Not for publication or presentation

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR CHRONIC LEUKEMIA
Salt Lake City, UT
Sunday, April 24, 2022, 12:15 p.m. – 2:15 p.m. MDT

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1. Introduction

*The Chronic Leukemia Working Committee (CKWC) met on **Sunday, April 24, 2022,** at 12:15 p.m. The chairs, scientific director and statisticians were all presented at the meeting. Attendees were asked to have their name badges scanned at the front gate for attendance purpose and to maintain the committee membership roster.*

As the scientific director of the CKWC, Dr. Wael Saber welcomed the attendees on behalf of the working committee leadership and presented Dr. Ryotaro Nakamura in charge or presenting the welcome slides.

2. Accrual summary

Dr. Nakamura referenced the accrual summary, but not formally presented due to a full agenda. The full accrual summary was available online as part of the attachments.

3. Presentations, Published or Submitted Papers

The following publications or submitted papers from 2021 were referenced, as well as abstracts that were presented at various conferences. Dr. Nakamura mentioned that it was a very productive year and emphasized the high metrics of the committee. He mentioned that CK18-02 was the most recent publication. At the time, four studies were published in scientific journals recently and four abstracts were presented or accepted for presentations. These include:

a. **CK17-02:** Oran B, Ahn KW, Fretham C, Beitinjaneh A, Bashey A, Pawarode A, Wirk B, Scott BL, Savani BN, Bredeson C, Weisdorf D, Marks DI, Rizzieri D, Copelan E, Hildebrandt GC, Hale GA, Murthy HS, Lazarus HM, Cerny J, Liesveld JL, Yared JA, Yves-Cahn J, Szer J, Verdonck LF, Aljurf M, van der Poel M, Litzow M, Kalaycio M, Grunwald MR, Diaz MA, Sabloff M, Kharfan-Dabaja MA, Majhail NS, Farhadfar N, Reshef R, Olsson RF, Gale RP, Nakamura R, Seo S, Chhabra S, Hashmi S, Farhan S, Ganguly S, Nathan S, Nishihori T,

Jain T, Agrawal V, Bacher U, Popat U, Saber W. Fludarabine and melphalan compared with reduced doses of busulfan and fludarabine improve transplantation outcomes in older patients with myelodysplastic syndromes. **Transplantation and Cellular Therapy. 2021 Nov 1; 27(11):921.e1-921.e10. doi:10.1016/j.jtct.2021.08.007.** ***Epub 2021 Aug 14.***

b. **CK18-03:** Guru Murthy GS, Kim S, Hu Z-H, Estrada-Merly N, Abid MB, Aljurf M, Bacher U, Badawy SM, Beitinjaneh A, Bredeson C, Cahn J-Y, Cerny J, Diaz Perez MA, Farhadfar N, Gale RP, Ganguly S, Gergis U, Hildebrandt GC, Grunwald MR, Hashmi S, Hossain NM, Kalaycio M, Kamble RT, Kharfan-Dabaja MA, Hamilton B, Lazarus HM, Liesveld J, Litzow M, Marks DI, Murthy HS, Nathan S, Nazha A, Nishihori T, Patel SS, Pawaride A, Rizzieri D, Savani B, Seo S, Solh M, Ustun C, van der Poel M, Verdonck LF, Vij R, Wirk B, Oran B, Nakamura R, Scott B, Saber W. Relapse and disease-free survival in patients with myelodysplastic syndrome undergoing allogeneic hematopoietic cell transplantation using older matched sibling donors vs younger matched unrelated donors**. JAMA Oncology. 2022 Mar 1; 8(3):404-411. doi:10.1001/jamaoncol.2021.6846.** ***Epub 2022 Jan 13. PMC8759031.***

c. **CK19-01A:** Murthy HS, Ahn KW, Estrada-Merly N, Alkhateeb HB, Bal S, Kharfan-Dabaja MA, Dholaria B, Foss F, Gowda L, Jagadeesh D, Sauter C, Bilal Abid M, Aljurf M, Awan FT, Bacher U, Badawy SM, Battiwalla M, Bredeson C, Cerny J, Chhabra S, Deol A, Diaz MA, Farhadfar N, Freytes C, Gajewski J, Gandhi MJ, Ganguly S, Grunwald MR, Halter J, Hashmi S, Hildebrandt GC, Inamoto Y, Jimenez-Jimenez AM, Kalaycio M, Kamble R, Krem MM, Lazarus HM, Lazaryan A, Maakaron J, Pashna N. Munshi PN, Munker R, Nazha A, Nishihori T, Oluwole OO, Ortí G, Pan DC, Patel SS, Pawarode A, Rizzieri D, Saba NS, Savani B, Seo S, Ustun C, van der Poel M, Verdonck LF, Wagner JL, Wirk B, Oran B, Nakamura R, Scott B, Saber W. Outcomes of Allogeneic Hematopoietic Cell Transplantation in T Cell Prolymphocytic Leukemia: A Contemporary Analysis from the Center for International Blood and Marrow Transplant Research. **Transplantation and Cellular Therapy. 2022 Apr 1; 28(4):187.e1-187.e10. doi:10.1016/j.jtct.2022.01.017.** ***Epub 2022 Jan 23.***

d. Mei M, Pillai R, Kim S, Estrada-Merly N, Afkhami M, Yang L, Meng Z, Abid MB, Aljurf M, Bacher U, Beitinjaneh A, Bredeson C, Cahn JY, Cerny J, Copelan E, Cutler C, DeFilipp Z, Diaz Perez MA, Farhadfar N, Freytes CO, Gadalla SM, Ganguly S, Gale RP, Gergis U, Grunwald MR, Hamilton BK, Hashmi S, Hildebrandt GC, Lazarus HM, Litzow M, Munker R, Murthy HS, Nathan S, Nishihori T, Patel SS, Rizzieri D, Seo S, Shah MV, Solh M, Verdonck LF, Vij R, Sobecks RM, Oran B, Scott BL, Saber W, Nakamura R. The mutational landscape in chronic myelomonocytic leukemia and its impact on allogeneic hematopoietic cell transplantation outcomes: a Center for Blood and Marrow Transplantation Research (CIBMTR) analysis**. Haematologica. 2022 Apr 21. doi: 10.3324/haematol.2021.280203.** ***Epub ahead of print. PMID: 35443559.***

e. **CK18-02:** The impact of somatic mutations on allogeneic transplant in chronic myelomonocytic leukemia. (M Mei/ R Nakamura/ R Pillai) ***Accepted in Haematologica. Oral presentation, ASH 2021.***

f. **CK16-01:** Identification of germline predisposition mutations in young myelodysplastic syndrome patients. (L Godley) ***Oral presentation, ASH 2021.***

g. **CK20-01:** Outcomes of allogeneic hematopoietic cell transplantation for myelofibrosis based on the conditioning regimen. (G Murthy/ W Saber) ***Oral presentation, ASH 2021.***

h. **CK19-01B:** Outcomes after HCT for rare chronic leukemias: Outcomes of chronic neutrophilic leukemia patients who underwent allogeneic hematopoietic cell transplantation. (B Dholaria/B Savani/M Kharfan-Dabaja). ***Oral presentation, EBMT 2022.***

4. Studies in Progress

Due to the full agenda, studies in progress were referenced but not presented at the meeting. Dr. Nakamura mentioned that the summary of the progress of the ongoing studies was available online as part of the attachments.

a. **CK16-01** Identification of germline predisposition mutations in young myelodysplastic syndrome patients. (L Godley). ***Submitted.***

b. **CK17-01** Development of a prognostic scoring system predictive of outcomes in patients with myelofibrosis after allogeneic hematopoietic cell transplantation. (T Roni/SA Giralt/J Palmer)***. Manuscript Preparation.***

c. **CK19-01b** Outcomes after HCT for rare chronic leukemias: Outcomes of chronic neutrophilic leukemia patients who underwent allogeneic hematopoietic cell transplantation. (B Dholaria/B Savani/M Kharfan-Dabaja). ***Accepted in BJH.***

d. **CK20-01** Outcomes of allogeneic hematopoietic cell transplantation for myelofibrosis based on the conditioning regimen. (G Murthy/ W Saber)***. Submitted.***

e. **CK21-01** Outcomes of allogeneic hematopoietic cell transplantation for myelofibrosis based on the conditioning regimen. (Tania Jain/ M Queralt Sala/V Gupta/ T Nishihori)***. Datafile Preparation.***

5. Future/Proposed Studies

Dr. Saber thanked the investigators whose proposals were submitted, but not selected for presentation, emphasizing that proposals were dropped due to overlaps with current studies. He also reminded the audience of the voting process.
Dr. Bart Scott then announced the presenters for the first proposal and asked the audience to stand up to the microphones and present themselves before asking the presenter about their proposed studies. Also welcomed Dr. Betul Oran which attended the session virtually helped moderating the virtual chat.

a. **PROP 2110-259:** Allogeneic Hematopoietic Cell Transplantation (HCT) for the Treatment of Myelodysplastic Syndromes (MDS) in Younger Adults. (A Jimenez/T Wang) (Attachment 4)

Dr. Jimenez presented the proposal on behalf of the group. The proposal hypothesizes that Consolidation with allogeneic Hematopoietic Cell Transplant (HCT) is an effective strategy for the treatment of Myelodysplastic Syndromes (MDS) in young patients. The study aims to evaluate the clinical outcomes following allogeneic HCT in younger MDS patients (i.e., <60 years at the time of HCT). To achieve this objective, it will focus on describing clinical features and outcomes (overall survival, relapse-free survival, GVHF-free, relapse-free survival, non-relapse mortality, and cumulative incidence of relapse) in younger patients with MDS receiving allogeneic HCT consolidation. Also, evaluate differences in transplant outcomes (overall survival, relapse-free survival, cumulative incidence of relapse, cumulative incidence of non-relapse mortality and cumulative incidence of acute and chronic GVHD) between sub-cohorts stratified based on IPSS-R categories, age (AYA: 16-39, 40-49, 50-59) conditioning regimen, graft/donor source and HCT-CI. A total of 1683 MDS patients reported to CIBMTR between the period 2008 to 2019

met the selection criteria for this concept. More than a half (56%) of this patients had 50-59 years of age when transplanted.

The proposal was open for discussion. The audience asked Dr. Jimenez if there are any publications stating differences in the biology of the disease when comparing young and old patients. Other member asked on why the inclusion of patients up to 59 years, when those cases would not be considered young cases. Audience suggested looking into three age groups and characterize clinical differences and outcomes. Another member suggested obtaining supplemental genetic information and analyze the genetic profiles of the cohort.

b. **PROP 2110-308:** Impact of Somatic Mutations on Outcomes after Allogeneic Hematopoietic Cell Transplantation in Patients with Myelodysplastic Syndrome with Ring Sideroblasts (MDS-RS) and MDS/myeloproliferative neoplasm with RS and thrombocytosis. (MDS/MPN-RS-T) (S Arslan/R Nakamura) (Attachment 5)

*Dr. Arslan presented the proposal on behalf of the group. The study hypothesizes that Allogeneic HCT is highly effective and associated with long-term survival in MDS-RS and MDS/MPD-RS-T and 2) Somatic mutations have prognostic relevance in MDS-RS and MDS/MPD-RS-T**.** The objectives of this study are to evaluate the outcome of patients with MDS-RS or MDS/MPD-RS-T who underwent allogeneic HCT and were registered in the CIBMTR database, characterize the mutation profile in the MDS-RS or MDS and MPD-RS-T in patients who underwent HCT, and determine the incidence of high-risk mutations in this population, and examine potential impact of somatic mutations on HCT outcomes adjusted for other clinical risk factors. A total of 329 cases Refractory anemia (RA), Refractory anemia with ringed sideroblasts (RARS), and MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN–RS–T) patients, with very low, low, and intermediate risk (IPSS-r) prior to HCT reported to CIBMTR between the period 2008 to 2019 met the criteria for this study.*

The proposal was open for questions and comments. An audience members asked on the how many patients had samples and if the study could include samples from Dr. Coleman's study published. A total of 202 recipients has samples in the NMDP biorepository, some of these cases might be reanalyzed from Dr. Coleman's study. Another member asked if there is any reason to exclude PT-Cy and Haploidentical donor cases. The study will exclude depleted grafts but will include any other haploidentical patients. Another comment raised consisted of the concern for misclassification of these diagnoses.

c. **PROP 2110-163/PROP 2110-310** Combined proposal: Impact of Pre-Allogeneic Hematopoietic Stem Cell Transplantation Treatment on Outcomes of Patients with Higher-Risk MDS and CMML: A Propensity Score Analysis. (P Kongtim/S Ciurea/R Shallis/A Zeidan) (Attachment 6)
Impact of Pre-transplant Hypomethylating Treatment on Outcomes of Patients with High Risk MDS and CMML Receiving Allogeneic Hematopoietic Stem Cell Transplantation: A Propensity Score Analysis. Exploring the Impact of Frontline Therapy Intensity in Higher-Risk Myelodysplastic Syndromes or Chronic Myelomonocytic Leukemia on Post-Allogeneic Stem Cell Transplant Outcomes.

Dr. Shallis presented virtually this proposal on behalf of the group. The study hypothesizes that pre-AHCT treatment with an HMA can reduce disease burden with acceptable toxicity and results in improved outcomes after AHCT for patients with higher-risk MDS and CMML when compared with patients either treated with pre-AHCT intensive chemotherapy or, among those without excess blasts, receiving no pre-AHCT therapy. The study aims to compare post-AHCT outcomes including relapse-free survival (RFS), overall survival (OS), GvHD-free relapse-free survival (GRFS), cumulative incidence of non-relapse

mortality (NRM), relapse, acute GvHD and chronic GvHD inpatients with higher-risk MDS and CMML who received pre-AHCT treatment with HMA vs. intensive chemotherapy vs. no therapy. Lastly, to identify factors that are associated with favorable outcomes of patients with higher-risk MDS and CMML based on each type of pre-AHCT strategy. A total of 1665 cases of MDS patients with <5% marrow blasts at diagnosis AND IPSS-R intermediate/high/very high-risk disease at diagnosis reported to CIBMTR between the period 2008 to 2019. The breakdown of these patients was 1112 received HMA alone, 164 received chemotherapy and 389 did not received any treatment.

The proposal was opened for comments and questions. A member of the audience asked if higher-risk MDS and Chronic myelomonocytic leukemia (CMML) are different? Leadership mentioned that MDS and CMML are captured as different entities and should they be analyzed separately in the study. Another member of the audience asked if patients treated with HMA + Chemotherapy; specifically, Venetoclax would be excluded from the study population. The patients mentioned are planned to be included in the study, and Venetoclax will be investigated from the other drugs specified in our forms collected. Additionally, we will look at different categorizations of intensive vs less intensive treatment. Another comment from the audience suggested to look at response to HCT, this information is collected and will be looked upon the analysis. The leadership clarified that we only collect the information on patients that made it into HCT, hence we cannot determine what determine what treatment therapy is better for patients that did not receive an HCT.

d. **PROP 2110-195/PROP 2110-339** Combined proposal: Characteristics Associated with Improved Survival Following Allogeneic Hematopoietic Cell Transplant (HCT) for Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Syndromes. (H Elmariah/T Nishihori/L Gowda/R Shallis) (Attachment 7)
Comparison of Haploidentical Donor Allogeneic Hematopoietic Cell Transplant (HCT) with Post-Transplant Cyclophosphamide to Matched Donor HCT for Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Syndromes.
Does Allografting help prolong remissions for MDS-MPN.

Dr. Elmariah presented the proposal on behalf of the group. This study hypothesizes that outcomes of allogeneic (allo) hematopoietic cell transplant (HCT) for patients with myelodysplastic syndrome/myeloproliferative neoplasm overlap syndromes (MDS/MPN) will be improved with the use of myeloablative conditioning (MAC) over reduced intensity conditioning (RIC), and that haploidentical donor HCT with post-transplant cyclophosphamide (PTCy) yields similar outcomes to matched sibling and matched unrelated donor transplants. The objectives of this study are to compare outcomes by histologic category, to compare outcomes by donor platform and conditioning intensity and finally to develop a predictive model for survival post allo-HCT for MDS/MPN's. A total of 2056 patients with MDS/MPN overlap syndromes as defined by the study group were reported to CIBMTR between the period 2010 to 2019 and met the initial selection criteria requirements. Of which 1156 were registered in the TED-level track.

The floor was opened from questions and comments from the audience. A member of the audience suggested restricting this study and exclude CMML patients (n=1169), while focus on aCML, MDS/MPN and RARS-T. Main reason being that CMML has been studied and described previously. Concerns were raised about small sample size after excluding CMML cases. Another member of the audience suggested focusing analyses into conditioning regime and donor type differences.

e. **PROP 2110-287/PROP 2110-345** Combined proposal: Impact of TP53 Mutational Burden, Conditioning Regimen, and HLA Match on Cumulative Incidence of Relapse and Overall Survival after Allogeneic Stem Cell Transplant for TP53-Aberrant Myeloid Neoplasms. (S Patel/J Cerny/J Maakaron/M Juckett) (Attachment 8)

Impact of TP53 Mutational Subtype, Conditioning Regimen, and Stem Cell Donor Choice on Cumulative Incidence of Relapse and Overall Survival after Allogeneic Stem Cell Transplant for TP53-Aberrant Myeloid Neoplasms.

Matched vs. Mismatched Hematopoietic Stem Cell Transplantation (HCT) for TP53 mutated acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

Dr. Shyam Patel presented this proposal on behalf of the group. This study hypothesizes at higher intensity conditioning regimens are more effective at elimination of genomic MRD. We hypothesize that a graft-vs-leukemia (GvL) effect is the primary mediator of superior long-term outcomes. If so, HLA-mismatched transplant may improve the chance of a successful outcome through enhanced GvL effect. The enhanced GvL effect from a mismatched donor may be more apparent following a non-myeloablative preparative regimen. The objectives of this study are to evaluate outcomes of TP53 mutated patients, evaluate TP53 mutational burden, asses the benefit of regimen-intensity, and to evaluate the HLA-matching. A total of 331 with MDS (n=293) and MPN (n=38) patients undergoing 1st allo-HCT with TP53 mutation at any timepoint, between 2013 and 2019 met the selection criteria for this concept.

The proposal was opened for comments and questions. A comment was raised on evaluating the TP53 at time of diagnosis and HCT. A comment was raised on availability of mutation subtype on the database. Committee leadership clarified that mutation subtype is not available on the database, it was suggested to review the cytogenetics and use as surrogate. Another member of the audience asked on the availability of post-HCT data. This data is not available for this cohort of patients. A member of the audience asked how this study would be different from previous studies and a BMT-CTN study. A member suggested to restrict to complex karyotype patients but concerns on small sample size were raised.

6. **Future/proposed studies to be presented at the CIBMTR Collaborative Working Committee Study Proposals Session**

*Dr. Saber mentioned that proposal "**PROP 2110-217/PROP 2110-99** Combined proposal: Long-term Outcomes of AML/MDS Patients Receiving Allogeneic Stem Cell Transplantation using Reduced-Intensity Conditioning: A propensity score analysis." was selected to be presented at the Collaborative Session.*

13 additional proposals were submitted but not presented as listed below:

a. **PROP 2109-17:** A personalized, machine learning derived prediction model for outcomes after allogeneic stem cell transplantation in patients with myelodysplastic/myeloproliferative overlap syndromes. ***Dropped due to low scientific impact among proposal.***

b. **PROP 2110-64:** Allogeneic stem cell transplantation for chronic myeloid leukemia 2010- 2020: How has the selection of patients and outcomes changed after the introduction of 2nd and 3rd generation TKIs? ***Dropped-supplemental data needed.***

c. **PROP 2110-76:** Early platelet count recovery before white cell count recovery after allogeneic hematopoietic cell transplantation and effect on clinical outcome. ***Dropped due to low scientific impact among proposal.***

d. **PROP 2110-129:** Outcomes of allogeneic hematopoietic cell transplantation for Myelofibrosis: PTCY vs ATG. ***Dropped due to overlap with current study/publication.***

e. **PROP 2110-138:** Clinical outcomes and impact of somatic mutations on outcomes of allogeneic blood or marrow transplantation in atypical chronic myeloid leukemia. ***Dropped due to small sample size.***

f. **PROP 2110-194:** Mutational Predictors of Outcomes following Allogeneic Blood or Marrow Transplantation (BMT) for Myelofibrosis (MF). ***Dropped due to small sample size.***

g. **PROP 2110-208:** Effect of pre-transplant ferritin on survival and non-transplant mortality in alternative donor types after hematopoietic stem cell transplant for myelofibrosis. ***Dropped-supplemental data needed.***

h. **PROP 2110-210:** Allogeneic Hematopoietic Cell Transplantation for Patients with Chronic Myelomonocytic Leukemia. ***Dropped due to overlap with current study/publication.***

i. **PROP 2110-213:** Impact of Measurable Residual Disease After Allo-HCT for Patients with Myelofibrosis. ***Dropped-supplemental data needed.***

j. **PROP 2110-224:** Outcomes after Hematopoietic Stem Cell Transplant for Chronic Myeloid Leukemia in Blast Crisis when using Busulfan-based versus Total Body Irradiation-based Conditioning Regimens. ***Dropped due to small sample size.***

k. **PROP 2110-255:** Impact of PTCY on Outcomes in Adults with Myelofibrosis. ***Dropped due to overlap with current study/publication.***

l. **PROP 2110-265:** Sequential Allogeneic Hematopoietic Stem Cell Transplantation for Myelodisplastic Syndrome. ***Dropped due to small sample size.***

m. **PROP 2110-309:** Optimal Donor Type for Allogeneic Hematopoietic Cell Transplant for Myelodysplastic Syndrome. ***Dropped due to overlap with current study/publication.***

7. Other Business

*The meeting was adjourned at **2:15** p.m. The chairs of the working committee, scientific director and statisticians had a post-WC meeting afterwards. After the new proposals were presented, attendees had the opportunity to vote on the proposals using the Tandem app until May 2. 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:*

Working Committee Overview Plan for 2022-2023		
Study Number and Title	**Current Status**	**Chairs Priority**
CK16-01: Identification of germline predisposition mutations in young myelodysplastic syndrome patients	Submitted	3
CK17-01: Development of a prognostic scoring system predictive of outcomes in patients with myelofibrosis after allogeneic hematopoietic cell transplantation	Manuscript Preparation	3
CK20-01: Outcomes of allogeneic hematopoietic cell transplantation for myelofibrosis based on the conditioning regimen.	Submitted	4
CK21-01: Haploidentical donor transplantation versus matched donor allogeneic hematopoietic cell transplantation outcomes in patients with myelofibrosis.	Datafile Preparation	3
CK22-01: Impact of somatic mutations on outcomes after allogeneic hematopoietic cell transplantation in patients with myelodysplastic syndrome with ring sideroblasts (MDS-RS) and MDS/myeloproliferative neoplasm with RS and thrombocytosis (MDS/MPN-RS-T).	Protocol Pending	1
CK22-02: Toxicity and survival of AML/MDS patients receiving allogeneic stem cell transplantation using reduced-intensity conditioning: A propensity score analysis.	Protocol Pending	2

Working Assignments for Working Committee Leadership (May 2022)

Bart Scott	**CK16-01:** Identification of germline predisposition mutations in young MDS patients.
	CK22-02: Toxicity and survival of AML/MDS patients receiving allogeneic stem cell transplantation using reduced-intensity conditioning: A propensity score analysis.
Ryotaro Nakamura	**CK17-01:** Development of a prognostic scoring system predictive of outcomes in patients with myelofibrosis after allogeneic hematopoietic cell transplantation.
Betul Oran	**CK20-01:** Outcomes of allogeneic hematopoietic cell transplantation for Myelofibrosis based on the conditioning regime.
	CK21-01: Haploidentical allogeneic stem cell transplantation in patients with myelofibrosis.
	CK22-01: Impact of somatic mutations on outcomes after allogeneic hematopoietic cell transplantation in patients with myelodysplastic syndrome with ring sideroblasts (MDS-RS) and MDS/myeloproliferative neoplasm with RS and thrombocytosis (MDS/MPN-RS-T).