Not for publication or presentation

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
Orlando, Florida
Thursday, February 23, 2017, 2:45 – 4:45 pm

Co-Chair:	**Sonali Smith, MD, The University of Chicago, Chicago, IL; Telephone: 773-702-4400; E-mail: smsmith@medicine.bsd.uchicago.edu**
Co-Chair:	**Anna Sureda, MD, PhD, Hospital Duran i Reynals, Barcelona, Spain; Telephone: +34 9326 07750; E-mail: asureda@iconcologia.net**
Co-Chair:	**Timothy Fenske, MD, Medical College of Wisconsin, Milwaukee, WI; Telephone: 414-805-4633; E-mail: tfenske@mcw.edu**
Scientific Director:	**Mehdi Hamadani, MD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0700; E-mail: mhamadani@mcw.edu**
Statistical Director:	**Kwang Woo Ahn, PhD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-456-7387; E-mail: kwooahn@mcw.edu**
Statistician:	**Alyssa DiGilio, MS, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0660; E-mail: adigilio@mcw.edu**

---

1. **Introduction**
   The CIBMTR Hodgkin and Non-Hodgkin Lymphoma Working Committee was called to order at 2:45 pm on Thursday, February 23, 2017 by Dr. Mehdi Hamadani. Dr. Tim Fenske introduced the working committee leadership as well as the EBMT representative, Dr. Peter Dreger. Dr. Fenske also outlined the Working Committee goals, expectations, and limitations and provided an update on the Working Committee productivity including 3 publications, and 3 abstracts at the 2017 BMT Tandem meetings. Dr. Anna Sureda went over the four submitted manuscripts and reviewed the voting guidelines. The guidelines are based on a scale from 1 to 9; 1=high scientific impact, 9=low scientific impact. Alyssa DiGilio explained the difference between the TED and CRF data collection forms, the study life cycle, and the rules for authorship: 1) substantial and timely contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval for the version to be published.

2. **Accrual summary**
   Dr. Anna Sureda presented a slide with the accruals on it. Due to the full agenda, there was not much discussion on the numbers, but it was mentioned that the committee has them in attachment 2.

3. **Presentations, published or submitted papers**
   Due to the full agenda, the 2016 presentations, published papers, and submitted papers were mentioned by Dr. Fenske and Dr. Sureda but were not presented.

   a. **LY14-02** Fenske TS, Ahn KW, Graff TM, DiGilio A, Bashir Q, Kamble RT, Ayala E, Bacher U, Brammer JE, Cairo M, Chen A, Chen YB, Chhabra S, D'Souza AD, Farooq U, Freytes C, Ganguly S, Hertzberg M, Inwards D, Jaglowski S, Kharfan-Dabaja MA, Lazarus HM, Nathan S, Pawarode A,

Perales MA, Reddy N, Seo S, Sureda A, Smith SM, Hamadani M. Allogeneic transplantation provides durable remission in a subset of DLBCL patients relapsing after autologous transplantation. **Br J Haematol. 2016 Jul; 174(2):235-48: doi: 10.1111/bjh. 14046. PMID: 27269951**

b. **LY15-02** Ghosh N, Karmali R, Rocha V, Ahn KW, DiGilio A, Hari P, Bachanova V, Bacher U, Dahi P, deLima M, D'Souza A, Fenske TS, Ganguly S, Kharfan-Dabaja MA, Prestidge TD, Savani BN, Smith SM, Sureda AM, Waller EK, Jaglowski S, Herrera AF, Armand P, Salit RB, Wagner-Johnston ND, Bolanos-Meade J, Hamadani M. Reduced-intensity transplantation for lymphomas using haploidentical related donors versus HLA-matched sibling donors. **J Clin Oncol. 2016 Sep 10;34(26): 3141-9. doi: 10.1200/JCO.2015.66.3476. PMID: 27269951. Oral presentation at the 2016 BMT Tandem Meetings in Honolulu, HI, February 2016.** https://www.cibmtr.org/ReferenceCenter/Patient/PatientSummaries/Documents/2016.10.21Ghosh.pdf

c. **LY16-01b** Hamadani M, Kanate A, DiGilio A, Ahn KW, Smith SM, Lee JW, Ayala E, Chao N, Hari P, Bolaños-Meade J, Gress R, Smedegaard Anderson N, Chen Y, Farooq U, Schiller G, Yared J, Sureda A, Fenske TS, Olteanu H. Allogeneic Hematopoietic Cell Transplantation for Aggressive NK-cell Leukemia. A CIBMTR Analysis. **Biol Blood Marrow Transplant. 2017 Feb 1. pii: S1083-8791(17)30237-9. doi: 10.1016/j.bbmt.2017.01.082. [Epub ahead of print]**

d. **LY16-01a** Kanate AS, Olteanu H, Ahn KW, DiGilio A, Sureda A, Fenske TS, Smith SM, Hamadani M. Allogeneic Hematopoietic Cell Transplantation (alloHCT) for Extranodal Natural Killer (NK)/T-cell Lymphoma, Nasal Type (ENKL): A CIBMTR Analysis. **Submitted to Haematologica. Oral presentation at the 2017 BMT Tandem Meetings in Orlando, FL, February 2017.**

e. **LY15-03** Casulo C, Friedberg JW, Ahn KW, DiGilio A, Sureda A, Fenske TS, Smith SM, Hamadani M. Autologous Hematopoietic Cell Transplant (autoHCT) is Associated with Improved Overall Survival (OS) of Follicular Lymphoma (FL) Patients (pts) Experiencing Early Therapy Failure after First line Chemo-immunotherapy: A National Lymphocare study (NLCS) and CIBMTR Analysis. **Submitted to JCO. Oral presentation at the 2017 BMT Tandem Meetings in Orlando, FL, February 2017.**

f. **LY16-05** Epperla N, Ahn KW, DiGilio A, Jagasia M, Armand P, Ahmed S, Devine S, Jaglowski S, Kharfan-Dabaja MA, Kennedy V, Rezvani A, Smith SM, Sureda A, Fenske TS, Hamadani M. Rituximab (R) versus Non-Rituximab (NR) containing Reduced Intensity Conditioning (RIC) Regimens for Allogeneic Hematopoietic Cell Transplantation (alloHCT) in B-cell Non-Hodgkin Lymphomas (B-NHL): A CIBMTR Analysis. **Submitted to Lancet Haematology. Oral presentation at the 2017 BMT Tandem Meetings in Orlando, FL, February 2017.**

4. Studies in progress (Attachment 3)

a. **LY16-03** Outcome of patients who have undergone haploidentical stem cell transplantation for diffuse large B cell lymphoma: A retrospective study of the CIBMTR Lymphoma WC and the EBMT Lymphoma WP (P Dreger/A Sureda) **Protocol Development**
Dr. Peter Dreger gave an update on LY16-03. He described the point of the study: to compare haploidentical transplants with HLA identical siblings, 8/8 unrelated donors, and 7/8 unrelated donors. The EBMT numbers for this were presented: 671 HLA identical siblings, 553 8/8 URD, 129 7/8 URD, and 82 haploidentical transplants (49 of whom received post-transplant cyclophosphamide).

b. **LY16-04** Utility of autologous vs allogeneic transplant as the first transplantation approach in follicular lymphoma patients with early chemoimmunotherapy failure (J Godfrey/S Smith) **Analysis**
Dr. Sonali Smith provided an update on this study. She said the main point was to compare autologous versus allogeneic transplantation for patients experiencing early chemo-immunotherapy failure in Follicular Lymphoma. The baseline characteristics table of the patients was shown, which highlighted the three groups that will be compared in the study: autoHCT (n=240), HLA identical sibling alloHCT (n=105), and 8/8 unrelated donors (n=95).

c. **LY06-03** HLA identical sibling allogeneic stem cell transplantation versus HLA matched unrelated donor allogeneic stem cell transplantation in patients with follicular lymphoma (A Sureda/H Schouten) **Manuscript Preparation**
d. **LY14-03** Multi-center retrospective study of outcomes of autologous hematopoietic cell transplantation for patients with EBER-ISH/LMP positive relapsed/refractory Hodgkin lymphoma (P Satwani) **Deferred** *currently collecting data from centers*
e. **LY16-02** Comparison of alternative donor source stem cell transplant versus matched related donor stem cell transplant for Hodgkin Lymphoma (S Ahmed/J Kanakry) **Deferred**

5. Introduction to TED (Transplant Essential Data) vs CRF (Comprehensive Report Form) (A DiGilio)
Alyssa DiGilio emphasized the difference between the TED and CRF databases. It was emphasized that CRF is a subset of the TED database, and that the CRF forms collect all disease specific information such as lines of therapy, extranodal involvement, and prior radiation. If a study needs any of these information, they will have to be a CRF study.

6. Future/proposed studies
a. **PROP 1610-12/1611-92** Allografts in lymphoma following reduced intensity conditioning (N Ghosh/S Ahmed) (Attachment 4)
Dr. Ghosh presented this study. This study will look at five of the most reduced intensity conditioning regimens for lymphoma in order to determine which, if any, have survival benefits for transplant. There are five different regimens being compared: Flu/Bu (N=860), Flu/Mel (N=1113), Flu/Cy/TBI (N=169), 2 Gy TBI +/- Flu (N=334), and Flu/Cy (N=540). The Working Committee asked if Rituxan vs non-Rituxan in conditioning regimen would be tested. Dr. Hamadani specified that there was just an abstract presented by Dr. Epperla that looked at this exact question, but this will be added as a covariate in the model. It was also asked if the three NMA conditioning regimens would be combined into one. Dr. Hamadani said that if they were found to be statistically similar to each other, they could be combined but until we know that we cannot combine them.

b. **PROP 1611-52** Clinical outcomes of Medicare eligible patients (age ≥ 65) undergoing allogeneic hematopoietic cell transplant for relapsed/refractory Non-Hodgkin's lymphoma (N Shah) (Attachment 5)
Dr. Shah presented this study. This study plans to look at outcomes of elderly patients undergoing allogeneic stem cell transplantation for Non-Hodgkin lymphoma to see if these patients should be eligible for Medicare coverage. There are 946 patients who meet these criteria. One member of the committee asked if this proposal could be combined with the previous one, but Dr. Hamadani said that these are two different populations that are looking at a different question, so this cannot be done. Another committee member asked if maintenance therapy information would be available, to which Dr. Hamadani said we have this on a subset of

patients. It was also noted that the year of transplant would be a covariate in the model to account for variability in treatments over time.

c. **PROP 1611-97** A comparison of consolidative autologous stem cell transplantation vs non-transplant consolidation in elderly patients with mantle cell lymphoma (J Cohen/I Greenwell) (Attachment 6)
Dr. Greenwell presented this study. This study looks to use the LEO/MER database as a control non-transplant arm to be compared with the CIBMTR transplant cohort for elderly patients with mantle cell lymphoma. In the CIBMTR database, there are 532 patients undergoing first autologous transplant over age 55 with mantle cell lymphoma, but the exact number of patients in the LEO/MER database was unknown (it was estimated to be roughly 220). There were some concerns about overlap between the two datasets, which could be solved by using some identifying information to try to link patients to ensure that the non-transplant cohort truly did not get a transplant. A member of the Working Committee also suggested to do propensity matching on the two cohorts to adjust for potential differences, but because multivariate analyses do just as well as propensity score matching without losing patients from matching it was decided to not do this.

d. **PROP 1611-63** Efficacy and safety of hematopoietic cell transplantation for intravascular large B-cell lymphoma (A Kanate/ N El Jurdi) (Attachment 7)
Dr. Kanate presented this study. This study aims to look at the outcomes of autologous transplantation for intravascular large B-cell lymphoma. There were 257 patients in the CIBMTR database that met these criteria. One member of the committee asked if the number of intravascular B cell patients for pediatrics was known, but it was not. It was noted that the pathology reports will have to be checked for these cases to ensure that they are truly intravascular large B-cell cases. It was also mentioned whether the CIBMTR should add this disease to be selected more frequently for CRF track as only 43 of these patients are on the CRF track.

e. **PROP 1611-103** Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant (M Tallarico/S Smith) (Attachment 8)
Dr. Smith presented this study. This study plans to look and compare the outcomes of mantle cell lymphoma patients who had relapsed after autologous transplantation. There are 172 patients who had relapsed within 2 years post autoHCT and 174 who had relapsed after 2 years post autoHCT. One member of the committee asked if the proportion of the patients who relapsed versus those who hadn't relapsed was looked at. Another recommended censoring patients who ended up getting an allogeneic transplant at the time of their alloHCT. It was also recommended that instead of using 2 years as the cut-off to look at the data to find an appropriate cut point.

f. **PROP 1612-01** Hematopoietic stem cell transplantation for mature T- and NK- cell malignancies in children, adolescents, and young adults (A Xavier/A Flowers/M Cairo) (Attachment 9)
Dr. Cairo presented this study. This study plans to look and compare the outcomes of alloHCT vs autoHCT in CAYA patients with T- and NK- cell malignancies. There are 851 alloHCT patients and 731 autoHCT patients in the population. One member of the committee asked if we would have EBV data on these patients, but it was noted that this is not collected on the CIBMTR forms.

g. **PROP 1611-09** Impact of allogeneic hematopoietic cell transplantation on the outcomes of angioimmunoblastic T-cell lymphoma (N Epperla) (Attachment 10)
Dr. Epperla presented this study, which will look at the outcomes of alloHCT for angioimmunoblastic T-cell lymphoma. There are 329 patients in the CIBMTR database with this disease, which would be the largest study population for this group to date. It was noted by the committee that this is a very important study. Another member of the committee asked about doing an auto vs alloHCT study for this, but it was noted that these comparisons are generally tough to do, but we could describe the characteristics of patients getting each type.

h. **PROP 1611-98** Allogeneic versus autologous hematopoietic cell transplantation in patients who achieve only partial remission to salvage therapy in relapsed/refractory classical Hodgkin lymphoma (V Kenkre/M Juckett/W Longo) (Attachment 11)
Dr. Kenkre presented this study, which aims to look at alloHCT vs autoHCT for patients not in complete remission for Hodgkin lymphoma at the time of transplant. There are 695 patients receiving alloHCT and 8864 receiving autoHCT. It was noted by the committee that PET data will be essential for completing this study, and it is currently only available for 1% of the population.

Fifteen additional proposals were submitted to the committee but were not presented due to the following reasons:

a. **PROP 1606-01** Outcomes of autologous hematopoietic transplants in elderly patients with Non-Hodgkin's lymphoma: A CIBMTR analysis. *Dropped due to feasibility*
b. **PROP 1610-13** Comparison of autologous versus allogeneic hematopoietic cell transplantation for patients with HIV-associated lymphomas. *Dropped due to feasibility-low number of patients (N=10 alloHCT HIV-lymphomas)*
c. **PROP 1610-16** Predictors of successful autologous stem cell transplantation for the treatment of primary CNS lymphoma. *Dropped due to feasibility-low number of patients (N=45)*
d. **PROP 1611-11** Outcomes of mantle cell lymphoma patients receiving allogeneic hematopoietic transplantation after autologous transplantation failure. *Dropped due to feasibility*
e. **PROP 1611-17** Clinical outcomes of patients with relapsed or refractory nodular lymphocyte predominant Hodgkin Lymphoma after autologous transplant. *Dropped due to feasibility-low number of patients (N=31)*
f. **PROP 1611-43** Allogeneic hematopoietic cell therapy for central nervous system lymphoma. *Dropped due to feasibility-low number of patients (N=5)*
g. **PROP 1611-55** Impact of autologous transplantation on outcomes for MYC+ diffuse large B cell lymphomas. *Dropped due to feasibility*
h. **PROP 1611-56** Long term effects of matched and alternative donor hematopoietic cell transplantation with or without total body skin electron beam therapy in patients with MF/SS. *Dropped due to feasibility*
i. **PROP 1611-57** Conditioning regimens for autologous transplantation in relapsed/refractory Hodgkin lymphoma: is total lymphoid irradiation (TLI) comparable to a non-TLI approach with or without brentuximab maintenance? *Dropped due to feasibility-low number of patients (N=88)*
j. **PROP 1611-75** Impact of concurrent overexpression of MYC and BCL2 in patients with diffuse large B cell lymphoma treated with allogeneic or autologous SCT. *Dropped due to feasibility*
k. **PROP 1611-83** Outcomes of allogeneic compared with autologous stem cell transplantation as consolidative therapy for high risk lymphomas. *Dropped due to feasibility*
l. **PROP 1611-93** Impact of Brentuximab vedotin salvage therapy on transplant outcomes in relapsed or refractory Hodgkin's lymphoma. *Dropped due to feasibility-low number of patients (N=115)*

m. **PROP 1611-94** Donor lymphocyte infusion for the prevention and treatment of relapse in patients undergoing reduced-intensity allogeneic transplantation in lymphoma. *Dropped due to feasibility*
n. **PROP 1611-146** The role of consolidative hematopoietic cell transplantation in first complete remission of patients with lymphoblastic lymphoma treated with ALL-type induction. *Dropped due to feasibility*
o. **PROP 1612-02** Outcomes of allogeneic hematopoietic transplantation for large granular lymphocyte (LGL) leukemia: A CIBMTR Analysis. *Dropped due to feasibility*

7. Other Business

After the new proposals were presented, the voting process was reiterated, and each participant had the opportunity to rate each new proposal using paper ballots. Without additional comments, the meeting was adjourned at 4:31 pm.

Working Committee Overview Plan for 2017-2018

a. **LY06-03** Sib vs MUD for follicular NHL/EBMT with CIBMTR. We anticipate the final analysis to be done by July 1, 2015. We anticipate that the manuscript will be submitted by the end of March 2017 and published by July 1, 2017.

b. **LY14-03** Multi-center retrospective study of outcomes of autologous hematopoietic cell transplantation for patients with EBER-ISH/LMP positive relapsed/refractory Hodgkin lymphoma. This study is currently deferred and will be deferred until July 1, 2018.

c. **LY16-02** Alternative donor source stem cell transplant vs matched donor stem cell transplant for Hodgkin lymphoma. This study is currently deferred and will be deferred until July 1, 2018.

d. **LY16-03** Outcomes of patients who have undergone a haploHCT for DLBCL. We anticipate having this study in data file preparation by July 1, 2017 and in manuscript preparation by July 1, 2018.

e. **LY16-04** Utility of autologous vs. allogeneic transplant as first transplantation approach in follicular lymphoma patients with early chemoimmunotherapy failure. We anticipate having this study submitted by July 1, 2017 and published by July 1, 2018. We are targeting this paper to be submitted to JCO.

f. **LY17-01 (Prop 1611-52)** Clinical outcomes of medicare eligible patients undergoing allogeneic hematopoietic cell transplant for relapsed/refractory Non-Hodgkin's lymphoma. We anticipate having this study in manuscript preparation by July 1, 2018.

g. **LY17-02 (Prop 1610-12/1611-92)** Allografts in lymphoma following reduced intensity conditioning. We anticipate having this study in manuscript preparation by July 1, 2018.

h. **LY17-03 (Prop 1611-09)** Impact of allogeneic hematopoietic cell transplantation on the outcomes of angioimmunoblastic T-cell lymphoma. We anticipate having this study in analysis by July 1, 2018.

Oversight Assignments for Working Committee Leadership (March 2017)

Tim Fenske	**LY17-01** Clinical outcomes of medicare eligible patients undergoing allogeneic hematopoietic cell transplant for relapsed/refractory Non-Hodgkin's lymphoma
Anna Sureda	**LY16-03** Outcomes of patients who have undergone haploHCT for DLBCL **LY17-02** Allografts in lymphoma following reduced intensity conditioning
Sonali Smith	**LY16-04** Utility of autologous vs allogeneic transplant as first transplantation approach in follicular lymphoma patients with early chemoimmunotherapy failure **LY17-03** Impact of allogeneic hematopoietic cell transplantation on the outcomes of angioimmunoblastic T-cell lymphoma