. Wudhikarn said that for certain products, the cell dose has a cap according to the body weight, while other CAR-T products have a total cell dose captured by the form. She also asked if this question could be addressed using the publicly available datasets on the CIBMTR website. Dr. Moskop said that we have several lymphoma studies that are to be completed in the future, with some missing variables like chemo dose.

e. **PROP 2310-53/2310-232:** Impact of renal injury before CAR-T therapy (H Murthy/ M Iqbal/ A Mirza /L Gowda)

Dr. Hamilton introduced Dr. Sayeef Mirza. The primary aim of this proposal is to determine if renal insufficiency can predict an increase in toxicities and inferior survival in patients receiving CAR-T. Among the adult CAR-T patients, CIBMTR identified 296 patients with a renal injury comorbidity (sCR > 2 mg/dL) and 11724 patients without the comorbidity (This data will become available in 2 years, or with company approval, after the end of the data embargo. With this embargo applied, we currently have 8365 patients without renal injury and 146 patients with renal injury eligible).

The first question noted that they may need to tease out that renal insufficiency is part of the disease process for myeloma patients. Dr. Mirza said that it is a good point to study two different groups, lymphoma and myeloma, by nature of the disease. He also asked if it would be more informative to look at post-CAR-T renal injury instead of pre-Car-T renal injury. Dr. Mirza said that it is definitely of interest, and we would like to look at these outcomes.

The second question asked if there is more than just the level of serum creatinine captured in the forms, such as creatinine clearance and eGFR. Dr. Mirza said that this data is collected, but not all of it is reported. The best way to capture all these patients is to use the comorbidity score. They could do this with eGFR, but they would use a smaller subset of patients. Dr. Moskop noted that the eGFR question was recently added and thus has low reporting.

The last question asked why the PIs are using an eGFR cutoff of 60. For instance, fludarabine can be adjusted by over 20%. Some references use a cutoff of 30. Dr. Mirza said that they can look at different benchmarks and would be happy to incorporate suggestions. This eGFR cutoff was discussed amongst the CIBMTR team and would be subject to change as needed. She also asked about capping the serum creatine for the elderly and the type of weight that they use. They are happy to clarify the body weight standard used if the study moves forward.

f. **PROP 2310-128/2310-136/2310-212/2310-245**: Immune effector cell associated HLH-like Syndrome (IEC-HS) in patients undergoing CAR T cell therapy (T Jain/ K McNerney/ J Roman Diaz/ C Freeman/ L Gowda/ A Mirza/ S Gupta/ V Bachanova)

Dr. Hamilton introduced Dr. Tania Jain. The primary aim of this proposal is to describe the real-world incidence and clinical outcomes of IEC-HS in CAR-T patients. Among CAR-T patients, CIBMTR identified 143 patients that reported IEC-HS in follow-up and 8338 patients that did not (This data will become available in 2 years, or with company approval, after the end of the data embargo. With this embargo applied, we currently have 5931 patients without IEC-HS and 93 with IEC-HS eligible).

The first question was a comment that took note on the number of events. Although more may be added at the time of the study, the statistical power may be a concern if they are to do a predictive score and have a training and a validation set.

The second question asked what kind of statistical methods they would use to model the internal and external validation. Dr. Jain said that for the matched cohort, they will probably use propensity score matching. For the validation cohort, perhaps they can explore an external cohort like EBMT.

The last question was another comment that said there are a few working committees that are looking at this disease, such as adult lymphoma and multiple myeloma. However, these studies may not have overlapping patients because they are not all CAR-T.

g. **PROP 2310-160:** Determinants of Immune Effector Cell-Associated Hematotoxicity (ICAHT) following CAR-T therapy across Disease Entities (K Rejeski/ R Shouval)

Dr. Hamilton introduced Dr. Kai Rejeski. The primary aim of this proposal is to identify predictive markers for immune effector cell-associated hematotoxicity (ICAHT) at time of

leukapheresis and lymphodepletion in CAR-T patients. Since there is ongoing work in another committee focused on multiple myeloma, the PIs were encouraged to focus on the lymphoma population. Among the adult patients with B-cell lymphoma, CIBMTR found 8294 patients that are eligible (This data will become available in 2 years (or with company approval) after the end of the data embargo. With this embargo applied, we currently have 7098 patients eligible).

The first question asked if there is any thought in including ALL patients because prolonged cytopenias are a huge problem in this patient population as well. Dr. Rejeski said that it would be interesting to look at this in a subgroup. They were asked to focus on lymphoma due to the overlapping MM study, but it would be very interesting to validate the CAR-HEMATOTOX score and other predictive factors for ALL.

The second question asked if they would account for bridging therapies since they will look at apheresis as our timepoint. Dr. Rejeski said that they would look at both LD and validate the CAR-HEMATOTOX, which would be after bridging. Nonetheless, if they want to collect stem cells for a potential stem cell boost, they will need to do it earlier. It would be good to look at the types of bridging therapies associated with hematological toxicities. Nevertheless, if they want to develop a tool that is helpful at a very early timepoint, going to apheresis is the nature of the game. Dr. Moskop added that the data we collect is pre-LD chemo, and we do have data on bridging therapies.

The last question asked if they know how many patients have all the labs, since it appears that each patient needs all the lab values to calculate the score. Dr. Rejeski responded that they anticipate a CBC that's going to be available in more patients closer to 5000. By doing univariate modeling, they can look at the impact of specific markers. However, to have all 5 markers, the limiting factor is the inflammatory markers (CRP and ferritin). Conservatively, 1,500-1,600 patients would be used to calculate this score and being the largest validation of the score to date.

h. **PROP 2310-173:** Return to work among adolescent and young adult survivors of autologous stem cell transplantation in the US (N Khan)

Dr. Hamilton introduced Dr. Niloufer Khan. The primary aim of this proposal is to determine the incidence and associated factors of not returning to work after autologous transplant. Among autologous transplant patients in the U.S. at ages 18-39 with malignant conditions, CIBMTR found 862 patients that are eligible for this study in the CRF retrieval (2008-2020).

The first question said that he was involved in a prior project with a similar topic. However, since autologous transplants are voluntarily collected, they considered excluding autologous and using allogeneic instead. He also mentioned that there was some missingness in the employment data they used for their project. Thus, the voluntary reporting and missingness may cause a skewed perspective. Also, the employment question was revised in 2021 with more detailed information on employment. Dr. Khan said that this is helpful to know and potentially using the PRO data, specifically financial toxicity, would be a great addition. Although the numbers seem a bit small, these updated questions will contribute to more granular data in the future.

Not for publication or presentation

Proposed studies; not accepted for consideration at this time

a. **PROP 2305-04:** Comparing Icteric Veno-occlusive disease with Anicteric Veno-occlusive disease (VOD) according to Overall Survival (OS), VOD resolution time (RT) under the Defibrotide treatment. *Dropped due to unavailability of bilirubin data.*

b. **PROP 2309-07**: Cardiac Toxicity in Haploidentical transplant with PTCy vs Matched transplant with PTCy vs Matched Transplant with CNI. *Dropped due to overlap with MRS 22-02.*

c. **PROP 2309-10:** Use of Anakinra for the Treatment of ICANS after Anti-CD19 Autologous CART in B-cell Lymphoma. *Dropped due to lower impact.*

d. **PROP 2310-48:** Psychiatric and Cognitive Health Among Survivors of Chimeric Antigen Receptor Therapy in the United States. *Dropped due to not enough PRO data.*

e. **PROP 2310-65:** Machine Learning based Mortality Risk Assessment in Stem cell Transplant for Non-Malignant Bone Marrow Disorders. *Dropped due to low power with rare disease and low mortality.*

f. **PROP 2310-69:** Trends in Primary Graft Failure in allogeneic hematopoietic stem Cell Transplant Recipients. *Dropped due to lower impact.*

g. **PROP 2310-95:** Merging CIBMTR and SEER data to provide a resource for studying rare prior and subsequent neoplasms. *May consider as a separate effort.*

h. **PROP 2310-148:** Incidence and risk factors of engraftment syndrome in autologous hematopoietic cell transplant recipients and its impact on outcomes. *Dropped due to lower impact.*

i. **PROP 2310-159:** Early Platelet count recovery before white cell count recovery after allogeneic hematopoietic cell transplantation and effect on transplant outcomes. *Dropped due to lower impact.*

j. **PROP 2310-163:** Risk factors for long-term osteoporosis and fragility fractures after pediatric HCT. *Dropped due to not enough data for pediatric osteoporosis/fracture.*

k. **PROP 2310-189:** Updated Analysis of the Prevalence of Cellular Therapy Survivors in the United States. *May consider as a separate effort.*

l. **PROP 2310-195:** A comparison of Melphalan (Mel) dosing in the setting of post-transplant cyclophosphamide (PTCy) GVHD prophylaxis. *Dropped due to limitations on Mel dosing data.*

m. **PROP 2310-211:** Sexual Health Among Survivors of Chimeric Antigen Receptor T-cell Therapy in the United States. *Dropped due to not enough PRO data.*

n. **PROP 2310-216:** Long-term survival and late mortality among patients treated with allogeneic hematopoietic cell transplant for inborn errors of metabolism. *Dropped due to two MRSWC studies looking at late mortality.*

o. **PROP 2310-217:** Comprehensive Assessment of Health-Related Quality of Life (HRQoL), Toxicity and Clinical Outcomes Following Chimeric Antigen Receptor T-Cell Therapy for Hematological Malignancies. *Dropped due to not enough PRO data.*

p. **PROP 2310-218:** Efficacy of Three Prophylactic Measures to Mitigate the Toxicities in Chimeric Antigen Receptor (CAR) T-cell Therapy in Lymphoma. *Dropped due to low numbers of patients*

receiving prophylactic therapies.

q. **PROP 2310-250:** Incidence of hypogammaglobulinemia following CD19-directed CAR-T therapy and its impact on CAR-T persistence and outcomes. *Dropped due to not enough data on this topic.*

r. **PROP 2310-269:** Late mortality and standardized mortality ratio (SMR) in patients surviving after allogeneic hematopoietic cell transplantation (HCT). *Dropped due to overlap with MRS 23-01.*

6. Closing Remarks

Dr. Phelan provided the closing remarks, starting with additional information and website links to find out more on what we have available and ongoing studies. We will send out a quarterly newsletter after we make decisions on proposals moving forward. Next, Dr. Phelan announced that "International Recommendations for Screening and Preparative Regimens for Long-Term Survivors of Transplantation and Cellular Therapy: A 2023 Update" has been published in TCT and BMT on February 27, 2024! Also, we have put out a call for systematic review on female-specific late effects. We have over 180 responses in our call for volunteers. Chosen volunteers will be selected shortly after Tandem and thank you all for your interest!

We would like to acknowledge our 2 outgoing chairs: Dr. Betty Hamilton from Cleveland Clinic Foundation and Dr. Bipin Savani from Vanderbilt University Medical Center. Thank you so much for your contributions!

We would like to welcome our incoming chair: Dr. Seth Rotz from Cleveland Clinic Foundation. We are excited to have you on the team!

Thank you everyone, and please reach out if you would like to talk through projects!

Not for publication or presentation

Working Committee Overview Plan for 2024-2025		
Study Number and Title	**Current Status**	**Chairs Priority**
LE12-03a: Outcomes for patients undergoing hematopoietic cell transplantation followed by solid organ transplants	Manuscript preparation	1
LE12-03b: Outcomes for patients undergoing solid organ transplants followed by hematopoietic cell transplantation	Manuscript preparation	1
LE17-01: Late effects after hematopoietic stem cell transplantation for sickle cell disease.	Data file preparation	1
LE19-01b: POP TA-DAH! - Predictors of Pediatric Transplant Associated Diffuse Alveolar Hemorrhage	Submitted	1
LE19-02: Incidence and predictors of long-term toxicities and late side effects in elderly patients (≥60 years) receiving allogeneic hematopoietic cell transplantation for hematological malignancies	Analysis	2
LE20-01: Cardiometabolic risk after total body irradiation during childhood	Analysis	1
LE21-01: Risk of subsequent neoplasms in patients with post-transplant cyclophosphamide use for graft-versus-host disease prophylaxis	Data file preparation	3
RT19-01: Analysis of comorbidity-associated toxicity at a regimen-based level	Data file preparation	2
RT19-02: Hemorrhagic cystitis as a complication of hematopoietic stem cell transplantation in the post-transplant cyclophosphamide graft-versus-host disease prophylaxis era compared to other allogeneic stem cell transplants	Protocol development	3
RT20-01: Toxicities of older adults receiving allogeneic hematopoietic cell transplant compared to younger patients	Data file preparation	1
MRS22-01: Racial/ethnic disparities and role of poverty in long-term health outcomes among survivors of allogeneic hematopoietic cell transplant performed in childhood	Protocol development	3
MRS22-02: Post-transplant cyclophosphamide related cardiomyopathy; incidence, risk factors and outcome: A retrospective review from CIBMTR database	Protocol development	3
MRS23-01: Updated Analysis of Long-Term Survival and Late Deaths after Allogeneic Hematopoietic Cell Transplantation for Hematologic Malignancies and Severe Aplastic Anemia	Protocol pending	3
MRS24-01: Toxicity profile and survival of patients with BMI >30 undergoing allogeneic stem cell transplantation	Protocol pending	3
MRS24-02: Determinants of immune effector cell-associated hematotoxicity (ICAHT) following CAR-T therapy across disease entities	Protocol pending	3