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MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR REGIMEN-RELATED TOXICITY AND SUPPORTIVE CARE
Houston, TX
Thursday, February 21, 2019, 12:15 – 2:15 pm

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1. **Introduction**

   Dr. Stadtmauer announced the CIBMTR Regimen-Related Toxicity and Supportive Care Committee (RRTWC) meeting started at 12:15pm on Thursday, February 21, 2019. He introduced the RRTWC leadership, the incoming and outgoing chairs, the goals, areas of focus and limitations of the RRTWC. He then introduced Marcelo up to the podium to continue.

2. **Accrual summary** (Attachment 2)

   The accrual summary was not presented in order to provide more time for the discussion of RT studies that are ongoing, published in the last year, and of the potential proposed studies to be presented at the meeting.

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

   Marcelo gave a brief overview of the studies published and submitted within the past year. Many studies were moved forward and publish or submitted. He also stated there is a wide variety of journals we are submitting to instead of staying only to BBMT. He believes it is good we are expanding our horizons.

   a. **RT07-01b** Broglie L, Thakar M, Logan B, Artz A, Jacobsohn D, Bunin N, Burroughs L, Martinez C, Nelson A, Woolfrey A, Pasquini M, Sorror, M. *Evaluation of the Hematopoietic Cell Comorbidity Index (HCT-CI) in Recipients of Allogeneic Transplantation for Non-Malignant Diseases.* ***European Society for Blood and Marrow Transplantation Annual Meeting, Lisbon, Portugal, March 2018.***

   b. **RT07-01b** Thakar M, Broglie L, Logan B, Artz A, Bunin N, Burroughs LM, Fretham C, Jacobsohn DA, Loren AW, Kurtzberg J, Martinez CA, Mineishi S, Nelson AS, Woolfrey A, Pasquini MC, Sorror ML. *The Hematopoietic Cell Transplant Comorbidity Index predicts survival after*

allogeneic transplant for non-malignant diseases. ***Blood.*** doi:10.1182/blood-2018-09-876284. Epub 2018 Dec 13.

c. **RT09-04b/IB09-06** Wang J, Clay-Gilmour A, Karaesman E, Rizvi A, Zhu Q, Yan L, Preus L, Liu S, Stram D, Pooler L, Sheng X, Haiman C, Van Den Berg D, Webb A, Brock G, Spellman S, Pasquini M, McCarthy P, Allen J, Onel K, Hahn T, Sucheston-Campbell L. *Genome wide association analyses identify pleiotropic variants associated with Acute Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS) susceptibility.* ***American Society of Hematology Annual Meeting, San Diego, CA, December 2018.***

d. **RT09-04b/IB09-06** Zhu Q, Yan L, Liu Q, Zhang C, Wei L, Hu Q, Preus L, Clay-Gilmour AI, Onel K, Stram DO, Pooler L, Sheng X, Haiman CA, Zhu X, Spellman SR, Pasquini M, McCarthy PL, Liu S, Hahn T, Sucheston-Campbell LE. *Exome chip analyses identify genes affecting mortality after HLA-matched unrelated-donor blood and marrow transplantation.* ***Blood. 2018 May 31; 131(22):2490-2499.*** doi:10.1182/blood-2017-11-817973. Epub 2018 Apr 2. PMC5981168.

e. **RT14-01** Parikh S, Satwani P, Ahn KW, Sahr NA, Fretham C, Abraham A, Agrawal V, Auletta J, Abdel-Azim H, Copelan E, Diaz MA, Dvorak C, Frangoul H, Freytes C, Gadalla SM, Gale RP, George B, Gergis U, Hashmi S, Hematti P, Hildebrandt G, Keating A, Lazarus HM, Myers K, Olsson R, Prestidge T, Rotz S, Savani B, Shereck EB, Williams K, Wirk B, Pasquini MC. *Survival Trends in Infants Undergoing Allogeneic Hematopoietic Cell Transplantation.* ***Journal of the American Medical Association – Pediatrics. Submitted January 2019 – pending decision.***

f. **RT14-03** Zinter MS, Logan BR, Fretham C, Sapru A, Abraham A, Aljurf MD, Arnold SD, Artz A, Auletta JJ, Chhabra S, Copelan E, Duncan C, Gale RP, Guinan E, Hematti P, Keating AK, Marks DI, Savani BN, Olsson R, Ustun C, Williams KM, Pasquini MC, Dvorak CC. *Optimizing Mortality Prognositcation for Critically Ill Pediatric Allogeneic Hematopoietic Cell Transplant Patients: Results from a Center for International Blood and Marrow Transplant Research (CIBMTR) and Virtual Pediatric Systems (VPS) Database Merger.* ***Intensive Care Medicine. Submitted January 2019 – pending decision.***

g. **RT15-01** Harris AC, Boelens JJ, Ahn KW, Fei M, Abraham A, Artz A, Dvorak C, Frangoul H, Freytes C, Gale RP, Hong S, Lazarus HM, Loren A, Mineishi S, Nishihori T, O'Brien T, Williams K, Pasquini MC, Levine JE. *Comparison of pediatric allogeneic transplant outcomes using myeloablative busulfan with cyclophosphamide or fludarabine.* ***Blood Advances. 2018 Jun 12; 2(11):1198-1206.*** doi:10.1182/bloodadvances.2018016956. Epub 2018 May 29. PMC5998928.

h. **RT15-02** McCune JS, Wang T, Bo-Subait K, Mahmoud A, Beitinjaneh A, Bubalo J, Cahn J-Y, Cerny J, Chhabra S, Cumpston A, Dupuis LL, Lazarus HM, Marks DI, Maziarz RT, Norkin M, Prestidge T, Mineishi S, Pasquini MC, Martin PJ. *Association of antiepileptic medications with outcomes after allogeneic hematopoietic cell transplantation with busulfan/cyclophosphamide conditioning.* ***Biology of Blood and Marrow Transplantation. Submitted November 2018 – pending decision.***

i. **RT16-01** Brunstein CG, Pasquini MC, Kim S, Fei M, Adekola K, Ahmed I, Aljurf M, Agrawal V, Auletta JJ, Battiwalla M, Bejanyan N, Bubalo J, Cerny J, Chee L, Ciurea S, Freytes C, Gadalla SM, Gale RP, Ganguly S, Hashmi SK, Hematti P, Hildebrandt G, Holmberg L, Lahoud OB, Landau H, Lazarus HM, de Lima M, Mathews V, Maziarz R, Nishihori T, Norkin M, Olsson R, Reshef R, Rotz S, Savani B, Schouten HC, Seo S, Wirk BM, Yared J, Mineishi S, Rogosheske J, Perales M-A. *The effect of conditioning regimen dose reduction in obese patients undergoing autologous hematopoietic cell transplantation.* ***Biology of Blood and Marrow Transplantation.*** doi:10.1016/j.bbmt.2018.11.005. Epub 2018 Nov 10.

4. Studies in progress (Attachment 3)

Marcelo presented the studies in progress. A few studies from many years back are being prioritized to finish this year. The rest of the studies are fairly new and are on schedule with their

current goals. The goal is to make sure studies stay on two-year timeline from here on out, with the goal to have a study presented at ASH, TCT, or another relevant meeting within one year of their inception.

Marcelo also brought up the issue of authorship and discussed that it is very important for writing committee members to contribute to these studies, but many participate and we only include authors who provide the utmost thought and work towards the protocol, analysis interpretation and manuscript.

a. **RT13-02** Safety of high-dose total body irradiation followed by an allogeneic hematopoietic cell transplant for hematologic malignancies (M Sabloff) **Manuscript preparation**
b. **RT14-01** Trends and risk factors for infant mortality following allogeneic hematopoietic cell transplant: Case-Control study (P Satwani/S Parikh) **Submitted**
c. **RT14-02** Endothelial injury complications after allogeneic hematopoietic cell transplantation (N Epperla/A Li) **Manuscript preparation**
d. **RT14-03** Multicenter cohort identification of transplant-related risk-factors for infection, organ failure, and mortality among pediatric hematopoietic stem cell transplant patients requiring intensive care unit admission (C Dvorak/M Zinter/A Sapru) **Submitted**
e. **RT15-02** Association of anti-epileptic medication with outcomes after conditioning with targeted busulfan followed by cyclophosphamide before allogeneic hematopoietic cell transplantation (PJ Martin/JS McCune) **Submitted**
f. **RT17-01** Allogeneic hematopoietic stem cell transplant outcome of patients with end stage renal disease on dialysis (N Farhadfar/JR Wingard/H Murthy/S Ganguly) **Data file preparation**
g. **RT18-01** A Modified Hematopoietic Cell Transplantation (HCT) Risk Assessment Tool for Pediatric and Young Adult Patients Undergoing Allogeneic Transplantation**.** (B Friend/L Broglie/G Schiller/M Thakar/M Sorror) **Protocol development**
h. **RT18-02** The effect of obesity on outcomes after alternative donor stem cell transplants (M Abou-Ismail/G Ravi/L Metheny/M de Lima) **Protocol development**
i. **RT18-03** An Analysis of Non-Infectious Pulmonary Toxicities in Total Body Irradiation versus Chemotherapy-Based Conditioning Regimens after Allogeneic Hematopoietic Cell Transplantation for Hematologic Malignancies (S Patel/B Hamilton/N Majhail/C Ustun) **Protocol development**
j. **RT18-04** Pulmonary Complications in Pediatric Patients after Allogeneic Hematopoietic Cell Transplantation (L Broglie) **Manuscript preparation**

5. Proposals

Future/proposed studies

Marcelo provided the information on the proposals for the year. There were 11 total proposals for the RRTWC. Four were combined into two, and three were dropped due to feasibility or overlap with current studies, which left six proposals to be presented at the meeting. The proposal themes were trends in NRM, toxicity, comorbidities, and conditioning regimens.

Marcelo reminded the audience about the importance of voting and voting highest on those that would impact a clinician's ability to treat patients.

a. **PROP 1811-45** Risk factor analysis for early vs intermediate vs late non-relapse mortality (M Battiwalla) (Attachment 4)

   Dr. Loren introduced Dr. Battiwalla. The hypothesis is that risk factors differentially impact early (<1 year) versus intermediate (1-3 years) versus late (>3 years) non-relapse mortality

(NRM) following alloHCT. The study aims to 1) evaluate the different clinical risk factors that predict early (<1 year) versus intermediate (1-3 years) versus delayed (>3 years) non-relapse mortality; and 2) understand which phase of NRM (early versus intermediate versus late) has most improved over recent years.

During the discussion, one attendee brought up why the study will restrict only to hematologic malignancies and why not to open up to other malignancies and also non-malignant diseases. Dr. Battiwalla responded that he is willing to expand the population. Another attendee mentioned looking at NRM at 30 days or less as this is a quality marker and has other implications. Dr. Battiwalla responded that he agrees and is interested in finding the right cutoff for time. Another attendee asked how we plan to account for the increasing number of patients with high numbers of comorbidities being transplanted and this effect on relapse and NRM. Dr. Battiwalla responded that he wants to consider HCT-CI as a variable in the model to account for this. Dr. Mineishi asked Dr. Battiwalla what he wants to do with this data if he has already found the factors associated with the three levels of NRM. Dr. Battiwalla said many are validated risk factors, but would like to explore this with larger data and exploring this outcome with a more time-dependent approach.

b. **PROP 1811-124** Second allogeneic hematopoietic cell transplantation for primary graft failure: effect of conditioning regimen, graft source and GVHD prophylaxis on outcome (S Prem/R Kumar/M Mahapatra) (Attachment 5)

Dr. Mineishi introduced Dr. Prem up to the podium. Dr. Prem introduced the study and stated the hypothesis is that the success of the second alloHCT for primary graft failure is influenced by conditioning regimen, GVHD prophylaxis, graft source, cell dose, disease, and other patient and transplant related factors. The study aims are to 1) study the effect of conditioning regimen on outcome of second hematopoietic cell transplantation (HCT) for primary graft failure; and 2) assess impact of GVHD prophylaxis regimen, primary disease, and stem cell source in outcomes after second HCT for primary graft failure.

During the discussion, one attendee asked if it is possible to clarify if the graft failure was caused by becoming aplastic or no autologous recovery. Dr. Prem mentioned that although this data would be helpful that it may not be available. Another attendee asked if we have data on time from graft failure to second transplant, as this would be important to consider. He also mentioned that GVHD prophylaxis and conditioning should be considered. Marcelo responded describing the way that graft failure is captured on CIBMTR forms and that we do not capture dates for this as some may never engraft and therefore we cannot capture a date. Dr. Mineishi asked if we should consider the chimerism data for this. Dr. Prem mentioned that for primary graft failure this will not be as applicable or needed for this study. Dr. Stadtmauer mentioned that the median age is showing a very young population and there is likely bimodal ages here with one younger group and one older group. If accepted, it should be considered. He is also interested in knowing the graft failure rate for this population. Dr. Prem mentioned it was 6.7% in the previous study, although that cohort was only myeloablative regimens.

c. **1811-160** Exploring Ensemble Machine Learning Methods to Better Predict Veno-Occlusive Disease Following Allogeneic Hematopoietic Stem Cell Transplantation (D Shyr/C Lee/ S Brewer) (Attachment 6)

Dr. Stadtmauer introduced Dr. Shyr to the stage for the presentation. The study hypothesizes that machine learning methods can be used to make robust predictions of VOD in patients receiving alloHCT prior to the clinical diagnosis of VOD. The proposed study aims to determine if ensemble machine (decision tree ensembles) learning methods to predict VOD is feasible.

During the discussion, Dr. Stadtmauer asked for clarification if machine learning is an algorithm and if we would need funding to utilize a method for this. Dr. Shyr clarified that no funding is needed and these methods are readily available in statistical programs as statistical packages that are open to the public. He also said this study is more of a data and statistical methods experiment. Another attendee asked if there is plan to validate this updated risk assessment for VOD. Dr. Shyr explained that he plans to validate by partitioning the original dataset into training and validations cohorts. Another attendee asked Dr. Shyr what a clinician could do with this type of analysis and how that would change practice. Marcelo followed up with Dr. Artz's question and asked how this study is different from the previous VOD risk score study. Dr. Shyr mentioned that he does not want to replace the old VOD risk score but rather improve upon the previous version. Another attendee mentioned his concern that the event rate is very low to generate a robust model with so few events and also asked if it is possible to sample patients overtime and collect data prospectively instead of retrospectively as VOD is ever changing. Dr. Shyr mentioned that this analysis has already been done so we can only build upon what we have already done and also agreed that we would have more information if we collected prospectively but is limited to the data that is provided.

d. **PROP 1811-189** Analysis of Comorbidity associated Toxicity at a Regimen based Level (R Shouval/B Savani/A Nagler) (Attachment 7)

Dr. Loren introduced Dr. Shouval to the stage to present. The study hypothesizes that the hazard of comorbidities is exerted in a regimen-specific manner. The aims of this study are to 1) evaluate the non-relapse mortality (NRM) hazard (primary outcome) associated with pre-transplantation comorbidities in predefined conditioning regimens; and 2) evaluate NRM hazard associated with pre-transplantation comorbidities in conditioning intensity categories (non-myeloablative, reduced intensity conditioning, myeloablative conditioning) and 3) explore toxicities associated with specific conditioning regimen stratified by preexisting comorbidities.

During the discussion, one attendee mentioned that they think it would be best to only include years 2008 and beyond due to comorbidity data only being available on forms starting in 2008. He also mentioned that it might be important to look at NRM at different time points such as occurring before or after 1-year post transplant. Dr. Shouval mentioned that he does not want to look at HCT-CI but rather separate comorbidities because HCT-CI has already been assessed with conditioning regimen in previous validation study. Dr. Shouval also responded that he is more interested in the later effects of NRM rather than immediate NRM events related to these risk factors. Marcelo mentioned that there is some overlap with this proposal and a current study. He said we would need to restrict to age 40 and older as well. Dr. Mineishi asked about what he plans to do with the population that receives post-transplant cyclophosphamide. Dr. Shouval said he would be willing to remove these patients and haplos if needed.

e. **PROP 1811-35/1811-167** Outcomes of Patients with Inflammatory Bowel Disease After Hematopoietic Cell Transplantation (D Faleck/K Boughan/M Scordo/MA Perales/L Cohen) (Attachment 8)

Dr. Mineishi introduced Dr. Boughan to the podium to present the next proposal. The study hypothesizes that outcomes after alloHCT and autoHCT will be similar among patients with IBD as compared to matched controls. The aims of the study are to 1) compare overall outcomes including adverse events, incidence of graft-versus-host disease (GVHD), non-relapse mortality (NRM), relapse, progression-free (PFS) and overall survival (OS) between patients with and without IBD undergoing HCT; and 2) Determine the impact of HCT on IBD activity and outcomes, including clinical and endoscopic response and the need for immunosuppressive therapy, hospitalization, and surgery post-HCT.

During the discussion, Dr. Stadtmauer if this would be considered a non-inferiority analysis and if this population would be feasible for this. Dr. Logan responded that there is large enough sample size that we can do a non-inferiority analysis here. Dr. Pasquini clarified that on the forms, we capture history of IBD in the comorbidities section but not current or active IBD at transplant. He also mentioned that we have no follow-up data on IBD outcomes post-transplant. Dr. Mineishi asked about if the Dr. Boughan anticipated any confusion regarding gut GVHD and if this would be related to active IBD at transplant. Dr. Pasquini mentioned that we could take a sample of the IBD cases and ask centers for more data on this data to see if patients with active IBD have higher probability of gut GVHD. Dr. Loren mentioned that we could also due a case-control type method where we only sample from centers with highest IBD reporting. Dr. Stadtmauer asked how often patients with active IBD are transplant and Dr. Boughan responded that it happens often enough to be interested in exploring.

f. **PROP 1811-85/1811-159** 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) (Attachment 9)

Dr. Stadtmauer introduced Dr. Ali to the podium to present. This study hypothesizes that the inclusion of post-CY as GVHD prophylaxis for patients getting haplo-HCT as well as non-haplo-SCT results in an increase in HC/ BK nephropathy. The study's primary aim is to determine the incidence of HC and BK nephropathy in patients who received post-Cy as part of GVHD prophylaxis regimen versus those who did not.

During the discussion, Dr. Stadtmauer asked if the plan is to look at HC and BK as a combined endpoint or separately. Dr. Pasquini said that BK nephropathy is not easily collected and is not necessarily collected as a part of hemorrhagic cystitis (HC) questions. We could look at incidence of HC and covariates associated with development and see if BK virus is a factor that contributes to the model. We also do not collected severity or grading for HC. One attendee commented that BK nephropathy is not relevant anymore and does not recommend analyzing these variables. He also recommended looking at engraftment kinetics as part of the model and as outcomes. Dr. Ali agreed with the attendee regarding engraftment.

Dropped proposed studies

a. **PROP 1811-21** Thrombopoietic agents in SCT and effect on outcomes (S Farhan/N Janakiraman/E Peres/J Emole) *Dropped due to feasibility of supplemental data collection.*
b. **PROP 1811-129** Transplant associated thrombotic microangiopathy (TA-TMA): Outcomes and late toxicities (M Schoettler/C Duncan) *Dropped due to overlap with current RRTWC study RT14-02.*
c. **PROP 1811-161** Metabolic health: Effect of donor and recipient BMI on post-transplant outcomes (N Chandhok/L Gowda/A Zeidan/R Perry/T Prebet) *Dropped due to overlap with current RRTWC study RT18-02.*

6. Other business

Dr. Stadtmauer adjourned the meeting and thanked all for attending. He reminded everyone the important of voting and asked all to consider thoughtful responses during voting.

Dr. Pasquini also mentioned that the pre-TED's next revision was just finished and there are some edits to both the comorbidities and regimen sections that will be impactful to our future studies and recommends everyone to review these for future meetings.

Biorepository Accruals (Attachment 10)

Study Proposal Acceptance:

Prior to meeting the CIMBTR Advisory Committee released recommendations for each committee with the numbers of proposals allowed to proceed as accepted CIBMTR WC studies. The RRTWC was recommended to accept no more than three studies, given the number of studies in progress and the statistical hours allocated to the committee. The RRTWC leadership has decided they will accept two studies: RT19-01 (proposal #1811-189) and RT19-02 (proposal #1811-85/1811-159). These were accepted based on voting scores, scientific impact in the TCT community and feasibility.

Working Committee Overview Plan for 2019-2020

Study number and title	Current status	Goal with date	Total hours to complete	Total hours to goal	Hours allocated to 6/30/2019	Hours allocated 7/1/2019-6/30/2020	Total Hours allocated
RT13-02: Safety of high-dose TBI followed by alloHCT for hematologic malignancies.	Manuscript preparation	Submission to BBMT by March 2019	20	20	20	5	**25**
RT14-01: Trends and risk factors for infant mortality following allogeneic hematopoietic cell transplant: a case-control study.	Submitted	Published by July 2019	0	0	0	0	**0**
RT14-02: Endothelial injury complications after alloHCT.	Manuscript preparation	Submission to BBMT by April 2019	70	70	70	5	**75**
RT14-03: Multicenter cohort identification of transplant-related risk factors for infection, organ failure, and mortality among pediatric alloHCT patients requiring PICU admission.	Submitted	Published by July 2019	10	10	10	5	**15**
RT15-02: Association of anti-epileptic medication with outcomes after conditioning with targeted busulfan	Submitted	Published by July 2019	10	10	10	5	**15**

followed by cyclophosphamide before alloHCT.							
RT17-01: AlloHCT outcome of patients with end stage renal disease on dialysis.	Data file preparation	Analysis by March 2019	160	30	90	70	**160**
RT18-01: A modified HCT risk assessment tool for pediatric and young adult patients undergoing alloHCT.	Protocol development	Data file preparation by March 2019.	250	20	50	180	**230**
RT18-02: The effect of obesity on outcomes after alternative donor stem cell transplants.	Protocol development	Data file preparation by July 2019.	310	100	60	180	**240**
RT18-03: An analysis of non-infectious pulmonary toxicities in regards to conditioning regimens, graft source and early vs. delayed engraftment.	Protocol development	Data file preparation by July 2019.	310	100	60	180	**240**
RT19-01: Analysis of comorbidity-associated toxicity at a regimen based level.	Protocol pending	Data file preparation by July 2020	330	0	100	230	**330**
RT19-02: Hemorrhagic cystitis as a complication of HCT in the Pt-Cy GVHD prophylaxis era compared to other alloHCTs.	Protocol pending	Data file preparation by July 2020	330	0	100	230	**330**

Oversight Assignments for Working Committee Leadership (March 2019)

Shin Mineishi	**RT13-02**: Safety of high-dose TBI followed by alloHCT for hematologic malignancies.
	RT18-03: An analysis of non-infectious pulmonary toxicities in regards to conditioning regimens, graft source and early vs. delayed engraftment.
Edward Stadtmauer	**RT14-02:** Endothelial injury complications after alloHCT.
	RT18-02: The effect of obesity on outcomes after alternative donor stem cell transplants.
Bipin Savani	**RT19-01: A**nalysis of comorbidity-associated toxicity at a regimen based level.
	RT19-02: Hemorrhagic cystitis as a complication of HCT in the Pt-Cy GVHD prophylaxis era compared to other alloHCTs.
Marcelo Pasquini	**RT17-01:** AlloHCT outcome of patients with end stage renal disease on dialysis.
	RT18-01: A modified HCT risk assessment tool for pediatric and young adult patients undergoing alloHCT.