



**MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
San Diego, CA
Friday, February 13, 2015, 12:15 – 2:15 pm**

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1. Introduction

The CIBMTR Hodgkin and Non-Hodgkin Lymphoma Working Committee was called to order at 12:17 pm on Friday, February 13, 2015, by Dr. David Maloney. Working Committee Leadership was introduced and the members were asked to introduce themselves as well. Dr. Maloney asked the Working Committee for approval of the 2014 minutes, and they were approved by the committee. Dr. Mehdi Hamadani introduced Dr. Timothy Fenske as the newly appointed Chair for the Hodgkin & Non-Hodgkin Lymphoma Working Committee starting March 1, 2015. Dr. Hamadani acknowledged Dr. Maloney for all of his efforts during the past years as Co-Chair. Dr. Hamadani introduced Alyssa DiGilio as the new MS statistician for the committee. He thanked Jeanette Carreras, the outgoing statistician, for all her work over the years. Working Committee goals, expectations and limitations were described by Dr. Sonali Smith as well as the CIBMTR guidelines for voting by Dr. Maloney. The guidelines are based on a scale from 1 to 9; 1=high scientific impact, 9= low scientific impact. These are consistent across all Working Committees. Each proposal was limited to 3 minutes for presentation and 5 minutes for questions and discussion. Rules of authorship were discussed. Authors must meet the following 3 conditions to assure 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. Significant contributions in productivity of the Working Committee were reported including 5 published papers, 2 oral presentations at the BMT Tandem Meetings in San Diego, CA, 1 abstract presented at ASCO 2014, and two additional abstracts currently submitted to ASCO 2015 and EHA 2015.

2. Accrual Summary (Attachment 2)

Due to the full agenda, the accrual summary of registration and research cases between 2000 and 2014 were not presented to the committee but were available as part of the Working Committee attachments.

3. Presentations, published or submitted papers

Due to the full agenda, the 2014 presentations and published papers were mentioned but not presented.

LY09-01 Wirk B, Fenske TS, Hamadani M, Zhang M-J, Hu Z-H, Akpek G, Aljurf MD, Armand P, Ayala E, Bachanova V, Bolwell B, Cairo MS, Cashen A, Chen Y-B, Costa LJ, Farhan S, Freytes CO, Gajewski JL, Gibson J, Hale GA, Holmberg LA, Hsu JW, Inwards DJ, Kamble RT, Maharaj D, Maziarz RT, Munker R, Nath R, Reddy NM, Reeder CB, Rizzieri DA, Sauter CS, Savani BN, Schouten HC, Sureda A, Vose JM, Waller EK, Wiernik PH, Gale RP, Burns LJ, Saber W. Outcomes of hematopoietic cell transplantation for diffuse large B cell lymphoma transformed from follicular lymphoma. ***Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation. 2014 Jul 1; 20(7):951-959.***

LY07-02 Lechowicz MJ, Lazarus HM, Carreras J, Laport GG, Cutler CS, Wiernik PH, Hale GA, Maharaj D, Gale RP, Rowlings PA, Freytes CO, Miller AM, Vose JM, Maziarz RT, Montoto S, Maloney DG, Hari PN. Allogeneic hematopoietic cell transplantation for mycosis fungoides and sezary syndrome. ***Bone Marrow Transplantation. 2014 Nov 1; 49(11):1360-1365.***

LY13-01 Hamadani M, Hari PN, Zhang Y, Carreras J, Akpek G, Aljurf MD, Ayala E, Bachanova V, Chen AI, Chen Y-B, Costa LJ, Fenske TS, Freytes CO, Ganguly S, Hertzberg MS, Holmberg LA, Inwards DJ, Kamble RT, Kanfer EJ, Lazarus HM, Marks DI, Nishihori T, Olsson R, Reddy NM, Rizzieri DA, Savani BN, Solh M, Vose JM, Wirk B, Maloney DG, Smith SM, Montoto S, Saber W. Early failure of frontline rituximab-containing chemoimmunotherapy in diffuse large B-cell lymphoma does not predict futility of autologous hematopoietic cell transplantation. ***Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation. 2014 Nov 1; 20(11):1729-1736.***

LY10-02 Bachanova V, Burns LJ, Wang T, Carreras J, Gale RP, Wiernik PH, Ballen KK, Wirk B, Munker R, Rizzieri DA, Chen Y-B, Gibson J, Akpek, Costa LJ, Kamble RT, Aljurf MD, Hsu JW, Cairo MS, Schouten HC, Bacher U, Savani BN, Wingard JR, Lazarus HM, Laport GG, Montoto S, Maloney DG, Smith SM, Brunstein C, Saber W. Alternative donors extend transplantation for patients with lymphoma who lack an HLA matched donor. ***Bone Marrow Transplantation. doi:10.1038/bmt.2014.259. Epub 2014 Nov 17.***

LY12-02/GV11-01 Alvaro Urbano Ispizua, Steve Pavletic, Mary Flowers, Mei-Jie Zhang, Jeanette Carreras, Sonali Smith, David Maloney, Silvia Montoto, Corey Cutler, Steve Spellman, Mukta Arora, and Wael Saber. Association of graft vs. host disease with a lower relapse/progression rate after allogeneic hemopoietic stem cell transplantation with reduced intensity conditioning in patients with follicular and mantle cell lymphoma. ***Submitted to Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation.***

LY12-01 Veronika Bachanova, Linda Burns, Kwang Woo Ahn, Jeanette Carreras, David Maloney, Anna Sureda, Sonali Smith, Mehdi Hamadani. Positive pre-allogeneic hematopoietic cell transplantation PET scan in patients with non-Hodgkin lymphoma predicts higher risk of relapse but has no impact on survival. ***Oral presentation at the BMT Tandem Meetings in San Diego, CA, February 2015.***

LY13-02 Prakash Satwani, Kwang Woo Ahn, Jeanette Carreras, David Maloney, Anna Sureda, Sonali Smith, Mehdi Hamadani. Risk Factors Predicting Outcomes of Autologous Hematopoietic Cell Transplantation in Children, Adolescents and Young Adults (CAYA) with Relapsed/Refractory (Rel/Ref)

Classical Hodgkin Lymphoma: A CIBMTR Analysis. **Oral presentation at the BMT Tandem Meetings in San Diego, CA, February 2015.**

4. Studies in progress (Attachment 3)

Update on the current status of studies in progress was provided by Dr. Mehdi Hamadani.

LY12-01 Positron Emission Tomography Imaging Prior to AlloHCT for lymphoma (V Bachanova)	Submitted
LY13-02 Outcome after AutoHCT for CAYA with relapsed/refractory Hodgkin lymphoma (P Satwani)	Submitted
LY13-03 Auto vs NMA/RIC for relapsed/refractory follicular lymphoma (E Klyuchnikov)	Manuscript Preparation
LY06-03 Sib vs MUD for follicular NHL/EBMT with CIBMTR (A Sureda)	Data File Preparation
LY14-02 AlloHCT for DLBCL after a failed AutoHCT (T Fenske)	Protocol Development

5. Future/proposed studies

PROP 1410-09 Comparison of allogeneic stem cell transplantation to autologous stem cell transplantation for patients with early relapsed and primary refractory diffuse large B cell lymphoma (N Ghosh) (Attachment 4)

Dr. Ghosh presented the study. This study will determine whether alloHCT is a better form of treatment than autoHCT in primary refractory or early relapsed diffuse large B-cell lymphoma. Currently autoHCT is the standard of treatment, but analyses proving that this is the best method have discrepancies. To sort out these discrepancies, this study will look at only chemosensitive patients who have early relapsed and primary refractory DLBCL and identify subsets of patients in which alloHCT has comparable or better outcomes to autoHCT. In the alloHCT arm, there are 77 patients, and in the autoHCT arm there are 300 patients. The Working Committee pointed out that time to transplant must be taken into account as there could be fewer allo patients due to the longer wait time to transplant. They also noted that the reasons why a particular patient received an alloHCT over an autoHCT must be taken into account in order to be able to compare the groups.

PROP 1410-10 Does Autologous Stem Cell Transplant Overcome the Increased Risk of Death in Patients with Follicular Lymphoma Relapsing Early after First Line Chemoimmunotherapy? (C Casulo/J Friedberg) (Attachment 5)

Dr. Casulo presented this study. The study will look at patients with Follicular Lymphoma who relapsed within two years of initial chemotherapy treatment and determine whether an autologous transplant for these patients improves outcomes. The control arm will be used from the National LymphoCare Study. There are 169 patients reported to the CIBMTR who meet this criterion. There were 68 patients in the control arm from the LymphoCare study. The Working Committee suggested limiting this to people who have had a transplant within a specified time limit of treatment failure. It was also suggested to only consider the first disease progression.

PROP 1411-17/1411-93 Hematopoietic Cell Transplantation for NK/T-cell Non-Hodgkin Lymphoma (S Barta/H Fung/G Akpek) (Attachment 6)

Dr. Barta presented the study. This study will evaluate transplant outcomes following autologous or allogenic HCT in patients with Natural Killer/T-cell Lymphoma. It will also look to see which type of transplant should be prioritized and which groups will benefit from these transplants. From the CIBMTR database, there were 99 patients who had filled out CRF forms for an allogenic HCT, and 51

for an autologous HCT. The Working Committee commented that there could be some pre-specific biases toward doing either an allogeneic or autologous transplant. They also suggested doing an age cut off to keep the groups comparable.

PROP 1411-35 Allogeneic Hematopoietic Stem Cell Transplantation in HTLV-1 associated Adult T-cell Lymphoma/Leukemia (P Dahi/C Sauter/MA Perales) (Attachment 7)

Dr. Dahi presented this study. The study will look at transplant in HTLV-1 ATLL. There is a current Japanese series exploring this, but this dataset using mostly Japanese-descent patients. The study will look at patients over 18 who had a HSCT for HTLV-1-ATLL from 2000-2013. There are 171 total patients in the CIBMTR database of which 70 are on the research track. The Working Committee brought up the limitation that there is no control or comparative group in this study.

PROP 1411-15 Hematopoietic cell transplantation (HCT) outcomes for relapsed or refractory marginal zone lymphomas (B William/B Hill/H Lazarus) (Attachment 8)

Dr. William presented this study. The study will look at whether HCT for relapsed or refractory marginal zone lymphoma will have better outcomes than conventional therapy. The non-transplanted MZL cohort has 358 patients. From the CIBMTR database, there are 293 patients who had autoHCT and 158 patients who had alloHCT. The Working Committee suggested that a better control would be relapsed or refractory disease without a transplant. Dr. William said if approved, he would look into this.

PROP 1411-83 A retrospective review of outcomes with allogeneic transplant outcomes for gamma-delta T cell lymphoma (J Gajewski/R Maziarz) (Attachment 9)

Dr. Gajewski presented this study. This study looks to see whether alloHCT can offer a long-term curative option for patients with gamma-delta T cell lymphoma. There were 63 patients in the CIBMTR database who received an allogeneic HCT for gamma-delta T-Cell lymphoma from 1999-2013. Dr. Gajewski recognized that this is a very small number, but said that this is larger than most non-transplant studies. He stressed the importance of reporting transplant usage and outcomes with rare diseases such as this. Dr. Sureda asked Dr. William whether pathology reviews were available on these patients. Dr. William said that they may be able to get this depending on funding.

PROP 1408-02/1411-27 Alternative Donor Allogeneic Hematopoietic Transplantation Strategies for Lymphoid Malignancies in Adult Patients: Comparing Matched Unrelated versus Haploidentical Related Donor Transplantation (A Kanate/A Mussetti/K Dabaja) (Attachment 10)

Dr. Kanate presented the study. This study will compare haploidentical donors to matched unrelated donors. It was noted that no studies on this have been done for lymphoid malignancies. The study looks at patients who underwent an allogeneic transplant (with either a haploidentical or matched unrelated donor) for lymphoma (either Hodgkin's or Non-Hodgkin's) between 2007 and 2013. This study will only look at those who had received RIC or NMA conditioning. In the CIBMTR database, there are 136 patients who underwent a haploidentical transplant and 553 who underwent a matched unrelated donor transplant. The Working Committee suggested excluding those with Hodgkin's Disease as most people with HD receiving an allogeneic transplant had a prior failed autologous transplant. It was also suggested to look at the center distribution to make sure that there is not a center effect.

PROP 1411-06/1411-36/1412-13 Comparing Outcomes between Haploidentical and HLA Matched Related Donor Transplants for Patients with Lymphoid Malignancies (R Karmali/N Ghosh/V Rocha) (Attachment 11)

Not for publication or presentation

Dr. Ghosh presented this study. The study looks to see whether there is any advantage to choosing a haploidentical donor over an HLA matched related donor. Like the previous proposal, there are 136 haploidentical transplants, and there were 1141 HLA identical sibling transplants conducted. The Working Committee suggested combining proposals 1408-02/1411-27 and 1411-06/1411-36/1412-13. This would make for a study comparing matched unrelated donors and HLA identical siblings to haploidentical donors. It was suggested to drop those patients who had received myeloablative conditioning in this proposal.

Twenty-two additional proposals were submitted to the committee but were not presented due to the following reasons:

LY14-01: Updated prognostic information for lymphoma survivors beyond 1 year from allogeneic hematopoietic cell transplantation. A landmark CIBMTR analysis (A Lazaryan). *Dropped due to feasibility.*

PROP 1408-01 Comparison of twin and autologous transplants for Non-Hodgkin Lymphoma (M Mir) *Dropped due to limited by heterogeneity and feasibility-low number of twin patients.*

PROP 1408-03 Role of FDG-PET prior to allogeneic transplantation in predicting outcomes for patients with relapsed or refractory Hodgkin lymphoma: A CIBMTR Analysis (A Lazaryan) *Dropped due to feasibility-supplemental data and low number of patients (n=70).*

PROP 1409-01 Allogeneic transplantation for older patients with non-Hodgkin Lymphoma (V Bachanova) *Dropped due to overlap with LK07-03c.*

PROP 1409-06 Outcome following autologous hematopoietic cell transplantation (AHCT) in plasmablastic lymphoma (PBL): A combined analysis of CIBMTR and EBMT data (M Al Malk) *Dropped due to feasibility-low number of patients (n=3).*

PROP 1409-08 Outcomes of upfront autologous stem cell transplantation in adult mantle cell lymphoma - is there an ideal induction regimen? (L Veltri) *Dropped due to feasibility.*

PROP 1401-01 Case control study of busulfan, melphalan, and thiotepa (BuMelTt) versus alternative myeloablative conditioning regimens in autologous hematopoietic stem cell transplant for relapsed/refractory Hodgkin's Lymphoma (HL) (J Brammer) *Dropped due to feasibility-low number of patients (n=3).*

PROP 1410-06 Comparison of outcomes for patients with relapsed/refractory mantle cell lymphoma after RIT-based versus standard autologous stem cell transplantation (E Klyuchnikov) *Dropped due to feasibility-low number of patients (n=7).*

PROP 1410-14 Comparison of consolidation with allogeneic versus autologous hematopoietic cell transplantation for patients with relapsed/refractory diffuse large B cell lymphoma achieving a partial metabolic response to salvage chemotherapy (D Landsburg) *Dropped due to feasibility-supplemental data.*

PROP 1411-04 Identifying Prognostic Factors and Treatment Strategies that Impact Clinical Outcomes in Patients with Primary Central Nervous System Lymphoma (PCNSL) undergoing Autologous Stem Cell Transplantation in the Rituximab Era (R Karmali) *Dropped due to feasibility-low number of patients (n=24).*

PROP 1411-05 Impact of Obesity and Diabetes on Outcomes after Autologous Hematopoietic Stem Cell Transplantation in Aggressive Lymphomas (R Karmali) *Dropped due to feasibility-supplemental data.*

PROP 1411-08 Multi-center retrospective study of outcomes of autologous hematopoietic cell transplantation for patients with EBER-ISH/LMP positive relapsed/refractory Hodgkin lymphoma (P Satwani) *Dropped due to feasibility.*

PROP 1411-25 Prognostic model for patients with DLBCL relapsing after auto-HCT (L Costa) *Dropped due to feasibility-supplemental data.*

PROP 1411-34 Prognostic model for relapsed Diffuse Large B Cell Lymphoma undergoing consolidation with hematopoietic cell transplant (HCT) (A Hallack Neto) *Dropped due to feasibility-supplemental data.*

PROP 1411-48 Is Reduced Intensity BEAM as equally effective as BEAM for relapsed Diffuse Large B-cell Lymphoma in 2nd Remission? (M Sharma) *Dropped due to feasibility.*

PROP 1411-51 Retrospective comparative study of blood or bone marrow transplantation for relapsed/refractory Hodgkin lymphoma by donor type (J Kanakry) *Dropped due to overlap with LY10-02 and low number of patients (n=27 in haploidentical cohort).*

PROP 1411-52 Impact of mobilization strategies with plerixafor versus chemomobilization with cyclophosphamide for non-Hodgkin lymphoma (NHL) on outcomes after autologous stem cell transplant (C Vigil) *Dropped due to feasibility-supplemental data.*

PROP 1411-62 Impact of brentuximab vedotin on outcomes of allogeneic hematopoietic cell transplantation for relapsed or refractory Hodgkin lymphoma (B Wirk) *Dropped due to feasibility-low number of patients (n=5).*

PROP 1412-07 Brentuximab Vedotin used to bridge patients into successful reduced intensity allogeneic or second autologous stem cell transplantation in relapsed or refractory Hodgkin's lymphoma post autologous stem cell transplantation (S Altouri) *Dropped due to feasibility-low number of patients (n=5).*

PROP 1411-91 Outcomes Following Allogeneic Stem Cell Transplant for Relapsed Primary or Secondary Central Nervous System Lymphoma (S Jaglowski) *Dropped due to low number of cases.*

PROP 1411-70 Autologous stem cell transplant in elderly patients with Hodgkin Lymphoma (MA Perales) *Dropped due to feasibility-low number of patients (n=39).*

PROP 1412-06 Efficacy of BCNU vs. non- BCNU containing conditioning regimens on the outcomes of autologous stem cell transplantation for relapsed Diffuse large B-cell lymphoma and Hodgkin's Lymphoma (S Altouri) *Dropped due to overlap with SC10-06.*

6. Other Business

After the new proposals were presented, Dr. Maloney reiterated the voting process, and each participant had the opportunity to rate each proposal using paper ballots. Without additional comments, the meeting was adjourned at 1:59 pm.

Working Committee Overview Plan for 2015-2016

- a. **LY12-01** Positron Emission Tomography Imaging Prior to AlloHCT for Lymphoma. We anticipate having the manuscript published before July 1, 2015.
- b. **LY13-02** Outcomes of autologous stem cell transplantation for children, adolescents and young adults with relapsed/refractory Hodgkin lymphoma. We anticipate having the manuscript published before July 1, 2015.
- c. **LY13-03** Comparison of autologous versus RIC allogeneic stem cell transplantation for relapsed/refractory patients with follicular lymphoma. We anticipate having one paper from this analysis submitted and another one in manuscript preparation by July 1, 2015. We anticipate having these published by July 1, 2016.
- d. **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 July 1, 2016.
- e. **LY14-02** Outcome of patients with relapsed diffuse large B-cell lymphoma treated with allogeneic hematopoietic cell transplantation following a failed autologous HCT. We anticipate having the data file preparation completed and ready for analysis before July 1, 2015.
- f. **LY14-03** Multi-center retrospective study of outcomes of autologous hematopoietic cell transplantation for patients with EBER-ISH/LMP positive relapsed/refractory Hodgkin lymphoma. We anticipate having this study in protocol development by July 1, 2015 and in the analysis stage by July 1, 2016.
- g. **LY15-01 (Prop 1408-02/1411-27)** Alternative donor allogeneic hematopoietic transplantation strategies for lymphoid malignancies in adult patients: comparing matched unrelated versus haploidentical related donor transplantation. We anticipate having this study submitted by July 1, 2016.
- h. **LY15-02 (Prop 1411-06/1411-36/1412-13)** Comparing outcomes between haploidentical and HLA matched related donor transplants for patients with lymphoid malignancies. We anticipate having this study submitted by July 1, 2016.
- i. **LY15-03 (Prop 1410-10)** Does autologous stem cell transplant overcome the increased risk of death in patients with follicular lymphoma relapsing early after first line chemoimmunotherapy? We anticipate having this study in manuscript preparation by July 1, 2016.

Oversight Assignments for Working Committee Leadership (March 2015)

Tim Fenske	<p>LY14-02 Outcome of patients with relapsed diffuse large B-cell lymphoma treated with allogeneic hematopoietic cell transplantation following a failed autologous HCT</p> <p>LY15-03 Does autologous stem cell transplant overcome the increased risk of death in patients with follicular lymphoma relapsing early after first line chemoimmunotherapy?</p>
Anna Sureda	<p>LY15-01 Alternative donor allogeneic hematopoietic transplantation strategies for lymphoid malignancies in adult patients: comparing matched unrelated versus haploidentical related donor transplantation.</p>
Sonali Smith	<p>LY15-02 Comparing outcomes between haploidentical and HLA matched related donor transplants for patients with lymphoid malignancies.</p>
Mehdi Hamadani	<p>LY13-02: Outcomes of autologous stem cell transplantation for children, adolescents and young adults with relapsed/refractory Hodgkin lymphoma.</p> <p>LY13-03: Comparison of autologous versus RIC allogeneic stem cell transplantation for relapsed/refractory patients with follicular lymphoma.</p> <p>LY06-03: Allogeneic hematopoietic cell transplantation for relapsed follicular lymphoma: impact of donor type and prognostic risk score for survival</p>