Not for publication or presentation

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A G E N D A
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
Orlando, FL
Wednesday, February 19, 2020 12:15-2:45 pm

Co-Chair:	**Timothy Fenske, MD, Medical College of Wisconsin, Milwaukee, WI; Telephone: 414-805-4633; E-mail: tfenske@mcw.edu**
Co-Chair:	**Mohamed Kharfan-Dabaja, MD, MBA, Mayo Clinic, Jacksonville, FL; Telephone: 904-953-2000; E-mail: kharfandabaja.mohamed@mayo.edu**
Co-Chair:	**Craig Sauter, MD, Memorial Sloan Kettering Cancer Center, New York, NY; Telephone: 212-639-3460; E-mail: sauterc@mskcc.org**
Scientific Director:	**Mehdi Hamadani, MD, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0700; E-mail: mhamadani@mcw.edu**
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Statistician:	**Andrew St. Martin, MS, CIBMTR Statistical Center, Milwaukee, WI; Telephone: 414-805-0682; E-mail: astmartin@mcw.edu**

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1. **Introduction**
   a. Minutes and Overview Plan from February 2019 meeting (Attachment 1)

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

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

   a. **LY17-01b** Allogeneic transplantation in elderly patients ≥65 years with non-Hodgkin lymphoma: a time-trend analysis. (N Shah) *Published in Blood Cancer Journal. Oral presentation at the 2019 EBMT Annual Meeting.*
   b. **LY17-02a** Impact of type of reduced-intensity conditioning regimen on the outcomes of allogeneic hematopoietic cell transplantation in classical Hodgkin lymphoma. *Submitted. Presented at ASH Annual Meeting.*
   c. **LY17-02b** Evaluating impact of reduced-intensity conditioning regimens on overall survival in non-Hodgkin lymphoma patients undergoing allogeneic transplantation. A CIBMTR registry analysis. *Submitted. Oral presentation at the ASH Annual Meeting.*
   d. **LY17-02c** Higher total body irradiation dose-intensity in fludarabine/TBI-based reduced-intensity conditioning regimen is associated with inferior survival in non-Hodgkin lymphoma patients undergoing allogeneic transplantation. *Submitted.*
   e. **LY17-02d** Reduced intensity conditioning in allografts for diffused large B-cell lymphoma (Internal) *Oral presentation at the upcoming 2020 EBMT Annual Meeting.*
   f. **LY18-01** Outcomes of rituximab-BEAM vs. BEAM conditioning regimen in patients with diffuse large B-cell lymphoma undergoing autologous transplantation. (D Jagadeesh) *Submitted. Oral presentation at the ASH Annual Meeting.*

4. **Studies in progress** (Attachment 3)

a. **LY17-02d** 2 versus 4 centigray fludarabine/total body irradiation in allografts for non-hodgkin lymphoma (Internal) **Manuscript Preparation**
b. **LY18-01b** Outcomes in b cell non-hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning regimens in partial remission (Internal) **Manuscript Development**
c. **LY18-02** Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant (P Riedell/S Smith) **Data file preparation**
d. **LY18-03** Transplantation for CLL undergoing Richter's Transformation arising in the setting of indolent lymphoma (A Herrera) **Data accrual**
e. **LY19-01** Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: A CIBMTR Lymphoma working committee and EBMT Lymphoma working party analysis (P Dreger/M Hamadani) **Data file preparation**
f. **LY19-02** Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation (M Scordo/C Sauter/A Jimenez) **Protocol Development**

5. Future/proposed studies

a. **PROP 1911-51** CAR-T cell Therapy versus Autologous Transplant in Early Rituximab Failure Patients with Diffuse Large B-cell Lymphoma (Shah) (Attachment 4)
b. **PROP 1911-22** Outcomes of hematopoietic stem cell transplant as treatment of post-transplant lymphoproliferative disorders (Farhan) (Attachment 5)
c. **PROP 1911-88** Outcomes of autologous and allogeneic hematopoietic cell transplantation for Burkitt Lymphoma (Hashmi, Khimani, Nishihori) (Attachment 6)
d. **PROP 1911-93** Evaluating outcomes of Hematopoietic Cell Transplantation in Hepatosplenic T Cell Lymphoma (Murthy, Iqbal, Kharfan-Dabaja) (Attachment 7)
e. **PROP 1911-267** Comparison of outcomes of DLBCL patients with partial response after salvage therapy who underwent CAR-T vs. ASCT. (Shadman) (Attachment 8)
f. **PROP 1910-01/1911-61/1911-185** Outcomes of salvage AHCT in double hit DLBCL (Manjappa, Karmali, Wirk, Caimi, Metheny) (Attachment 9)
g. **PROP 1911-256** Outcome of Patients with Primary Refractory Diffuse large B cell lymphoma (DLBCL) undergoing Autologous Stem Cell Transplantation (AHCT) (Bal, Sauter, Costa) (Attachment 10)
h. **PROP 1911-121** Outcomes of autologous stem cell transplantation in patients with follicular lymphoma with early relapse after frontline Bendamustine/Rituximab treatment. (Sheikh, Keating, Kuruvilla) (Attachment 11)
i. **PROP 1911-42** Outcomes of Allogeneic HCT in patients with Hodgkin Lymphoma in the era of Checkpoint Inhibitors: A joint CIBMTR and EBMT analysis. (Perales, Sureda, Awan, Montoto) (Attachment 12)
j. **PROP 1911-204** Trends in Survival post-autologous transplant in Classical Hodgkin Lymphoma. (Shah) (Attachment 13)

Proposed studies; not accepted for consideration at this time

a. **PROP 1909--04** Outcomes of allogeneic stem cell transplantation with different donor types for patients with lymphomas not in remission at the time of transplant.
b. **PROP 1910-02** Optimizing timing of autologous transplantation for transformed follicular lymphoma.

c. **PROP 1911-11** Efficacy of allogeneic transplant in marginal zone lymphoma.
d. **PROP 1911-22** Outcomes of hematopoietic stem cell transplant as treatment of post-transplant lymphoproliferative disorders.
e. **PROP 1911-28** Outcomes of relapsed/refractory lymphoma patients treated with benda-EAM (bendamustine, etoposide, cytarabine, melphalan) versus BEAM (carmustine, etoposide, cytarabine, melphalan) high dose chemotherapy followed by autologous stem cell transplantation.
f. **PROP 1911-32** Impact of pre-transplant induction therapy on outcomes of patient who undergo autologous stem cell transplantation for mantle cell lymphoma in CR1.
g. **PROP 1911-47** Hematopoietic stem cell transplantation for relapsed/refractory marginal zone lymphoma.
h. **PROP 1911-70** Clinical impact of partial remission versus complete remission on outcomes in follicular lymphoma after autologous stem cell transplantation.
i. **PROP 1911-72** Determination of outcomes of upfront consolidative autologous stem cell transplantation in patients with high FLIPI score follicular lymphoma.
j. **PROP 1911-85** Outcomes of allogeneic hematopoietic cell transplantation for mycosis fungoides and Sezary syndrome.
k. **PROP 1911-87** Outcomes of autologous and allogeneic hematopoietic cell transplantation for primary mediastinal large B-Cell lymphoma.
l. **PROP 1911-98** Evaluating the efficacy of high-dose therapy and autologous hematopoietic cell transplantation for primary effusion lymphoma.
m. **PROP 1911-101** Outcomes of patients with mantle cell lymphoma with aberrant TP53 treated with consolidative autologous or allogeneic stem cell transplant.
n. **PROP 1911-126** Outcomes in elderly patients (age ≥ 70) received autologous hematopoietic stem cell transplantation for non-Hodgkin lymphoma.
o. **PROP 1911-136** Matched versus alternative donor allogeneic hematopoietic stem cell transplantation in HTLV-1 associated adult T-cell lymphoma/leukemia in patients of non-Japanese descent.
p. **PROP 1911-151** Outcomes of reduced intensity allografts in classical Hodgkin lymphoma after brentuximab maintenance therapy.
q. **PROP 1911-157** Outcomes of patients ≥ 65 years old undergoing autologous stem cell transplant for mantle cell lymphoma.
r. **PROP 1911-192** Outcomes following allogeneic hematopoietic stem cell transplantation for mycosis fungoides and Sezary syndrome.
s. **PROP 1911-208** Autologous stem cell transplantation for HIV seropositive patients with hematological malignancies.
t. **PROP 1911-222** Utilization and outcomes of autologous and allogeneic HSCT in CNS lymphomas.
u. **PROP 1911-227** Outcomes of patients with HTLV-1 associated adult T cell lymphoma/leukemia: A combined American and European experience.
v. **PROP 1911-229** Effect of mobilization agent on risk of second hematological malignancy in patients with lymphoma who received autologous transplant.
w. **PROP 1911-231** Outcome of autologous and allogeneic hematopoietic cell transplant in marginal zone lymphoma.
x. **PROP 1911-239** High dose therapy and autologous stem cell transplantation in primary central nervous lymphoma in older adults.
y. **PROP 1911-244** Impact of pre- and post-transplantation lymphopenia and 18F-fluorodeoxy glucose–positron emission tomography status on outcomes after autologous hematopoietic cell transplantation for peripheral T-cell lymphoma.

z. **PROP 1911-257** Outcome of autologous hematopoietic stem cell transplant in older patients (age >70 years) with non-Hodgkin's lymphoma.

7. **Other Business**

MINUTES AND OVERVIEW PLAN
CIBMTR LYMPHOMA WORKING COMMITTEE
Houston, Texas
Thursday, February 21, 2019, 12:15 – 2:15 pm

Co-Chair:	**Mohamed Kharfan-Dabaja, MD, MBA, Mayo Clinic, Jacksonville, FL; Telephone: 904-953-2000; E-mail: kharfandabaja.mohamed@mayo.edu**
Co-Chair:	**Anna Sureda, MD, PhD, Institut Català d'Oncologia, Barcelona, Spain; Telephone: +34 9326 07353; 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**
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1. Introduction

The CIBMTR Hodgkin and Non-Hodgkin Lymphoma Working Committee was called to order at 12:15 pm on Thursday, February 21, 2019 by Dr. Mehdi Hamadani. Dr. Anna Sureda introduced the working committee leadership. Dr. Sureda also outlined the Working Committee goals, expectations, and limitations and provided an update on the Working Committee productivity including 5 publications, and 1 oral presentation at the 2019 EBMT meetings, and 3 poster presentations at American Society of Hematology, American Society of Clinical Oncology and 2019 TCT meetings. Dr. Timothy Fenske went over the seven studies in progress and reviewed the voting guidelines. The guidelines are based on a scale from 1 to 9; 1=high scientific impact, 9=low scientific impact. In addition, Dr. Fenske presented the future priority of our studies. Dr. Mehdi Hamadani explained the difference between the TED and CRF data collection forms, the study life cycle, disclosure of conflict of interest 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. Dr. Hamadani emphasized that WC authorship is open to any LYWC Tandem Meetings attendees and encouraged junior faculty, fellows and assistant professors to collaborate actively with the Lymphoma Writing Committee.

2. Accrual summary

Dr. Timothy Fenske presented a slide with the accruals, highlighting a change in the past years. It was mentioned that the accrual summary was available in the LYWC materials, attachment 2.

3. Presentations, published or submitted papers

Dr. Timothy Fenske listed the presentations and publications during 2018, highlighting the great

productivity of the LYWC, including the following studies published or presented:

1. **LY06-03** Sureda A, Zhang M-J, Dreger P, Carreras J, Fenske T, Finel H, Schouten H, Montoto S, Robinson S, Smith SM, Boumedil A, Hamadani M, Pasquini MC. Allogeneic hematopoietic stem cell transplantation for relapsed follicular lymphoma: A combined analysis on behalf of the Lymphoma Working Party of the EBMT and the Lymphoma Committee of the CIBMTR. **Cancer. 2018 Apr 15; 124(8):1733-1742.**
2. **LY16-03** Dreger P, Sureda A, Ahn KW, Eapen M, Litovich C, Finel H, Boumendil A, Gopal A, Herrera AF, Schimd C, Diez-Martin JL, Fuchs E, Bolaños-Meade, J, Gooptu M, Al Malki MM, Castagna L, Ciurea SO, Dominetto A, Blaise D, Ciceri F, Tischer J, Corradini P, Montoto S, Robinson S, Gülbas Z, Hamadani M. 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) **Blood Advances (In Press).**
3. **LY16-04** Smith SM, Godfrey J, Ahn KW, DiGilio A, Ahmed S, Agrawal V, Bachanova V, Bacher U, Bashey A, Bolaños-Meade J, Cairo M, Chen A, Chhabra S, Copelan E, Dahi PB, Aljurf M, Farooq U, Ganguly S, Hertzberg M, Holmberg L, Inwards D, Kanate AS, Karmali R, Kenkre VP, Kharfan-Dabaja MA, Klein A, Lazarus HM, Mei M, Mussetti A, Nishihori T, Ramakrishnan Geethakumari P, Saad A, Savani BN, Schouten HC, Shah N, Urbano-Ispizua A, Vij R, Vose J, Sureda A, Hamadani M. Autologous transplantation versus allogeneic transplantation in patients with follicular lymphoma experiencing early treatment failure. **Cancer. 2018 Jun 15; 124(12):2541-2551.**
4. **LY17-01** Shah NN, Ahn KW, Litovich C, Fenske TS, Ahmed S, Battiwalla M, Bejanyan N, Dahi PB, Bolaños-Meade J, Chen AI, Ciurea SO, Bachanova V, DeFilipp Z, Epperla N, Farhadfar N, Herrera AF, Haverkos BM, Holmberg L, Hossain NM, Kharfan-Dabaja MA, Kenkre VP, Lazarus HM, Murthy HS, Nishihori T, Rezvani AR, D'Souza A, Savani BN, Ulrickson ML, Waller EK, Sureda A, Smith SM, Hamadani M. Outcomes of Medicare-age eligible NHL patients receiving RIC allogeneic transplantation: A CIBMTR analysis. **Blood Advances. 2018 Apr 24; 2(8):933-940.**
5. **LY17-03** Epperla N, Kwang AW, Litovich C, Kharfan-Dabaja MA, Smith SM, Sureda A, Fenske TS, Hamadani M. Impact of allogeneic hematopoietic cell transplantation on the outcomes of Angioimmunoblastic T-cell lymphoma. **Journal of Hematologic Oncology (In Press).**
6. **LY17-03** Impact of allogeneic hematopoietic cell transplantation on the outcomes of Angioimmunoblastic T-cell lymphoma (N Epperla) **Accepted for oral presentation at the 2018 American Society of Hematology Meeting in San Diego, December 2018.**

4. Studies in progress

Dr. Timothy Fenske presented the studies in progress and gave an overview of the current standing of each study.

7. **LY16-02** Comparison of alternative donor source stem cell transplant versus matched related donor stem cell transplant for Hodgkin lymphoma (S Ahmed/J Kanakry) **Submitted**
8. **LY17-01b** Clinical outcomes of patients age >=65 undergoing allogeneic hematopoietic cell transplant for non-Hodgkin lymphoma (N Shah) **Manuscript Preparation**
9. **LY17-02** Allografts in lymphoma following reduced intensity conditioning (N Ghosh/S Ahmed) **Analysis**
10. **LY18-01** Outcomes in b cell non-Hodgkin lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning regimens (D Jagadeesh/N Majhail/B Hill) **Protocol Development**
11. **LY18-02** Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant (P Riedell/S Smith) **Protocol Development**

12. **LY18-03** Does outcome after allogeneic hematopoietic stem cell transplant differ between patients with de novo diffuse large b-cell lymphoma and transformed diffuse large b cell lymphoma arising in the setting of indolent lymphoma (A Herrera) **Protocol Development**
13. **LY18-G1** Maintenance therapies for Hodgkin and non-Hodgkin lymphomas after autologous transplantation: a consensus project of ASBMT, CIBMTR and EBMT (M Hamadani) **Manuscript Preparation**

5. Introduction to TED (Transplant Essential Data) vs CRF (Comprehensive Report Form)
(M Hamadani)
Dr. Mehdi Hamadani 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 this information, CRF level data is needed on the study.

6. Future/proposed studies

1. **PROP 1808-02** Evaluating the efficacy of high-dose therapy and autologous hematopoietic cell transplantation for gray zone lymphoma or aggressive B-cell lymphoma with features intermediate between diffuse large B- cell and Hodgkin lymphoma. (Kharfan-Dabaja, Ayala, Murthy) (Attachment 4) *The optimal treatment for GZL remains undefined. This concepts intends to study outcomes of rare disease histology.*
2. **PROP 1809-01** Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell Lymphoma: A CIBMTR Lymphoma working committee & EBMT Lymphoma working party analysis (Dreger, Hamadani) (Attachment 5) *This concept intends to compare outcomes for different donor types in PTCL, the most common indication for alloHCT in NHL.*
3. **PROP 1810-02/1811-56** Evaluating the impact of checkpoint inhibitor exposure on the outcomes of allogeneic hematopoietic cell transplantation in patients with Hodgkin lymphoma; Outcomes of allogeneic HCT in patients with Hodgkin lymphoma in the era of checkpoint inhibitors (Awan, Perales, Sureda) (Attachment 6) *This concept pretends to test if results of alloHCT for HL have improved in the recent era due to improvement of post-HCT outcomes through disease relapse, due to prior CPI.*
4. **PROP 1810-07** Autologous transplantation vs allogeneic transplantation in patients with angioimmunoblastic t-cell lymphoma (Epperla) (Attachment 7) *This concept intends to study outcomes of a rare histology of NHL, testing if allogeneic HCT provides durable remission compared to autoHCT.*
5. **PROP 1811-08/1811-191** An evaluation of the use and impact of post-transplant brentuximab vedotin in patients with classical Hodgkin lymphoma; The use of hematopoietic stem cell transplant for Hodgkin lymphoma: an analysis of treatment patterns in the modern era of novel agents (Cohen, Parsons, Kumar, Hahn; Smith) (Attachment 8) *This concept pretends to identify trends of HCT use, and determine if patients undergoing HCT for HL in the novel agent era have improved OS and DFS compared to prior era.*
6. **PROP 1811-19/1811-156** The impact of conditioning regimens on outcomes of autologous hematopoietic stem cell transplantation in peripheral t cell lymphoma; Impact of conditioning regimen on outcomes for patients with peripheral T-cell lymphoma undergoing high-dose therapy with autologous hematopoietic cell transplantation (Jagadeesh, Majhail, Hu; DHolaria, Savani, Kharfan-Dabaja) (Attachment 9) *This concept aims to evaluate the effect of conditioning regimen on survival of patients with PTCL.*

7. **PROP 1811-40** Hematopoietic stem cell transplantation for relapsed/refractory primary mediastinal b cell lymphoma (Mussetti, Sureda) (Attachment 10) *This concept intends to compare auto vs. alloHCT strategies in outcomes of a new subtype of DLBCL.*
8. **PROP 1811-89/1811-135** Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation; A comparison of thiotepa and busulfan (TB)-based vs. thiotepa and carmustine (TT-BCNU) conditioned autologous transplantation in the treatment of primary and secondary CNS lymphoma. (Scordo, Sauter; Wang, Jimenez) (Attachment 11) *This concept intends to describe the optimal conditioning regimenf or primary CNS lymphoma patients.*
9. **PROP 1811-101** Outcomes in elderly patients (Age ≥ 70 years) received autologous hematopoietic stem cell transplant for non-Hodgkin lymphoma (Zhou, Rabinowitz, Nath) (Attachment 12) *This study aims to study outcomes in elderly NHL patients who received an autoHCT, in comparison with younger cohort.*

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

1. **PROP 1811-06** Outcomes of patients with relapsed/refractory Hodgkin and non-Hodgkin lymphoma treated with radiotherapy in addition to high-dose chemotherapy and stem cell transplantation. *Dropped with current CIBMTR study.*
2. **PROP 1811-25** Rate of large granular lymphocytosis in SCT and effect on the long-term prognosis of post-transplant patients. *Dropped due to feasibility.*
3. **PROP 1811-37** Clinical outcome of patients 50 years and older with Hodgkin lymphoma receiving allogeneic hematopoietic stem cell transplantation. *Dropped due to feasibility.*
4. **PROP 1811-48** Evaluating the efficacy of high-dose therapy and autologous hematopoietic cell transplantation for primary effusion lymphoma. *Dropped due to feasibility.*
5. **PROP 1811-61** Impact of allogeneic hematopoietic cell transplantation on the outcomes of adult T cell Leukemia Lymphoma. *Dropped due to feasibility.*
6. **PROP 1811-65** Does BV maintenance after autoHCT decrease the chance and success of alloHCT in high risk HL patients. *Dropped due to feasibility.*
7. **PROP 1811-70** Role of consolidation therapy post auto transplant in T cell lymphomas. *Dropped due to feasibility.*
8. **PROP 1811-76** Outcomes of auto compared to allo transplants for diagnosis of high risk non-Hodgkin lymphoma. *Dropped due to feasibility.*
9. **PROP 1811-80** Outcomes of long-term survivors of non-Hodgkin lymphoma who underwent reduced intensity alloHCT: matched unrelated vs haploidentical donor (Dholaria, Savani, Kharfan-Dabaja). *Dropped due to feasibility.*
10. **PROP 1811-91** Evaluation of outcomes of patients with B-PLL undergoing allogeneic stem cell transplant**.** *Dropped due to feasibility.*
11. **PROP 1811-111** Clinical and pathologic factors predictive of refractoriness or early relapse (<12 months) to autologous stem cell transplant in patients with primary refractory DLBCL. *Dropped due to feasibility.*
12. **PROP 1811-122** The impact of adding Rituximab to BEAM conditioning for patients with DLBCL undergoing autoHCT. *Dropped due to overlap with current CIBMTR study (LY18-01).*
13. **PROP 1811-140** Donor and recipient t cell exhaustion markers before allogeneic transplantation in Hodgkin lymphoma. *Dropped due to feasibility.*
14. **PROP 1811-152** Survival after autologous and allogeneic stem cell transplantation in peripheral T-cell lymphoma. *Dropped due to overlap with current CIBMTR study (LY06-05).*

15. **PROP 1811-164** Outcomes of autologous hematopoietic stem cell transplantation in primary effusion lymphoma. *Dropped due to small sample size.*
16. **PROP 1811-181** Hematopoietic cell transplantation outcomes for cutaneous T cell lymphoma. *Dropped due to overlap with current CIBMTR study (LY06-05).*
17. **PROP 1811-182** For post-transplant cyclophosphamide-based GVHD prophylaxis, is survival after matched unrelated donor allogeneic transplantation better than haploidentical transplantation for relapsed lymphomas. *Dropped due to feasibility.*
18. **PROP 1811-183** Retrospective study of blood or bone marrow transplantation for enteropathy-associated T-cell lymphoma and hepatosplenic T-cell lymphoma. *Dropped due to feasibility.*
19. **PROP 1812-11** To evaluate outcomes of HSCT with TBI vs. Flu/Mel conditioning in treatment of cutaneous T-cell lymphoma. *Drooped due to overlap with current CIBTMR study (LY17-02).*

7. Other Business

After the 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 1:52 pm.

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
LY17-02 Allografts in lymphoma following reduced intensity conditioning.	Analysis	Submission – 6/30/2019	150	150	150	0	150
LY18-01 Outcomes in B-cell non-Hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning Regimens.	Data file preparation	Manuscript preparation – 6/30/2019	230	160	160	70	230
LY18-02 Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant.	Draft protocol received	Data file preparation – 6/30/2019	310	60	60	250	310
LY18-03 Transplantation for CLL undergoing Richter's transformation arising in the setting of indolent lymphoma.	Protocol development	Data file preparation – 6/30/2019	290	20	20	200	220
LY19-01 Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: a CIBMTR lymphoma working committee and EBMT lymphoma working party analysis.	Protocol pending	Manuscript preparation – 7/1/2020	330	260	0	260	260

LY19-02 Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation.	Protocol pending	Data file preparation – 7/1/2020	330	100	0	100	100

Oversight Assignments for Working Committee Leadership (March 2019)

Anna Sureda	**LY17-02** Allografts in lymphoma following reduced intensity conditioning.
Timothy Fenske	**LY18-01** Outcomes in B-cell non-Hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning Regimens.
	LY18-02 Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant.
Mohamed Kharfan-Dabaja	**LY18-03** Transplantation for CLL undergoing Richter's transformation arising in the setting of indolent lymphoma.
Craig Sauter	**LY19-02** Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation.
Mehdi Hamadani	**LY19-01** Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: a CIBMTR lymphoma working committee and EBMT lymphoma working party analysis.

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2019

	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	Research	TED only	Research
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Anaplastic large cell	297	51	364	147	1757	166
PIF	38 (13)	9 (18)	39 (11)	23 (16)	174 (10)	12 (7)
CR1	40 (13)	8 (16)	52 (14)	23 (16)	676 (38)	70 (42)
Rel 1	31 (10)	7 (14)	24 (7)	10 (7)	171 (10)	20 (12)
CR2	81 (27)	17 (33)	99 (27)	43 (29)	424 (24)	36 (22)
Other/Unknown	107 (36)	10 (20)	150 (41)	48 (33)	312 (18)	28 (17)
Burkitt/small noncleaved	169	55	100	96	554	128
PIF	19 (11)	7 (13)	8 (8)	19 (20)	55 (10)	19 (15)
CR1	35 (21)	14 (25)	19 (19)	17 (18)	193 (35)	53 (41)
Rel 1	24 (14)	7 (13)	8 (8)	14 (15)	49 (9)	12 (9)
CR2	42 (25)	21 (38)	33 (33)	34 (35)	133 (24)	34 (27)
Other/Unknown	49 (29)	6 (11)	32 (32)	12 (13)	124 (22)	10 (8)
Diffuse large cell/Immunoblastic	1823	307	2029	664	21472	2329
PIF	326 (18)	79 (26)	326 (16)	190 (29)	2600 (12)	313 (13)
CR1	174 (10)	47 (15)	212 (10)	88 (13)	3814 (18)	455 (20)
Rel 1	282 (15)	41 (13)	213 (10)	73 (11)	3649 (17)	424 (18)
CR2	245 (13)	28 (9)	337 (17)	93 (14)	6080 (28)	668 (29)
Other/Unknown	796 (44)	112 (36)	941 (46)	220 (33)	5329 (25)	469 (20)
Follicular	1487	507	1328	637	4943	831
PIF	171 (11)	66 (13)	134 (10)	107 (17)	486 (10)	68 (8)
CR1	104 (7)	37 (7)	86 (6)	39 (6)	557 (11)	105 (13)
Rel 1	201 (14)	103 (20)	151 (11)	96 (15)	853 (17)	159 (19)
CR2	183 (12)	75 (15)	173 (13)	78 (12)	1184 (24)	196 (24)
Other/Unknown	828 (56)	226 (45)	784 (59)	317 (50)	1863 (38)	303 (36)
Lymphoblastic	172	49	133	98	281	31
PIF	18 (10)	7 (14)	8 (6)	12 (12)	14 (5)	2 (6)
CR1	50 (29)	11 (22)	21 (16)	18 (18)	124 (44)	17 (55)
Rel 1	28 (16)	8 (16)	10 (8)	16 (16)	24 (9)	0
CR2	32 (19)	12 (24)	36 (27)	33 (34)	35 (12)	5 (16)
Other/Unknown	44 (26)	11 (22)	58 (44)	19 (19)	84 (30)	7 (23)
Mantle	922	201	1126	394	8030	844
PIF	119 (13)	38 (19)	104 (9)	62 (16)	666 (8)	76 (9)
CR1	181 (20)	38 (19)	169 (15)	75 (19)	5350 (67)	572 (68)

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2019

	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	Research	TED only	Research
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Rel 1	142 (15)	35 (17)	174 (15)	65 (16)	245 (3)	27 (3)
CR2	180 (20)	30 (15)	334 (30)	81 (21)	430 (5)	56 (7)
Other/Unknown	300 (33)	60 (30)	345 (31)	111 (28)	1339 (17)	113 (13)
Marginal	90	27	99	36	361	41
PIF	11 (12)	8 (30)	14 (14)	9 (25)	41 (11)	9 (22)
CR1	8 (9)	3 (11)	14 (14)	5 (14)	57 (16)	4 (10)
Rel 1	10 (11)	1 (4)	12 (12)	5 (14)	45 (12)	3 (7)
CR2	12 (13)	3 (11)	9 (9)	4 (11)	73 (20)	10 (24)
Other/Unknown	49 (54)	12 (44)	50 (51)	13 (36)	145 (40)	15 (37)
NK T cell	244	51	289	110	736	72
PIF	34 (14)	7 (14)	54 (19)	22 (20)	86 (12)	14 (19)
CR1	59 (24)	14 (27)	78 (27)	40 (36)	311 (42)	31 (43)
Rel 1	25 (10)	5 (10)	17 (6)	7 (6)	52 (7)	4 (6)
CR2	46 (19)	4 (8)	60 (21)	25 (23)	121 (16)	12 (17)
Other/Unknown	80 (33)	21 (41)	80 (28)	16 (15)	166 (23)	11 (15)
T cell	902	188	1152	427	3310	360
PIF	211 (23)	59 (31)	262 (23)	156 (37)	357 (11)	48 (13)
CR1	165 (18)	39 (21)	213 (18)	87 (20)	1790 (54)	183 (51)
Rel 1	103 (11)	15 (8)	106 (9)	39 (9)	248 (7)	36 (10)
CR2	130 (14)	26 (14)	207 (18)	46 (11)	339 (10)	43 (12)
Other/Unknown	293 (32)	49 (26)	364 (32)	99 (23)	576 (17)	50 (14)
NHL Not specified	180	24	123	99	888	26
PIF	15 (8)	4 (17)	8 (7)	30 (30)	94 (11)	7 (27)
CR1	13 (7)	0	5 (4)	13 (13)	112 (13)	6 (23)
Rel 1	28 (16)	2 (8)	12 (10)	13 (13)	64 (7)	5 (19)
CR2	15 (8)	2 (8)	23 (19)	14 (14)	114 (13)	2 (8)
Other/Unknown	109 (61)	16 (67)	75 (61)	29 (29)	504 (57)	6 (23)
Other	596	168	682	280	5583	651
PIF	117 (20)	47 (28)	153 (22)	77 (28)	953 (17)	126 (19)
CR1	114 (19)	25 (15)	129 (19)	70 (25)	1736 (31)	200 (31)
Rel 1	58 (10)	18 (11)	61 (9)	29 (10)	670 (12)	65 (10)
CR2	76 (13)	10 (6)	119 (17)	32 (11)	1279 (23)	144 (22)
Other/Unknown	231 (39)	68 (40)	220 (32)	72 (26)	945 (17)	116 (18)

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2019

	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	Research	TED only	Research
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Hodgkin	1399	207	2008	462	17724	1722
PIF	206 (15)	34 (16)	256 (13)	93 (20)	2526 (14)	277 (16)
CR1	72 (5)	11 (5)	117 (6)	51 (11)	1991 (11)	217 (13)
Rel 1	165 (12)	42 (20)	222 (11)	64 (14)	3353 (19)	322 (19)
CR2	152 (11)	25 (12)	252 (13)	51 (11)	5101 (29)	528 (31)
Other/Unknown	804 (57)	95 (46)	1161 (58)	203 (44)	4753 (27)	378 (22)
Graft type	8281	1835	9433	3450	65639	7201
BM	838 (10)	169 (9)	1668 (18)	777 (23)	691 (1)	52 (1)
PBSC	7383 (89)	1660 (90)	7074 (75)	2179 (63)	63916 (97)	7094 (99)
Other/Unknown	60 (1)	6 (0)	691 (7)	494 (14)	1032 (2)	55 (1)

Unrelated Donor HCT Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired samples, recipient only samples and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	4526	1191	734
Source of data			
CRF	2165 (48)	502 (42)	338 (46)
TED	2361 (52)	689 (58)	396 (54)
Number of centers	188	136	172
Disease at transplant			
NHL	3703 (82)	1012 (85)	606 (83)
Hodgkin Lymphoma	823 (18)	179 (15)	128 (17)
NHL Disease status at transplant			
CR1	483 (13)	173 (17)	69 (11)
CR2	684 (19)	177 (18)	101 (17)
CR3+	316 (9)	86 (9)	51 (8)
PR	431 (12)	108 (11)	78 (13)
Advanced	1711 (47)	451 (45)	294 (49)
Missing	46 (1)	8 (1)	10 (2)
Recipient age at transplant			
0-9 years	49 (1)	7 (1)	12 (2)
10-19 years	208 (5)	36 (3)	33 (4)
20-29 years	551 (12)	131 (11)	88 (12)
30-39 years	633 (14)	171 (14)	105 (14)
40-49 years	855 (19)	217 (18)	153 (21)
50-59 years	1264 (28)	318 (27)	184 (25)
60-69 years	899 (20)	279 (23)	149 (20)
70+ years	67 (1)	32 (3)	10 (1)
Median (Range)	50 (2-79)	51 (3-76)	49 (2-74)
Recipient race/ethnicity			
Caucasian, non-Hispanic	3922 (88)	1006 (87)	574 (88)
African-American, non-Hispanic	197 (4)	46 (4)	25 (4)
Asian, non-Hispanic	73 (2)	27 (2)	21 (3)
Pacific islander, non-Hispanic	5 (<1)	2 (<1)	0
Native American, non-Hispanic	4 (<1)	7 (1)	1 (<1)
Hispanic	231 (5)	66 (6)	31 (5)
Other	1 (<1)	4 (<1)	1 (<1)
Unknown	93 (N/A)	33 (N/A)	81 (N/A)
Recipient sex			
Male	2843 (63)	786 (66)	480 (65)
Female	1683 (37)	405 (34)	254 (35)
Karnofsky score			
10-80	1526 (34)	433 (36)	244 (33)
90-100	2774 (61)	670 (56)	444 (60)
Missing	226 (5)	88 (7)	46 (6)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
HLA-A B DRB1 groups - low resolution			
<=3/6	3 (<1)	3 (<1)	0
4/6	9 (<1)	7 (1)	3 (<1)
5/6	531 (12)	123 (11)	74 (10)
6/6	3910 (88)	939 (88)	628 (89)
Unknown	73 (N/A)	119 (N/A)	29 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	39 (1)	6 (1)	3 (1)
6/8	110 (3)	13 (2)	9 (2)
7/8	842 (20)	153 (18)	112 (21)
8/8	3284 (77)	690 (80)	402 (76)
Unknown	251 (N/A)	329 (N/A)	208 (N/A)
HLA-DPB1 Match			
Double allele mismatch	704 (29)	58 (22)	40 (25)
Single allele mismatch	1374 (56)	129 (49)	87 (55)
Full allele matched	364 (15)	76 (29)	31 (20)
Unknown	2084 (N/A)	928 (N/A)	576 (N/A)
High resolution release score			
No	2062 (46)	1181 (99)	720 (98)
Yes	2464 (54)	10 (1)	14 (2)
KIR typing available			
No	3756 (83)	1185 (99)	732 (>99)
Yes	770 (17)	6 (1)	2 (<1)
Graft type			
Marrow	932 (21)	232 (19)	170 (23)
PBSC	3593 (79)	951 (80)	563 (77)
PBSC+UCB	1 (<1)	8 (1)	0
Others	0	0	1 (<1)
Number of cord units			
Unknown	4526 (N/A)	1191 (N/A)	734 (N/A)
Conditioning regimen			
Myeloablative	1842 (41)	431 (36)	263 (36)
RIC/Nonmyeloablative	2652 (59)	753 (63)	465 (63)
TBD	32 (1)	7 (1)	6 (1)
Donor age at donation			
To Be Determined/NA	24 (1)	206 (17)	10 (1)
0-9 years	1 (<1)	0	0
10-19 years	117 (3)	30 (3)	19 (3)
20-29 years	2004 (44)	469 (39)	301 (41)
30-39 years	1303 (29)	270 (23)	215 (29)
40-49 years	840 (19)	167 (14)	133 (18)
50+ years	237 (5)	49 (4)	56 (8)
Median (Range)	31 (3-69)	30 (18-68)	32 (19-59)
Donor/Recipient CMV serostatus			
+/+	1042 (23)	281 (25)	150 (21)
+/-	541 (12)	175 (15)	121 (17)
-/+	1334 (30)	309 (27)	205 (29)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
-/-	1553 (35)	371 (33)	239 (33)
CB - recipient -	0	1 (<1)	0
Unknown	56 (N/A)	54 (N/A)	19 (N/A)
GvHD Prophylaxis			
Ex vivo T-cell depletion	53 (1)	10 (1)	13 (2)
CD34 selection	53 (1)	12 (1)	4 (1)
Post-CY + other(s)	94 (2)	55 (5)	23 (3)
Post-CY alone	1 (<1)	2 (<1)	1 (<1)
Tacrolimus + MMF +- others	790 (17)	163 (14)	136 (19)
Tacrolimus + MTX +- others (except MMF)	2021 (45)	559 (47)	238 (32)
Tacrolimus + others (except MTX, MMF)	284 (6)	101 (8)	55 (7)
Tacrolimus alone	152 (3)	51 (4)	16 (2)
CSA + MMF +- others (except Tacrolimus)	470 (10)	96 (8)	82 (11)
CSA + MTX +- others (except Tacrolimus, MMF)	373 (8)	89 (7)	100 (14)
CSA + others (except Tacrolimus, MTX, MMF)	67 (1)	18 (2)	15 (2)
CSA alone	42 (1)	5 (<1)	26 (4)
Other GVHD prophylaxis	77 (2)	20 (2)	14 (2)
Missing	49 (1)	10 (1)	11 (1)
Donor/Recipient sex match			
Male-Male	2073 (46)	543 (47)	323 (45)
Male-Female	1062 (24)	246 (21)	136 (19)
Female-Male	752 (17)	219 (19)	151 (21)
Female-Female	612 (14)	150 (13)	115 (16)
CB - recipient M	0	5 (<1)	0
CB - recipient F	1 (<1)	3 (<1)	0
Unknown	26 (N/A)	25 (N/A)	9 (N/A)
Year of transplant			
1986-1990	3 (<1)	1 (<1)	1 (<1)
1991-1995	44 (1)	12 (1)	13 (2)
1996-2000	228 (5)	56 (5)	39 (5)
2001-2005	722 (16)	139 (12)	157 (21)
2006-2010	1369 (30)	255 (21)	188 (26)
2011-2015	1579 (35)	422 (35)	230 (31)
2016-2019	581 (13)	306 (26)	106 (14)
Follow-up among survivors, Months			
N Eval	1854	555	310
Median (Range)	70 (3-269)	48 (2-268)	54 (3-218)

Unrelated Cord Blood Transplant Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired, recipient only and cord blood only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006-recipient only), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	470	108	107
Source of data			
CRF	361 (77)	81 (75)	68 (64)
TED	109 (23)	27 (25)	39 (36)
Number of centers	87	39	48
Disease at transplant			
NHL	378 (80)	83 (77)	85 (79)
Hodgkin Lymphoma	92 (20)	25 (23)	22 (21)
NHL Disease status at transplant			
CR1	59 (16)	5 (6)	16 (19)
CR2	71 (19)	18 (22)	24 (29)
CR3+	42 (11)	10 (12)	9 (11)
PR	65 (17)	12 (14)	11 (13)
Advanced	138 (37)	37 (45)	23 (27)
Missing	0	1 (1)	1 (1)
Recipient age at transplant			
0-9 years	22 (5)	5 (5)	3 (3)
10-19 years	34 (7)	4 (4)	8 (7)
20-29 years	58 (12)	13 (12)	14 (13)
30-39 years	86 (18)	15 (14)	22 (21)
40-49 years	83 (18)	29 (27)	17 (16)
50-59 years	113 (24)	18 (17)	23 (21)
60-69 years	70 (15)	23 (21)	19 (18)
70+ years	4 (1)	1 (1)	1 (1)
Median (Range)	45 (1-73)	46 (5-73)	44 (7-71)
Recipient race/ethnicity			
Caucasian, non-Hispanic	264 (58)	73 (69)	57 (61)
African-American, non-Hispanic	91 (20)	21 (20)	16 (17)
Asian, non-Hispanic	33 (7)	3 (3)	6 (6)
Pacific islander, non-Hispanic	1 (<1)	0	0
Native American, non-Hispanic	6 (1)	0	0
Hispanic	60 (13)	9 (8)	15 (16)
Unknown	15 (N/A)	2 (N/A)	13 (N/A)
Recipient sex			
Male	277 (59)	65 (60)	59 (55)
Female	193 (41)	43 (40)	48 (45)
Karnofsky score			
10-80	135 (29)	28 (26)	23 (21)
90-100	314 (67)	68 (63)	81 (76)
Missing	21 (4)	12 (11)	3 (3)
HLA-A B DRB1 groups - low resolution			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
<=3/6	16 (4)	3 (4)	0
4/6	229 (51)	41 (50)	51 (52)
5/6	173 (39)	31 (38)	38 (39)
6/6	29 (6)	7 (9)	9 (9)
Unknown	23 (N/A)	26 (N/A)	9 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	243 (63)	43 (72)	54 (68)
6/8	93 (24)	12 (20)	15 (19)
7/8	33 (9)	5 (8)	7 (9)
8/8	14 (4)	0	3 (4)
Unknown	87 (N/A)	48 (N/A)	28 (N/A)
HLA-DPB1 Match			
Double allele mismatch	44 (36)	2 (29)	2 (20)
Single allele mismatch	66 (54)	5 (71)	6 (60)
Full allele matched	12 (10)	0	2 (20)
Unknown	348 (N/A)	101 (N/A)	97 (N/A)
High resolution release score			
No	388 (83)	105 (97)	106 (99)
Yes	82 (17)	3 (3)	1 (1)
KIR typing available			
No	394 (84)	108 (100)	106 (99)
Yes	76 (16)	0	1 (1)
Number of cord blood units			
1	371 (79)	0	72 (67)
2	98 (21)	0	35 (33)
3	1 (<1)	0	0
Unknown	0 (N/A)	108 (N/A)	0 (N/A)
Graft type			
UCB	428 (91)	100 (93)	102 (95)
PBSC+UCB	40 (9)	8 (7)	3 (3)
Others	2 (<1)	0	2 (2)
Conditioning regimen			
Myeloablative	193 (41)	44 (41)	37 (35)
RIC/Nonmyeloablative	277 (59)	63 (58)	70 (65)
TBD	0	1 (1)	0
Donor age at donation			
To Be Determined/NA	13 (3)	12 (11)	8 (7)
0-9 years	415 (88)	83 (77)	93 (87)
10-19 years	12 (3)	5 (5)	4 (4)
20-29 years	8 (2)	1 (1)	0
30-39 years	7 (1)	2 (2)	1 (1)
40-49 years	6 (1)	2 (2)	1 (1)
50+ years	9 (2)	3 (3)	0
Median (Range)	3 (0-68)	4 (0-68)	3 (1-43)
Donor/Recipient CMV serostatus			
+/+	110 (23)	19 (18)	24 (22)
+/-	59 (13)	11 (10)	14 (13)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
-/+	78 (17)	22 (20)	16 (15)
-/-	51 (11)	14 (13)	15 (14)
CB - recipient +	107 (23)	23 (21)	24 (22)
CB - recipient -	60 (13)	13 (12)	11 (10)
CB - recipient CMV unknown	5 (1)	6 (6)	3 (3)
GvHD Prophylaxis			
Ex vivo T-cell depletion	4 (1)	1 (1)	1 (1)
CD34 selection	29 (6)	5 (5)	1 (1)
Post-CY + other(s)	0	1 (1)	1 (1)
Tacrolimus + MMF +- others	160 (34)	28 (26)	29 (27)
Tacrolimus + MTX +- others (except MMF)	13 (3)	4 (4)	1 (1)
Tacrolimus + others (except MTX, MMF)	31 (7)	7 (6)	5 (5)
Tacrolimus alone	26 (6)	10 (9)	3 (3)
CSA + MMF +- others (except Tacrolimus)	169 (36)	47 (44)	55 (51)
CSA + MTX +- others (except Tacrolimus, MMF)	3 (1)	1 (1)	1 (1)
CSA + others (except Tacrolimus, MTX, MMF)	11 (2)	1 (1)	3 (3)
CSA alone	1 (<1)	0	1 (1)
Other GVHD prophylaxis	16 (3)	2 (2)	3 (3)
Missing	7 (1)	1 (1)	3 (3)
Donor/Recipient sex match			
CB - recipient M	277 (59)	65 (60)	59 (55)
CB - recipient F	193 (41)	43 (40)	48 (45)
Year of transplant			
2001-2005	6 (1)	6 (6)	2 (2)
2006-2010	151 (32)	33 (31)	35 (33)
2011-2015	247 (53)	52 (48)	51 (48)
2016-2019	66 (14)	17 (16)	19 (18)
Follow-up among survivors, Months			
N Eval	218	43	43
Median (Range)	61 (2-144)	43 (12-134)	49 (2-123)

Related Donor HCT Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired, recipient only and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	908	126	83
Source of data			
CRF	292 (32)	32 (25)	29 (35)
TED	616 (68)	94 (75)	54 (65)
Number of centers	60	31	17
Disease at transplant			
NHL	747 (82)	102 (81)	65 (78)
Hodgkin Lymphoma	161 (18)	24 (19)	18 (22)
NHL Disease status at transplant			
CR1	126 (17)	19 (19)	11 (17)
CR2	141 (19)	20 (20)	11 (17)
CR3+	84 (11)	9 (9)	2 (3)
PR	65 (9)	13 (13)	7 (11)
Advanced	324 (44)	40 (40)	34 (52)
Missing	2 (<1)	0	0
Recipient age at transplant			
0-9 years	8 (1)	1 (1)	0
10-19 years	46 (5)	7 (6)	1 (1)
20-29 years	93 (10)	17 (13)	5 (6)
30-39 years	94 (10)	18 (14)	13 (16)
40-49 years	150 (17)	18 (14)	20 (24)
50-59 years	265 (29)	38 (30)	26 (31)
60-69 years	240 (26)	25 (20)	17 (20)
70+ years	12 (1)	2 (2)	1 (1)
Median (Range)	52 (3-74)	51 (2-73)	51 (20-72)
Recipient race/ethnicity			
Caucasian, non-Hispanic	619 (70)	73 (62)	56 (71)
African-American, non-Hispanic	90 (10)	16 (14)	10 (13)
Asian, non-Hispanic	38 (4)	13 (11)	2 (3)
Pacific islander, non-Hispanic	3 (<1)	1 (1)	0
Native American, non-Hispanic	4 (<1)	0	0
Hispanic	128 (15)	14 (12)	11 (14)
Unknown	26 (N/A)	9 (N/A)	4 (N/A)
Recipient sex			
Male	578 (64)	82 (65)	51 (61)
Female	330 (36)	44 (35)	32 (39)
Karnofsky score			
10-80	288 (32)	38 (30)	22 (27)
90-100	585 (64)	82 (65)	54 (65)
Missing	35 (4)	6 (5)	7 (8)
Graft type			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Marrow	115 (13)	22 (17)	16 (19)
PBSC	793 (87)	103 (82)	67 (81)
BM+PBSC	0	1 (1)	0
Conditioning regimen			
Myeloablative	336 (37)	42 (33)	26 (31)
RIC/Nonmyeloablative	569 (63)	82 (65)	57 (69)
TBD	3 (<1)	2 (2)	0
Donor age at donation			
To Be Determined/NA	5 (1)	0	2 (2)
0-9 years	16 (2)	1 (1)	0
10-19 years	49 (5)	6 (5)	0
20-29 years	96 (11)	22 (17)	12 (14)
30-39 years	132 (15)	21 (17)	17 (20)
40-49 years	184 (20)	25 (20)	17 (20)
50+ years	426 (47)	51 (40)	35 (42)
Median (Range)	49 (0-81)	46 (0-71)	47 (0-74)
Donor/Recipient CMV serostatus			
+/+	365 (41)	58 (48)	28 (36)
+/-	121 (14)	12 (10)	7 (9)
-/+	164 (18)	22 (18)	20 (26)
-/-	243 (27)	30 (25)	22 (29)
Unknown	15 (N/A)	4 (N/A)	6 (N/A)
GvHD Prophylaxis			
Ex-vivo T-cell depletion	9 (1)	2 (2)	0
CD34 selection	4 (<1)	0	0
Post-CY + other(s)	171 (19)	28 (22)	18 (22)
Post-CY alone	4 (<1)	1 (1)	0
TAC + MMF +- other(s) (except post-CY)	124 (14)	13 (10)	6 (7)
TAC + MTX +- other(s) (except MMF, post-CY)	398 (44)	38 (30)	39 (47)
TAC + other(s) (except MMF, MTX, post-CY)	91 (10)	34 (27)	13 (16)
TAC alone	11 (1)	0	0
CSA + MMF +- other(s) (except post-CY)	9 (1)	3 (2)	0
CSA + MTX +- other(s) (except MMF, post-CY)	21 (2)	0	0
CSA + other(s) (except MMF, MTX, post-CY)	15 (2)	4 (3)	1 (1)
CSA alone	2 (<1)	0	0
Other(s)	23 (3)	2 (2)	2 (2)
Missing	26 (3)	1 (1)	4 (5)
Donor/Recipient sex match			
Male-Male	342 (38)	49 (39)	35 (42)
Male-Female	166 (18)	20 (16)	13 (16)
Female-Male	235 (26)	33 (26)	16 (19)
Female-Female	164 (18)	24 (19)	19 (23)
Unknown	1 (N/A)	0 (N/A)	0 (N/A)
Year of transplant			
2006-2010	111 (12)	13 (10)	14 (17)
2011-2015	476 (52)	60 (48)	34 (41)
2016-2019	321 (35)	53 (42)	35 (42)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Follow-up among survivors, Months			
N Eval	557	81	60
Median (Range)	39 (3-126)	36 (3-101)	48 (3-124)

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TO: Lymphoma Working Committee Members

FROM: Mehdi Hamadani, MD; Scientific Director for the Lymphoma Working Committee

RE: Studies in Progress Summary

LY17-02d: Reduced intensity conditioning in allografts for diffused large B-cell lymphoma (Internal) This study looks to describe post-allogeneic transplant outcomes in diffuse large B-cell lymphoma patients following reduced intensity or non-myeloablative conditioning. This study is in manuscript preparation. The goal of this study is to submit the study for publication by June 2020.

LY18-01b: Outcomes in b cell non-hodgkin's lymphoma patients who underwent autologous stem cell transplantation following rituximab containing conditioning regimens in partial remission (Internal) This study evaluates outcomes of rituximab containing conditioning regimen in DLBCL patients undergoing auto-HCT compared to non-rituximab conditioning regimen after partial remission status before HCT. This study is currently in manuscript preparation. The goal of this study is to finalize the analysis by June 2020.

LY18-02: Effect of time to relapse on overall survival in mantle cell lymphoma patients following frontline autologous stem cell transplant (P Riedell/S Smith) This study compares post-relapse survival among patients relapsing <2 years and ≥2 years following frontline autologous stem cell transplant for mantle cell lymphoma. This study is currently under protocol development. The goal of this study is to finalize the analysis by June 2020.

LY18-03: Transplantation for CLL undergoing Richter's Transformation arising in the setting of indolent lymphoma (A Herrera) This study evaluates outcomes of patients undergoing Richter's Transformation and transplanted for diffuse large B-cell lymphoma. This study is currently in data file preparation and accruing data. The goal of this study is to finalize the data file preparation by June 2020.

LY19-01: Post-transplant cyclophosphamide-based haploidentical transplantation versus matched sibling or well-matched unrelated donor transplantation for peripheral T-cell lymphoma: A CIBMTR Lymphoma working committee and EBMT Lymphoma working party analysis (P Dreger/M Hamadani) This study will combine data from the CIBMTR and EBMT to look at haploidentical transplants against other donor options for peripheral T-cell lymphoma. This study is currently in data file preparation. The goal is to have the analysis completed by June 2020.

LY19-02: Determining the optimal conditioning regimen for patients with primary central nervous system lymphoma undergoing autologous hematopoietic cell transplantation (M Scordo/C Sauter/A Jimenez) This study looks to compare most frequent conditioning regimens in post autologous transplant outcomes in central nervous system lymphoma patients. This study is currently under protocol development. The goal of this study is to finalize the datafile preparation by June 2020.

Proposal: 1911-51

Title:
CAR-T cell Therapy versus Autologous Transplant in Early Rituximab Failure Patients with Diffuse Large B-cell Lymphoma

Nirav N. Shah MD, MSHP, nishah@mcw.edu, Medical College of Wisconsin

Hypothesis:
CAR-T cell therapy improves OS in patients with early Rituximab failure (<12 months) compared to autologous transplant

Specific aims:
To evaluate clinical outcomes in terms of progression free and overall survival

- Primary outcome will be to compare overall survival among patients who relapse within 1 year of initial diagnosis after first-line rituximab-based chemo-immunotherapy who undergo autologous transplant versus those who receive CAR-T cell therapy against CD19.
- Secondary outcomes will include overall survival, relapse rates, and rates of non-relapse mortality.

Scientific justification:
Diffuse large B-cell lymphoma (DLBCL) is the most common form of aggressive non-Hodgkin lymphoma (NHL) accounting for approximately 30-40% of cases[1]. The standard frontline treatment option generally includes combination chemo-immunotherapy given for 6-8 cycles of which R-CHOP (Rituximab, Cyclophosphamide, Adriamycin, and Prednisone) is considered standard of care for most patients[1, 2]. Despite long-term remissions achieved in approximately 60% of patients, for those with high risk features such as single or double hit lymphoma, primary refractory disease, or early relapse within <12 months, outcomes remain poor [3, 4].
For patients with early Rituximab failure (ERF) defined as relapse within <12 months of receiving a rituximab containing chemo-immunotherapy regimen, the standard approach had been salvage chemotherapy followed by consideration of autologous transplant in chemosensitive patients. The CIBMTR evaluated outcomes specifically in ERF patients with DLBCL and compared them to patients with late Rituximab failure (>1 year) and found that while ERF patients had a higher risk of treatment failure, the 3-year progression free survival was still an impressive 44% in this high-risk population. They concluded that even in this high-risk population that autologous transplant was an appropriate consideration in any chemosensitive patients[5].
Over the last few years, the development of novel cell-based therapies has challenged the existing algorithms for relapsed DLBCL. Chimeric Antigen Receptor modified T (CAR-T) cells redirected against the CD19 antigen on B-cells has produced remarkable outcomes in patients with relapsed, refractory large cell lymphoma[6, 7]. With CAR-T cell therapy, patients with resistant disease following 2 lines of chemotherapy or for those who relapse after autologous transplant, studies have demonstrated a 1-year PFS of 30-40% in this highly refractory population[7-9]. With two recent FDA approvals[10], CAR-T cell therapy is quickly challenging the role of autologous transplant in relapsed DLBCL.
In this study we aim to compare outcomes among patients with DLBCL and ERF who undergo autologous transplant versus CAR-T cell therapy.

Patient eligibility population:
Inclusion/exclusion criteria:

Autologous transplant patients

- Adults>18 years of age at the time of transplant from 2010-2016
- First line therapy with rituximab plus an anthracycline based regimen
- Early Rituximab Failure cohort (patients with primary refractory disease or those with first relapse within 1 year of initial diagnosis)

CAR-T cell patients

- Adults>18 years who received anti-CD19 CAR-T cell therapy reported to CIMBTR
- First line therapy with rituximab plus an anthracycline based regimen
- Early Rituximab Failure cohort (patients with primary refractory disease or those with first relapse within 1 year of initial diagnosis)

Data Requirements:

- Data will be captured through CIBMTR collection forms

Demographic/patient level variables to be analyzed:

Main effect:

- CAR-T cell cohort vs Auto-HCT cohort

Patient-related:

- Age at time of transplant or CAR-T treatment, Continuous & decades
- Gender: male or female
- Karnofsky performance status at transplant: < 90% vs. ≥ 90%
- HCT comorbidity index at transplant 0, 1, 2, and ≥ 3

Disease-related:

- Disease stage at diagnosis: I/II vs III/IV
- Chemo-resistant vs Chemo-sensitive disease

Treatment related:

- Year of transplant: 2010-2013 vs 2014-2016

Study outcomes:

Progression-free survival (PFS):

Survival without recurrence or tumor progression. Recurrence of progression of disease and death would be counted as events. Those who survive without recurrence or progression would be censored at the time of last contact.

Overall survival (OS):

Time to death. Death from any cause will be considered an event. Surviving patients will be censored at the time of last follow up.

Non-relapse mortality (NRM):

Death without relapse or progression, where relapse or progression would be competing risks. Those who survive without recurrence or progression would be censored at the time of last contact.

Relapse/progression:
Progressive disease or recurrences of disease would be counted as events. Treatment related death, defined as death without relapse or progression, is the competing event. Those who survive without recurrence or progression would be censored at the time of last contact.

Study design:
A retrospective multicenter study will be conducted utilizing CIBMTR dataset involving patients with a diagnosis of early rituximab failure DLBCL (as defined in inclusion criteria) who subsequently underwent either auto-HCT versus CAR-T cell therapy. Patients will be eligible if they satisfied the criteria detailed in the patient eligibility section above. The objective of this analysis is report outcomes, survival, and NRM with the two approaches.
PFS and OS will be calculated using the Kaplan-Meier estimator. For NRM, relapse/progression will be the competing event. For relapse rate, NRM will be the competing event. Data on patients without an event will be censored at last follow up. For univariate analysis, the log-rank test will be used to identify factors influencing survival and to compare survival among patients receiving auto-HCT versus CAR-T for relapsed DLBCL. The association between treatment groups and outcomes will be studied with multivariate Cox regression models. P values are 2 sided and values < 0.05 will be considered significant. The other variables tested will be retained in the final multivariate model if the variable will attain the level of significance set for these analyses. Results will be expressed as hazard ratio (HR) with 95% confidence intervals (CI). Possible interactions within the treatment groups and other variables will be tested. All models will be tested regarding proportional hazard of assumptions (PHA). If the assumption will be violated, time dependent covariates will be constructed.

References:
1. Chaganti, S., et al., *Guidelines for the management of diffuse large B-cell lymphoma.* British Journal of Haematology, 2016. **174**(1): p. 43-56.
2. Armitage, J.O., *How I treat patients with diffuse large B-cell lymphoma.* Blood, 2007. **110**(1): p. 29-36.
3. Crump, M., et al., *Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study.* Blood, 2017.
4. Costa, L.J., et al., *Diffuse Large B-Cell Lymphoma with Primary Treatment Failure: Ultra-high Risk Features and Benchmarking for Experimental Therapies.* Am J Hematol, 2016.
5. Hamadani, M., et al., *Early failure of frontline rituximab-containing chemo-immunotherapy in diffuse large B cell lymphoma does not predict futility of autologous hematopoietic cell transplantation.* Biol Blood Marrow Transplant, 2014. **20**(11): p. 1729-36.
6. Schuster, S.J., et al., *Chimeric Antigen Receptor T Cells in Refractory B-Cell Lymphomas.* N Engl J Med, 2017. **377**(26): p. 2545-2554.
7. Neelapu, S.S., et al., *Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma.* N Engl J Med, 2017. **377**(26): p. 2531-2544.
8. Abramson, J.S., et al., *High Durable CR Rates in Relapsed/Refractory (R/R) Aggressive B-NHL Treated with the CD19-Directed CAR T Cell Product JCAR017 (TRANSCEND NHL 001): Defined Composition Allows for Dose-Finding and Definition of Pivotal Cohort.* Blood, 2017. **130**(Suppl 1): p. 581-581.
9. Schuster, S.J., et al., *Primary Analysis of Juliet: A Global, Pivotal, Phase 2 Trial of CTL019 in Adult Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma.* Blood, 2017. **130**(Suppl 1): p. 577-577.
10. Nair, R. and S.S. Neelapu, *The promise of CAR T-cell therapy in aggressive B-cell lymphoma.* Best Pract Res Clin Haematol, 2018. **31**(3): p. 293-298.

Baseline characteristics for patients undergoing 1st commercial CAR-T or 1st AutoHCT for DLBCL who had early frontline rituximab failure

Characteristic	CAR-T	AutoHCT
No. of patients	448	141
No. of centers	59	66
Age at infusion, by category - no. (%)		
Median (min-max)	62 (18-88)	59 (20-79)
20-29	13 (3)	7 (5)
30-39	22 (5)	11 (8)
40-49	47 (10)	14 (10)
50-59	109 (24)	40 (28)
60-69	165 (37)	47 (33)
≥ 70	92 (21)	22 (16)
Gender - no. (%)		
Male	286 (64)	101 (72)
Female	162 (36)	40 (28)
Recipient race - no. (%)		
White	383 (86)	91 (65)
African-American	21 (5)	23 (16)
Asian	17 (4)	16 (11)
Other	1 (<1)	6 (4)
More than one race	13 (3)	3 (2)
Not reported	13(3)	2 (1)
Recipient ethnicity - no. (%)		
Hispanic or Latino	48 (11)	13 (9)
Non Hispanic or non-Latino	378 (84)	116 (82)
Non-resident of the U.S.	6 (1)	11 (8)
Unknown	16 (4)	1 (1)
Karnofsky performance score prior to CT - no. (%)		
90-100	162 (36)	73 (52)
80	144 (32)	49 (35)
< 80	91 (20)	15 (11)
Not reported	51 (11)	4 (3)
Disease status prior to CT - no. (%)		
CR2	2 (<1)	77 (55)
CR3+	2 (<1)	2 (1)
Relapse	193 (43)	62 (44)
PIF	251 (56)	77 (55)
Types of prior HCTs - no. (%)		
No prior HCT	448	141
Year of CT - no. (%)		

Characteristic	CAR-T	AutoHCT
2017	2 (<1)	47 (33)
2018	275 (61)	77 (55)
2019	171 (38)	17 (12)
Product - no. (%)		
Kymriah	61 (14)	NA
Yescarta	387 (86)	NA

Proposal: 1911-22

Title:
Outcomes of hematopoietic stem cell transplant as treatment of post-transplant lymphoproliferative disorders

Shatha, Farhan, MD, Sfarhan1@hfhs.org, Henry Ford Health system

Hypothesis:
HSCT is a reasonable option for patients with relapsed PTLD after solid organ transplant

Specific aims:
- PFS of PTLD treated with SCT
- OS of PTLD treated with SCT

Scientific justification:
Post transplant lymphoproliferative disorders (PTLD) are associated with significant morbidity and mortality following solid organ transplant. About 85% of PTLDs in the United States are of B-cell origin. The optimal treatment of PTLD is not clearly defined due to a lack of randomized phase III trials. Current treatment options include reduction in immunosuppression , surgery, radiation, rituximab, chemotherapy. Despite these treatments, the overall mortality of PTLD after solid organ transplantation is high.
For patients with relapsed or refractory PTLD after first-line treatment, no current standard therapy options are available. Data are based only on case reports and very small retrospective studies. No randomized trial is expected because of the numbers.

Patient eligibility population:
Patients with PTLD
EBV positive and negative
Any age
Auto , Matched related and Matched and mismatched unrelated donors and alternative donors
Year of HSCT >=2000
HSCT with myeloablative, reduced intensity regimen and non myeloablative regimens

Data requirements:
This study will use the following forms:
Acute Myelogenous Leukemia, ALL and MDS/MPN and lymphoid malignancies Pre-HSCT Data
Acute Myelogenous Leukemia, ALL and MDS/MPN and lymphoid malignancies Post-HSCT Data
Pre-Transplant Essential Data
Post-transplant Essential data
Form 2018
List of Variables needed: Age of patient at diagnosis, gender of patient, date of diagnosis, date of HSCT, Donor type, conditioning regimen, GVHD prophylaxis, date of relapse or progression, date of death, date of last follow up.

Sample requirements:
None

Study design:
Data will be collected and analyzed. We will retrospectively reviewed patients who had-HSCT since year 2000 to treat PTLD. Objectives are to explore
Demographics, disease-related and transplant-related variables mentioned above will be collected. PFS is defined as the time from HSCT to the time of progression, death or last contact whichever occurred first. OS is defined as the time from HSCT to the time of death or last contact. OS and PFS will be estimated using the Kaplan-Meier method.

Non-CIBMTR data source:
none

References:
1. Kinga Ligeti, Lutz P Müller, Carsten Müller-Tidow, Thomas Weber. Risk factors, diagnosis, and management of posttransplant lymphoproliferative disorder: improving patient outcomes with a multidisciplinary treatment approach vol 2017:9 Pages 1—14

First Auto HCT for adults (18+) with PTLD, 2008-2018

Characteristic	N (%)
No. of patients	100
No. of centers	53
Research patient	7 (7)
CCN region - no. (%)	
US	77 (77)
Canada	7 (7)
Asia	1 (1)
Australia/New Zealand	1 (1)
Mideast/Africa	11 (11)
Central/South America	3 (3)
Age at HCT - median (min-max)	39 (18-73)
Disease status prior to HCT - no. (%)	
CR	65 (65)
PR	27 (27)
Chemoresistant	7 (7)
Unknown	1 (1)
Graft type - no. (%)	
Bone marrow	1 (1)
Peripheral blood	99 (99)
TX year - no. (%)	
2009	3 (3)
2010	3 (3)
2011	5 (5)
2012	1 (1)
2013	1 (1)
2014	3 (3)
2015	1 (1)
2016	2 (2)
2017	11 (11)
2018	70 (70)
Follow-up - median (min-max)	12 (2-113)

First Allo HCT for adults (18+) with PTLD, 2008-2018

Characteristic	N (%)
No. of patients	19
No. of centers	15
Research patient	10 (53)
CCN region - no. (%)	
US	14 (74)
Asia	1 (5)
Australia/New Zealand	2 (11)
Mideast/Africa	2 (11)
Prior auto-HCT - no. (%)	
No	11 (58)
Yes	8 (42)
Age at HCT - median (min-max)	39 (21-68)
Disease status prior to HCT - no. (%)	
CR	10 (53)
PR	5 (26)
Chemoresistant	4 (21)
Donor type - no. (%)	
HLA-identical sibling	5 (26)
Other related	4 (21)
Well-matched unrelated (8/8)	3 (16)
Partially-matched unrelated (7/8)	3 (16)
Mis-matched unrelated (≤ 6/8)	1 (5)
Unrelated (matching TBD)	3 (16)
Graft type - no. (%)	
Bone marrow	6 (32)
Peripheral blood	13 (68)
Reported planned conditioning intensity - no. (%)	
RIC/NMA	14 (74)
MAC	5 (26)
Year of HCT - no. (%)	
2008	1 (5)
2009	1 (5)
2012	1 (5)
2015	1 (5)
2017	4 (21)
2018	11 (58)
Follow-up - median (min-max)	12 (6-120)

Proposal: 1911-88

Title:
Outcomes of autologous and allogeneic hematopoietic cell transplantation for Burkitt Lymphoma

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Hypothesis:
Hematopoietic cell transplantation (HCT) results in long-term disease control for relapsed/refractory Burkitt lymphoma

Specific aims:
- To determine overall survival (OS) after autologous and allogeneic HCT for relapsed/refractory Burkitt lymphoma
- To determine progression-free survival (PFS), transplant-related mortality (TRM), cumulative incidences of acute and chronic graft-versus-host disease (GVHD), and cumulative incidence of relapse after autologous and allogeneic HCT for relapsed/refractory Burkitt lymphoma

Scientific impact:
There is limited data available on the outcomes of HCT for Burkitt lymphoma in modern era. This retrospective study will evaluate the outcomes of both autologous and allogeneic HCT for relapsed/refractory Burkitt lymphoma to understand the optimal application of each modality. This study could identify patient- or disease- related factors that may impact the outcomes of autologous and/or allogenic HCT and could lead to future novel research on improving the transplant outcomes.

Scientific justification:
Burkitt lymphoma is an aggressive but highly curable mature B cell, non-Hodgkin lymphoma (NHL) (1). Median age at diagnosis of Burkitt lymphoma is 45 years old and 30% of patients are over the age of 60 years (2). Higher level evidence based therapeutic recommendations are lacking in adult Burkitt lymphoma in part due to its relative rarity in adults, lack of randomized trials in adult Burkitt lymphoma (2) and excellent outcomes with front line chemoinnumotherapy (2,3). Based on prior CIBMTR data (4) evaluating outcomes after autologous or allogeneic HCT for Burkitt lymphoma between 1985 and 2007, overall survival (OS) at 5 years for the autologous cohort was 83% for those in CR1, and 31% for non-CR1 status, respectively. Corresponding progression free survival (PFS) was 78% and 27%, respectively. After allogeneic HCT, OS at 5 years was 53% and 20% for the CR1 and non-CR1 cohorts while PFS was 50% and 19%, respectively. Allogeneic HCT was performed mostly for high-risk/advanced Burkitt lymphoma and resulted in long-term PFS only in a minority of patients with mortality occurring mainly within first year after transplant, mostly due to disease relapse/progression (4). Most of the patients received myeloablative conditioning prior to transplant. There is paucity of data on the outcomes in modern era with availability of haploidentical donors, use of reduced intensity conditioning, and improvement in non-relapse mortality since 2007. We propose to evaluate the outcomes of patients undergoing autologous and/or allogenic HCT after 2000 to understand the impact of HCT in patients with higher risk relapsed/refractory Burkitt lymphoma treated in modern era.

Patient eligibility population:
Inclusion criteria:

Adult patients who received autologous and/or allogeneic HCT for relapsed/refractory Burkitt lymphoma from 2000 to 2018

Exclusion criteria:
None

Variables to be described: (**variables to be included in the multivariate are bolded**)
Recipient-related:

- Age at transplant: continuous and separated by decades
- Gender: male vs. female
- Race: Caucasian vs. African American vs. Asian/Pacific Islander vs. Hispanic vs. Others vs. missing
- Ethnicity: Hispanic or Latino vs. Non-Hispanic or non-Latino vs. non-resident of the U.S.
- Karnofsky performance status at transplant: <90% vs. ≥90%
- Co-morbidity index 0 vs. 1-2 vs. ≥3
- ABO status: (allo only – ABO matching)
- CMV status: (allo only – CMV matching)

Recipient-related: (allo only)

- Age: continuous and categorical by decade
- Gender: male vs. female
- CMV status: positive or negative
- ABO status:
- CD34 cell dose (/recipient body weight):
- Total nucleated cell dose (for umbilical cord):
- Graft type: bone marrow, peripheral blood, vs. cord blood
- Donor type: HLA-matched sibling, well-matched unrelated donor, partially matched unrelated donor, mismatched unrelated donor, haploidentical related donor vs. umbilical cord

Disease-related:

- Disease stage at diagnosis: I-II vs. III-IV
- Presence of bulky disease (size >10 cm): yes vs. no
- Bone marrow involvement at time of diagnosis: yes vs. no
- CNS involvement at the time of diagnosis: yes vs. no
- Extra nodal involvement at time of diagnosis: yes vs. no
- Disease status prior to transplant: CR, PR, SD vs. PD
- Chemotherapy sensitivity at transplant: sensitive vs. resistant
- Number of prior chemotherapy lines: continuous
- Rituximab prior to transplant: yes vs. no
- Methotrexate or cytarabine prior to transplant: yes vs. no

Transplant-related:

- Time from diagnosis to transplant: continuous (months)
- Prior autologous HCT: yes vs. no (allo only)

- Conditioning regimen intensity: MAC vs. RIC/NMA
- TBI based vs. non TBI based conditioning: yes vs. no
- GVHD prevention: tac/MTX, tac/MMF, tac/rapa, CSA/MTX, CSA/MMF, CSA/rapa, PTCY
- Use of ATG and/or alemtuzumab: yes vs. no

Data requirements:
No additional data collection requested.

Sample requirements:
No samples requested.

Study design:

Outcomes:
Overall survival:
Time from HCT to death from any cause. Patients will be censored at the time of last follow up.

Progression-free survival:
Time from HCT to death or relapse. Patients will be censored at the time of last follow up.

Transplant-related mortality:
Death due to any cause in the first 28 days or death due to conditions other than disease relapse or progression beyond 28 days. Events will be summarized by the cumulative incidence estimate with relapse as a competing risk.

Relapse:
Development of relapse as defined by the CIBMTR. The event will be summarized by the cumulative incidence estimate and patients analyzed at last follow-up. TRM will be a competing risk for this outcome.

Acute GVHD:
Time to development of grade II-IV acute GVHD using the Glucksberg grading system. The event will be summarized by the cumulative incidence estimate, where death and relapse without grade II-IV acute GVHD will be treated as a competing risk.

Chronic GVHD:
Time to the development of limited or extensive chronic GVHD. The event will be summarized by the cumulative incidence estimate, where death without chronic GVHD will be treated as the competing risk. Patients will be censored at second transplant or date of last follow-up. This will have both univariate and multivariate analyses.

The goal of this study is evaluate the clinical outcomes of both autologous and allogeneic HCT for patients with Burkitt lymphoma between 2000 and 2018 while adjusting for significant patient-, disease-, and transplant-related variables. Patient-, disease-, and transplant-related factors will be separately evaluated on autologous and allogeneic HCT groups. The probabilities of OS and PFS will be calculated using the Kaplan-Meier estimator. Probabilities of TRM, relapse/progression and GVHD endpoints will be generated using cumulative incidence estimates to account for competing risks. Cox proportional

hazards regression will performed. The variables to be considered in the multivariate models are listed in previous section. The assumption of proportional hazards for each factor in the Cox model will be tested using time-dependent covariates. The proportionality assumptions will be further tested. A backward stepwise model selection approach will be used to identify all significant risk factors. Each step of model building may contain the main effect. Factors that are significant at 5% level will be kept in the final model. The potential interactions between the main effect and all significant risk factors will be tested. Adjusted probability of PFS and OS and adjusted cumulative incidence curves for competing risks endpoints will be generated from the final regression models. We also consider comparing the outcomes based on the year of HCT if there is sufficient number of cases for such evaluation to understand the impact of year of HCT in Burkitt lymphoma.

Non-CIBMTR data source:
N/A

References:

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2. Kelly JL, Toothaker SR, Ciminello L, et al. Outcomes of patients with Burkitt lymphoma older than age 40 treated with intensive chemotherapeutic regimens. Clin Lymphoma Myeloma. 2009; 9:307–310. [PubMed: 19717381]
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First HCT for adults (18+) with Burkitt lymphoma, 2008-2018

Characteristic	Auto	Allo
No. of patients	236	108
No. of centers	102	65
Research patient	67 (28)	38 (35)
CCN region - no. (%)		
US	166 (70)	82 (76)
Canada	14 (6)	1 (1)
Europe	29 (12)	13 (12)
Asia	7 (3)	0
Australia/New Zealand	0	5 (5)
Mideast/Africa	14 (6)	6 (6)
Central/South America	6 (3)	1 (1)
Prior auto-HCT - no. (%)		
No	NA	100 (93)
Yes	NA	8 (7)
Age at HCT - median (min-max)	48 (18-74)	42 (18-72)
Disease status prior to HCT - no. (%)		
CR	155 (66)	66 (61)
PR	62 (26)	23 (21)
Chemoresistant	12 (5)	15 (14)
Untreated	0	2 (2)
Unknown	7 (3)	2 (2)
Donor type - no. (%)		
Autologous	236	0
HLA-identical sibling	0	54 (50)
Other related	0	10 (9)
Well-matched unrelated (8/8)	0	28 (26)
Partially-matched unrelated (7/8)	0	2 (2)
Mis-matched unrelated (≤6/8)	0	1 (1)
Unrelated (matching TBD)	0	7 (6)
Cord blood	0	6 (6)
Graft type - no. (%)		
Bone marrow	1 (<1)	11 (10)
Peripheral blood	234 (99)	91 (84)
Umbilical cord blood	0	6 (6)
Missing	1 (<1)	0

Characteristic	Auto	Allo
Reported planned conditioning intensity - no. (%)		
RIC/NMA	NA	34 (31)
MAC	NA	73 (68)
Missing	NA	1 (1)
TX year - no. (%)		
2008	22 (9)	17 (16)
2009	23 (10)	14 (13)
2010	29 (12)	17 (16)
2011	28 (12)	12 (11)
2012	26 (11)	8 (7)
2013	27 (11)	8 (7)
2014	20 (8)	8 (7)
2015	13 (6)	3 (3)
2016	24 (10)	4 (4)
2017	11 (5)	10 (9)
2018	13 (6)	7 (6)
Follow-up - median (min-max)	38 (2-121)	50 (3-122)

Proposal: 1911-93

Title:
Evaluating outcomes of Hematopoietic Cell Transplantation in Hepatosplenic T Cell Lymphoma

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Hypothesis:
Hematopoietic Cell Transplantation (HCT) is associated with durable remissions in patients with Hepatosplenic T cell Lymphoma (HSTL)

Study objectives:
To describe clinical outcomes of patients with Hepatosplenic T cell Lymphoma (HSTL) undergoing hematopoietic cell transplantation including:

- Overall Survival (OS)
- Progression-free Survival (PFS)
- Non-relapse mortality (NRM)
- Cumulative incidence of acute graft versus host disease (aGVHD) and chronic graft versus host disease (cGVHD) (Allo-HCT only)
- Cumulative incidence of relapse/progression

To identify the impact of patient-, disease-, and transplant-related factors on the outcomes of PFS, OS, relapse and NRM for hematopoietic cell transplantation.

Scientific justification:
Hepatosplenic T cell Lymphoma (HSTL) is a rare and aggressive subtype of peripheral T cell lymphoma. The peak incidence is in adolescents and young adults, and is more common in males. The disease typically presents with hepatosplenomegaly, thrombocytopenia and systemic symptoms. Typically response of HSTL to standard chemotherapy regimens is poor. The clinical course progressive with a 5-year survival of only 7% and is considered incurable with standard conventional induction therapy alone (1,2).

Small retrospective studies have shown effect of HCT, allogeneic or autologous, on attainment of remissions in HSTL. The MSKCC group reported 14 patients with 12 who received HCT (4 auto-hct, 8 allo-hct). More than 50% of the HCT transplant recipients are alive, with relapse rate 50% in auto-hct and 28.5% in allo-hct (3). The European Society for Blood and Marrow Transplantation (EBMT) published outcomes of 25 patients, of which 18 received allogeneic hematopoietic cell transplantation (allo-HCT) and 7 autologous hematopoietic cell transplantation (auto-HCT). Allo-HCT had 3-year progression-free survival of 48% while 5 out of the 7 auto-hct patients relapsed and died from progressive disease (4). No randomized controlled trials (RCTs) exist comparing the efficacy of HCT to chemotherapy alone. Due to the rare nature of HSTL, it is highly unlikely that a RCT will ever be conducted. It is increasingly becoming a standard practice to offer an allogeneic HCT early in their treatment course, generally as front-line consolidation. We believe that there is an unmet need for larger observational studies to help guide and to better inform clinical decision-making regarding the role of HCT in HSTL. The most feasible way to evaluate post-transplant outcomes in these rare diseases is by using registry-based data. Thus, we propose to utilize the Center for International Blood and Marrow Transplantation Research (CIBMTR) database to evaluate outcomes of autologous and allogeneic HCT recipients with the diagnosis of HSTL.

Patient Eligibility:

Inclusion criteria:

- Diagnosis of HSTL
- First HCT between 2000-2017

Exclusion criteria:

- T-cell depleted Allo-HCT

Outcomes:

Primary outcomes:

- OS: Time to death. Death from any cause will be considered an event. Surviving patients will be censored at the time of last follow up.

Secondary outcomes:

- PFS: Survival following HCT without relapse or progression. Relapse or progression of disease are considered events
- Relapse/progression: Progressive disease or recurrences of disease would be counted as events. Treatment related death, defined as death without relapse or progression, is the competing event. Those who survive without recurrence or progression would be censored at the time of last contact
- NRM: Cumulative incidence of NRM. NRM is defined as death without preceding disease relapse/progression. Relapse and progression are competing events.
- Incidence of acute and chronic GVHD (Allo-HCT only): Cumulative incidence of grade II-IV and grade III-IV acute GVHD per CIBMTR consensus criteria(5), with death as competing risk. Cumulative incidence of chronic GVHD by 2014 NIH consensus criteria (6), with death as competing risk.
- Incidence of sinusoidal obstruction syndrome/ veno-occusive disease during the first 100 days after transplantation
- Cause of death: Descriptive only

Variables to be described (bolded variables will be considered in multivariate analysis):

Patient-related:

- **Age at transplant: continuous & by age group: decades**
- **Patient sex: male vs. female**
- **Karnofsky performance status at transplant: ≥ 90 vs. < 90 vs. missing**
- **HCT comorbidity index at transplant: 0 vs 1-2 vs ≥ 3 vs. missing**
- **Race: Caucasian vs. others vs. missing**

Disease-related:

- **Disease subtype (gamma/delta vs other)**
- **Disease state at time of transplant: CR1 vs CR2 vs PR vs SD vs PD**
- **Time from diagnosis to HCT**
- **Number of pre-transplant lines of therapy**
- **Organ involvement: (yes/no)**
- **Splenomegaly (yes/no)**
- **Induction therapy: ICE vs other induction strategies**
- **BM involvement: (yes/no)**
- **Cytogenetic abnormalities at diagnosis**

Transplant-related:

Auto-HCT:
- Time period transplant was performed: Continuous
- Conditioning: BEAM vs non-BEAM

Allo-HCT:
- **Cell source: bone marrow vs. peripheral blood**
- **Transplant donor type: Match related donor vs. match unrelated donor vs. mismatch unrelated donor vs haploidentical donor vs cord blood**
- **Conditioning intensity: myeloablative vs. reduced intensity conditioning**
- **Total Body Irradiation: TBI vs non-TBI based conditioning regimen**
    - **Myeloablative: TBI vs non-TBI based conditioning regimen**
    - **RIC/NMA: TBI vs non-TBI based conditioning regimen**
- **GVHD prophylaxis: CNI + MTX ± others except MMF, post Cy vs. CNI + MMF ±others except post Cy vs. CNI + others except MMF, MTX vs. missing vs. other**
- Donor-recipient sex match: male-male vs. male-female vs. female-male vs. female-female vs. missing
- **CMV serostatus matching (+/-, +/+, -/-, -/+) between donor and recipient**
- ABO compatibility: Minor vs Major vs matched
- **Year of transplant: continuous**
- Post transplant treatment: DLI vs others vs None

Study design:
A retrospective multicenter study will be conducted utilizing CIBMTR dataset. Patients will be eligible if they satisfied the criteria detailed in the "Patient Eligibility" section. Patients will be stratified first by type of transplant received (auto-HCT or Allo-HCT).
For Auto-HCT, Descriptive tables of patient, disease-, and transplant-related factors will be created. The tables will list median and range for continuous variables and percent of total for categorical variables. Cumulative incidence of relapse/progression and NRM will be calculated while accounting for competing events. Probabilities of OS will be calculated using the Kaplan-Meier estimator.
For Allo-HCT, patients will be stratified by conditioning intensity (myeloablative vs. reduced intensity) according to established definitions(7) such that subsequent analysis will compare these approaches and their effects on HCT outcomes. Descriptive tables of patient, disease-, and transplant-related factors will be created. The tables will list median and range for continuous variables and proportions for categorical variables. Cumulative incidence of chronic GVHD, relapse/progression, and NRM will be calculated while accounting for competing events. Probabilities of OS will be calculated using the Kaplan-Meier estimator. If Sample size and number of events allow, multivariate analysis will be performed using Cox proportional hazards models for outcomes for chronic GVHD, relapse/progression, NRM, PFS, and OS and logistic regression for acute GVHD. A stepwise model building approach will then be used to identify the significant risk factors associated with the outcomes. Factors which are significant at a 5% level will be kept in the final model. The potential interactions between main effect and all significant risk factors will be tested. The proportional hazards assumption will be checked for the Cox model. If violated, it will be added as time-dependent covariates.

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First Auto HCT for adults (18+) with hepatosplenic T-cell lymphoma, 2008-2018

Characteristic	N (%)
No. of patients	44
No. of centers	31
Research patient	5 (11)
CCN region - no. (%)	
US	31 (70)
Canada	1 (2)
Europe	2 (5)
Asia	3 (7)
Australia/New Zealand	1 (2)
Mideast/Africa	1 (2)
Central/South America	5 (11)
Age at HCT - median (min-max)	45 (18-75)
Disease status prior to HCT - no. (%)	
CR	33 (75)
PR	10 (23)
Chemoresistant	1 (2)
Graft type - no. (%)	
Peripheral blood	44
TX year - no. (%)	
2008	4 (9)
2009	5 (11)
2010	4 (9)
2011	2 (5)
2012	3 (7)
2013	2 (5)
2014	6 (14)
2015	5 (11)
2016	4 (9)
2017	8 (18)
2018	1 (2)
Follow-up - median (min-max)	59 (5-116)

First Allo HCT for adults (18+) with hepatosplenic T-cell lymphoma, 2008-2018

Characteristic	N (%)
No. of patients	130
No. of centers	73
Research patient	40 (31)
CCN region - no. (%)	
US	108 (83)
Canada	6 (5)
Europe	10 (8)
Asia	1 (1)
Australia/New Zealand	1 (1)
Mideast/Africa	2 (2)
Central/South America	2 (2)
Prior auto-HCT - no. (%)	
No	117 (90)
Yes	13 (10)
Age at HCT - median (min-max)	38 (18-70)
Disease status prior to HCT - no. (%)	
CR	64 (49)
PR	42 (32)
Chemoresistant	18 (14)
Untreated	3 (2)
Unknown	3 (2)
Donor type- no. (%)	
HLA-identical sibling	43 (33)
Other related	23 (18)
Well-matched unrelated (8/8)	27 (21)
Partially-matched unrelated (7/8)	8 (6)
Unrelated (matching TBD)	7 (5)
Cord blood	22 (17)
Graft type - no. (%)	
Bone marrow	17 (13)
Peripheral blood	91 (70)
Umbilical cord blood	22 (17)
Reported planned conditioning intensity - no. (%)	

Characteristic	**N (%)**
RIC/NMA	43 (33)
MAC	87 (67)
Year of HCT - no. (%)	
2008	9 (7)
2009	6 (5)
2010	6 (5)
2011	10 (8)
2012	12 (9)
2013	14 (11)
2014	15 (12)
2015	11 (8)
2016	15 (12)
2017	13 (10)
2018	19 (15)
Follow-up - median (min-max)	36 (3-120)

Proposal: 1911-267

Title:
Comparison of outcomes of DLBCL patients with partial response after salvage therapy who underwent CAR-T vs. ASCT

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Background:
- axicabtagene ciloleucel and tisagenlecleucel are approved for treatment of DLBCL and similar histologies after 2 or more lines of treatment.
- In practice, this label often includes patients who have measurable disease after first or subsequent line of salvage therapy even if they had a significant response to the most recent chemotherapy.
- Autologous stem cell transplant (ASCT) is sometimes offered to patients with partial response to salvage chemotherapy. This practice was more common in the pre CAR-T era.
- Patients with chemosensitive disease after salvage therapy could be potential candidates for both treatment modalities and there has been no randomized study comparing CAR-T vs. ASCT
- Current randomized trials comparing CAR-T vs. ASCT (ZUMA-7, TRANSFORM), consider ASCT standard for patients with a partial response after salvage.
- Factors like disease bulk and level of chemosensitivity after are important factors to consider while comparing these 2 modalities.

Research hypothesis:
CAR-T therapy provides better clinical outcome compared to ASCT in patients with partial response to salvage therapy

Specific aims:
- Comparison of progression-free survival (PFS) after CAR-T or ASCT in patients with PR after most recent chemotherapy
- Comparison of overall response and complete response rates (OR and CR) after CAR-T or ASCT in patients with PR after most recent chemotherapy
- Comparison of overall survival (OS) after CAR-T or ASCT in patients with PR after most recent chemotherapy

Scientific impact:
- Patients with chemosensitive disease but detectable disease after salvage therapy could be potential candidates for both treatment modalities and there has been no randomized study comparing CAR-T vs. ASCT. This study will help with clinical decision making in this setting.

Scientific justification:
- Given the design of ZUMA-7 and TRANSFORM studies, this specific question will not be answered but the clinical question will remain to be an important one in upcoming years

Patient eligibility population:
- CAR-T group
    - Adult patient with a diagnosis of DLBCL (or other aggressive lymphomas) who received Axicabtagene Ciloleucel (axi-cel; Yescarta) or Tisagenlecleucel (Kymriah) commercially.

    - Patients who had partial response to the most recent chemotherapy before lymphodepletion
- ASCT group
    - Patients with DLBCL (or other aggressive lymphomas) who received ASCT
    - Active disease at the time of ASCT
    - No prior CAR-T therapy
- Would start with CAR-T group and based on the number of patients, would select 1:1 or 1:2 matching from the ASCT patients

Data Requirements:
Forms 4000 and 4100
At minimum:
Baseline:
- Age
- Sex
- Prior lines of treatment (n and type)
- Response to the most recent chemotherapy before lymphodepletion
- Bridging therapy between lymphodepletion and cell infusion (type)

Post CAR-T:
- Cytokine-release syndrome (CRS) (yes/no, grade)
- Neurotoxicity (NT) (yes/no, grade)
- Response at first assessment (1 month) (CR,PR,SD,PD)
- Relapse (yes/no)
- Date of relapse
- Died (yes/no)
- Date of death
- Date of last contact

Post ASCT:
- Response at first assessment (3 month) (CR,PR,SD,PD)
- Relapse (yes/no)
- Date of relapse
- Died (yes/no)
- Date of death
- Date of last contact

Sample requirements:
N/A

Study design:
Retrospective analysis

Non-CIBMTR data source:
N/A

Conflicts of interest:
None

References:
None

Baseline characteristics for patients undergoing 1st commercial CAR-T prior to HCT or 1st auto-HCT for DLBCL in PR

Characteristic	CAR-T	AutoHCT
No. of patients	165	251
No. of centers	49	85
Age at infusion, by category - no. (%)		
Median (min-max)	62 (19-82)	57 (18-80)
18-29	5 (3)	18 (7)
30-39	11 (7)	22 (9)
40-49	15 (9)	27 (11)
50-59	40 (24)	75 (30)
60-69	65 (39)	84 (33)
≥ 70	29 (18)	25 (10)
Gender - no. (%)		
Male	112 (68)	153 (61)
Female	53 (32)	98 (39)
Race - no. (%)		
White	143 (87)	160 (64)
African-American	8 (5)	53 (21)
Asian	6 (4)	21 (8)
Pacific Islander	0	2 (1)
Native American	0	5 (2)
More than one race	5 (3)	5 (2)
Not reported	3 (2)	5 (2)
Ethnicity - no. (%)		
Hispanic or Latino	15 (9)	21 (8)
Non Hispanic or non-Latino	142 (86)	211 (84)
Non-resident of the U.S.	3 (2)	12 (5)
Not reported	5 (3)	7 (3)
Karnofsky performance score prior to HCT - no. (%)		
90-100	71 (43)	131 (52)
80	57 (35)	82 (33)
< 80	19 (12)	36 (14)
Not reported	18 (11)	2 (1)
Disease response at HCT - no. (%)		

Characteristic	CAR-T	AutoHCT
PR	165	251
Disease status prior to HCT - no. (%)		
Relapse, 1st	31 (19)	104 (41)
Relapse, other	48 (29)	22 (9)
PIF/Untreated	86 (52)	125 (50)
Types of prior HCTs - no. (%)		
No	104 (63)	NA
Yes	61 (37)	NA
Prior allo-HCT(s)	5 (3)	NA
Prior auto-HCT(s)	52 (32)	NA
Product - no. (%)		
Kymriah	17 (10)	NA
Yescarta	148 (90)	NA
Year of CT/HCT - no. (%)		
2011	0	1 (0)
2012	0	3 (1)
2013	0	17 (7)
2014	0	39 (16)
2015	0	68 (27)
2016	0	46 (18)
2017	0	32 (13)
2018	104 (63)	39 (16)
2019	61 (37)	6 (2)

Combined Proposal: (1910-01 / 1911-61 / 1911-185)

Title:
Outcomes of Salvage AHCT in Double Hit DLBCL

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Research hypothesis:
We hypothesize that disease status and chemosensitivity impacts long-term outcomes of relapsed/refractory DHL treated with AHCT (Autologous Hematopoietic cell transplant) consolidation after salvage chemotherapy

Specific aims:
- Aim 1: To determine the effect of disease status and chemosensitivity of relapsed / refractory DHL treated with AHCT on disease outcomes, including OS, PFS, RFS and NRM.
- Aim 2: Identify patient, disease and transplant related factors associated with improved survival and disease control after AHCT in relapsed/refractory DHL.
- Aim 3: Compare outcomes of relapsed/ refractory DHL treated with AHCT to relapsed/ refractory DLBCL with only MYC rearrangement undergoing AHCT.

Scientific impact:
Data regarding the role of AHCT in relapsed DHL is limited and the results from this large database study (i) will help inform current clinical practice on the use of AHCT for relapsed/refractory DHL and ii) identify factors that might impact transplant outcomes in this patient population.

Scientific justification:
Diffuse large B cell lymphoma (DLBCL) is increasingly considered a heterogeneous disease with various subgroups that can be identified based on morphology, molecular testing and gene expression profile.[1] Double hit lymphoma (DHL) is an aggressive subtype of DLBCL that is characterized by rearranged MYC and co-existing BCL2 and/or BCL6 rearrangement. DHL has been shown to have poor outcomes after standard chemoimmunotherapy, with lower progression free survival and less durable remission.[2,3]
Salvage chemotherapy followed by AHCT is considered as the standard of care for relapsed/ refractory DLBCL.[4] However, there are limited data regarding role of AHCT in patients with DHL. Epperla and coworkers observed that 2-year OS following AHCT was inferior among patients with MYC positive DLBCL compared to MYC negative patients, irrespective of the presence of additional rearrangements involving BCL2 or BCL6.[5] In the Bio-CORAL study, patients with MYC positive disease had poor outcomes after salvage chemotherapy and AHCT. Further analysis revealed the majority of these MYC positive patients had DHL identified by FISH.[6]
A multicenter study evaluated the impact of baseline clinical factors, salvage regimen and AHCT on the outcomes of previously untreated DHL. Among 311 patients included in this study, 83 received AHCT (39

in CR1 and 14 in PR1). The number of patients receiving AHCT for salvage was too small to evaluate transplant in the salvage setting.[7] Recently, Herrera and colleagues evaluated the use of AHCT for treatment of relapsed/refractory DLBCL, including a subgroup of patients with DEL and DHL. In this retrospective study of 117 patients 44% of patients had DEL and 10% DHL. Patients with DHL had inferior PFS and OS than non-DHL patients (4-year PFS: 28% vs. 57% [P=.013], and 4-year OS: 25% vs. 61% [P=.002], respectively). In multivariate analysis, both DEL and DHL status were independently associated with inferior PFS after controlling for disease status at AHCT. DHL and partial response at AHCT were associated with inferior OS.[8]

Taken together, these retrospective studies are limited by sample size and the impact of AHCT on the outcomes of relapsed DHL remains unclear. In addition, the small sample sizes limit the ability to identify predictive and prognostic factors. Several confounding factors, including wide age range as well as variable performance status and access to transplant, preclude conducting an inclusive prospective cohort study of DHL patients. A large database such as CIBMTR represents a unique opportunity for a retrospective study of DHL in transplant with adequate statistical power to evaluate role of salvage AHCT and potentially identify prognostic factors that can help select DHL patients who will most benefit from AHCT.

Patient eligibility population:

Inclusion criteria:

- Patients undergoing AHCT for relapsed/refractory DHL (Rearrangements of MYC and either BCL2 and/or BCL6)
- Patients undergoing AHCT for relapsed/refractory DLBCL with MYC rearrangement only and no BCL2 or BCL6 rearrangements
- Age ≥ 18 years
- Transplant between 2008 and 2018

Data requirements:

The following variables will be collected using CRF forms and analyzed:

Patient related variables:

- Age at diagnosis
- Age at AHCT
- Gender: male vs. female
- Race: White vs. African American vs. Hispanics vs. others
- Karnofsky performance score
- HCT-CI- 0-2 vs. ≥3

Disease related variables:

- Cell of origin- GCB (Germinal center B-Cell) vs. Non- GCB
- Immunohistochemistry (MYC, BCL2) – Positive vs. negative
- IPI score at diagnosis: 0-1 vs 2 vs 3 vs 4-5
- Prior follicular lymphoma (ie transformed disease vs not)
- Bulky disease at diagnosis: yes vs no
- Disease stage at diagnosis
- FISH results for MYC, BCL2 and BCL6
- Time to relapse from CR1
- Type of first line therapy
- Type and Number of salvage chemotherapy lines
- Time from diagnosis to HCT

- Remission status at transplant (CR vs. PR)
- CNS involvement yes vs. no
- Bone marrow involvement at diagnosis: yes vs. no vs. missing
- Bone marrow involvement at AHCT: yes vs. no vs. missing

Transplant related variables:
- BEAM/BEAC vs. others
- CD34 cell dose
- Pre- or post-Transplant RT
- Time to relapse/progression from AHCT
- Time to death from AHCT

Sample requirements:
No biological samples required

Study design:
Descriptive patient, disease and transplant characteristics will be compared with Chi-square or Fisher's exact test statistics for categorical and T- test for continuous variables as appropriate. Univariate probabilities of OS and PFS will be calculated using the Kaplan-Meier estimator with log-rank test for univariate comparisons. Cumulative incidence of NRM and relapse will be estimated by Fine and Gray's method of competing risk regression model.[9] Multivariate analysis will be performed by step-wise Cox proportional hazard model to analyze patient, disease and transplant related variables and build a predictive model by retaining variables significant at 0.05[10].
Definitions for our endpoints are as follows:
- Non-relapse mortality (NRM): Cumulative incidence of NRM at day 100 and 1 year. NRM is defined as death without preceding disease relapse/progression. Relapse and progression are competing events.
- Relapse/Progression: Cumulative incidence of disease relapse/progression at 1 year with NRM as competing event.
- Progression-free survival (PFS): survival without disease progression or relapse from CR. Progression, relapse, and death are considered events. Patients who are alive and in remission are censored at the time of last follow-up.
- Overall survival (OS): time to death. Death from any cause will be considered an event. Surviving patients will be censored at the time of last follow-up.

Non-CIBMTR data source:
Not applicable

Conflicts of interest:
No conflict of interest applicable

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First Auto HCT for adults (18+) with DHL DLBCL, 2010-2018

Characteristic	DHL
No. of patients	167
No. of centers	62
Research patient	24 (14)
CCN region - no. (%)	
US	138 (83)
Canada	24 (14)
Europe	2 (1)
Asia	1 (1)
Australia/New Zealand	2 (1)
Age at HCT - median (min-max)	63 (18-80)
Disease status prior to HCT - no. (%)	
CR	120 (72)
PR	40 (24)
Chemoresistant	6 (4)
Untreated	1 (1)
Graft type - no. (%)	
Bone marrow	0
Peripheral blood	167
TX year - no. (%)	
2010	4 (2)
2011	4 (2)
2012	7 (4)
2013	27 (16)
2014	14 (8)
2015	12 (7)
2016	6 (4)
2017	11 (7)
2018	82 (49)
Follow-up - median (min-max)	13 (3-77)

Proposal: 1911-256

Title:
Outcome of Patients with Primary Refractory Diffuse large B cell lymphoma (DLBCL) undergoing Autologous Stem Cell Transplantation (AHCT)

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Specific aims:
To evaluate clinical outcomes of patients with primary refractory diffuse large B cell lymphoma undergoing autologous hematopoietic stem cell transplant (AHCT) as it relates to the following:

- Overall survival (OS)
- Progression-free survival (PFS)
- Treatment-related mortality (TRM)
- Relapse

Scientific justification:
About 10–15% of patients with diffuse large B-cell lymphoma DLBCL treated with R-CHOP will have primary refractory disease. It includes patients with documented persistent disease at completion of therapy, patients with less than partial response (PR) to frontline therapy and or patients progressing within 3 months of completion of therapy[1–3].
Optimal management of patients with primary refractory DLBCL is unknown. However, most patients proceed with rituximab combined with salvage chemotherapy (ST). Among those achieving either a PR or CR to ST, consolidation with high–dose therapy and autologous stem cell transplant (HDT/ASCT) is the standard of care. The data for this approach is largely borrowed from the PARMA trial. However, primary refractory disease were not included and the study was performed in the pre-rituximab era[4].
Vardhana et al. reported on the outcomes of 82 transplant-eligible patients with primary refractory DLBCL who underwent salvage therapy with the intent of administering high-dose therapy and ASCT to patients achieving chemo-sensitive remission. The estimated 3-year overall and progression-free survival for all patients was 38% and 29%, respectively, and 65% and 60% respectively for patients proceeding to stem cell transplant. The authors concluded that salvage chemotherapy with the intent of subsequent high-dose therapy and ASCT remains a feasible strategy in certain patients with primary refractory DLBCL, particularly for those achieving a PR to frontline therapy[5].
There are no randomized trials restricted to patients with primary refractory DLBCL; all prospective studies have included patients with both relapsed and refractory disease. Prior studies, including results from the Autologous Blood and Marrow Transplant Registry (ABMTR) and the Southwest Oncology Group (SWOG) have suggested that HDT/ASCT may be beneficial in patients with chemo-sensitive disease[6,7], but the patients in these studies did not receive rituximab as part of front-line therapy.
Recently, SCHOLAR 1 study reported on patient-level data available for patients with refractory DLBCL from 4 sources: observational cohorts from MD Anderson Cancer Center (MDACC) and the Molecular Epidemiology Resource of the University of Iowa/Mayo Clinic Lymphoma Specialized Program of Research Excellence (IA/MC) and follow-up of 2 large phase 3 randomized controlled trials, Canadian Cancer Trials Group study LY.12, and the Lymphoma Academic Research Organization (LYSARC) Collaborative Trial in Relapsed Aggressive Lymphoma (CORAL) study. While the median overall survival of patients with primary refractory disease was 7.1 months (1-year OS 29% and 2-year OS 24%), the patients with CR to salvage therapy had median OS of 14.9 months and for those undergoing ASCT (14.4

months). Thirty-one patients who achieved a CR underwent ASCT, and their median OS was more than 6 years at the time of this analysis. Of the 54 patients who achieved a partial response (PR) and underwent ASCT, the median OS was 17.8 months. Fifty-seven patients who received ASCT were alive at last follow-up (range, 1-14 years)[8].
While Chimeric Antigen Receptor T cells (CART) have been revolutionary for patients with advanced disease, they are approved for patients with DLBCL refractory to two prior lines of therapy and is not widely accessible to a majority of the patients. Thus, it is important to understand the outcomes of patients with primary refractory disease who respond to salvage therapy and undergo HDT/ASCT.

Patient eligibility population:

- > 18 years of age undergoing AHCT for primary refractory DLBCL.

Data requirements:

Type of data	Data point	Specific data
Patient Specific	Patient specific characteristics	• Age at transplant (Date of birth) • Gender • Race • Significant comorbidities • Primary disease • FISH for cMYC, BCL2, BCL6 • Prior line(s) of therapy • HCT-CI • HCT-CI/age
Transplant Specific	Transplant date	• Transplant date
	Preparative regimen used	• BEAM • Others
Outcome Measures	Engraftment	• Time to absolute neutrophil count $\geq$500 cells/mm^3 for 3 consecutive laboratory readings • Time to unsupported platelets $\geq$20 x 10^9 cells/L and $\geq$50 x 10^9 cells/L • Graft failure (primary and secondary)
	Mortality	• Time to mortality • Day 100, 6 months and 1 year mortality • Treatment related mortality at 6 months and 1 year • Cause of mortality
	Disease relapse	• Incidence of disease relapse • Time to disease relapse

Sample requirements:
None

Study design:
The goal of this study is to evaluate the clinical outcomes of adult patients with primary refractory diffuse large b cell lymphoma undergoing autologous HCT according to clinical endpoints as listed above.

The probabilities of PFS and OS will be calculated using the Kaplan Meier method. Full statistical analysis will be performed by members of the statistical team of the CIBMTR.

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First Auto HCT for adults (18+) with primary refractory DLBCL (CRF Track), 2008-2018

Characteristic	N (%)
No. of patients	174
No. of centers	79
CCN region - no. (%)	
US	153 (88)
Canada	12 (7)
Asia	3 (2)
Central/South America	6 (3)
Age at HCT - median (min-max)	56 (20-76)
Disease status prior to HCT - no. (%)	
Chemosensitive	125 (72)
Chemoresistant	49 (28)
Graft type - no. (%)	
Peripheral blood	174
TX year - no. (%)	
2008	17 (10)
2009	5 (3)
2010	3 (2)
2011	2 (1)
2012	3 (2)
2013	10 (6)
2014	29 (17)
2015	41 (24)
2016	30 (17)
2017	22 (13)
2018	12 (7)
Follow-up - median (min-max)	36 (3-118)

Proposal: 1911-121

Title:
Outcomes of autologous stem cell transplantation in patients with follicular lymphoma with early relapse after frontline Bendamustine/Rituximab treatment.

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Research hypothesis:
Patients with follicular lymphoma (FL) who have early disease progression (within 24 months/POD24) after frontline treatment have poor outcomes compared to patients without POD24.
We hypothesize that patients with FL and POD24 after frontline treatment with Bendamustine/Rituximab (BR) may benefit from autologous stem cell transplantation (ASCT) at first relapse.

Specific aims:
- Establish the number of patients with FL and POD24 on the CIBMTR database who were treated with autologous stem cell transplantation at first relapse after BR chemo-immunotherapy
- Establish 2-year progression free survival (PFS) and overall survival (OS) of patients with FL and POD24 treated with autologous stem cell transplantation at first relapse after frontline therapy with BR
- Collect information on salvage chemotherapy regimens, and stem cell mobilization and conditioning in patients with FL and POD24 who have relapsed after frontline BR

Scientific impact:
POD24 in follicular lymphoma is now a well established concept.
In this observational study, we aim to characterize the outcomes of those patients with follicular lymphoma and POD24 who undergo autologous stem cell transplantation after failure of frontline BR chemo-immunotherapy. This data will be useful in informing the care of individual patients as well as constituting the basis for designing clinical trials in this underserved patient population.

Scientific justification:
Follicular lymphoma (FL) is a common lymphoma, accounting for about 20% of total cases of non-Hodgkin Lymphoma (NHL). Bendamustine/Rituximab (BR) has relatively recently been adopted as the preferred frontline chemo-immunotherapy regimen, after it was demonstrated to lead to superior outcomes when compared with other commonly used frontline regimens such as, for example R-CHOP or R-CVP, in two Phase 3 clinical trials (1, 2).
However, FL remains a clinically heterogeneous disease, and a significant number of patients relapse early after frontline treatment. Previous research led by CIBMTR established the concept of POD24, where relapse of FL within 24 months of chemo-immunotherapy initiation identified a group of patients with poor outcomes and worse overall survival (3).
The prospective observational National LymphoCare Study (NLCS), published in 2015, analyzed 2727 patients with FL enrolled between 2004 and 2007, at over 200 sites in the US. Of the 588 patients treated with R-CHOP chemotherapy, POD24 occurred in approximately 20% of patients, and was associated with inferior overall survival (OS) of 50% at 5 years, compared to 90% in the group without

progression (3). This finding was subsequently also validated by other groups: for example, the German Low-Grade Lymphoma Study Group (GLSG) (151 patients) and the British Columbia Cancer Agency (BCCA) (107 patients from a population-based registry) demonstrated POD24 in 17% and 23% of evaluable patients, respectively. Five-year OS rates were 41% (vs 91% for those without POD24, $P < .0001$) in the GLSG cohort, and 26% (vs 86%, $P < .0001$) in the BCCA cohort (4). Finally, in a large validation cohort of 5453 patients with FL treated across 13 international randomized controlled clinical trials, POD24 emerged as the most robust independent risk factor for poor survival (Hazard Ratio 5.67) (5).

Importantly, the type of induction therapy may influence outcomes patients with POD24: for example, early progression after chemo-immunotherapy appears to predict for worse outcomes when compared to early progression after single-agent rituximab (6). Moreover, an exploratory analysis performed as part of the GALLIUM study which compared obinutuzumab-based chemotherapy with rituximab-based chemotherapy, showed a reduction in the number of patients with POD24 but still confirmed an increased risk of mortality in this patient population (7).

The advent of BR chemo-immunotherapy as a relatively new frontline choice of treatment for follicular lymphoma may impact patterns of disease recurrence in FL, and only limited information as regards the use and impact of autologous stem cell transplantation in this area is available. For instance, fewer patients may relapse after frontline BR, with single centre series reporting POD24 to be in the range of 9-12% (8). In addition, more patients with early relapse after BR may have high grade transformation (HGT) events; in the GALLIUM study, for example, approximately 20% of patients with POD24 were reported to have a HGT event (7), whereas in a more recent series from British Columbia, 76% of patients with POD24 after BR were thought to have HGT at disease progression (with not all events having been histologically confirmed) (8).

In summary, therefore, we think it is timely to establish the incidence of first relapse events after frontline BR chemotherapy in patients with FL, and the uptake of auto-transplantation in this setting. This dataset will constitute a useful comparator for previously collected data from CIBMTR as regards the role of ASCT in patients with early relapsed FL, and will help to establish the characteristics and outcomes of this difficult-to-treat patient population.

Patient eligibility population:

Inclusion criteria:

- age ≥ 18 years
- histological diagnosis of FL (Grade 1, 2, or 3a)
- FL stage II, III, or IV disease requiring frontline treatment
- received BR as frontline treatment
- relapsed/refractory FL within 24 months of initiation of BR (POD24)
- treated for POD24 with autologous stem cell transplant (ASCT)

Exclusion criteria:

- Patients not receiving BR as first therapy for FL
- Patients undergoing ASCT for high grade transformation events

Data requirements:

This study aims to analyze patient-, disease- and treatment-related data collected by CIBMTR for patients with FL undergoing ASCT for relapsed/refractory disease, between 2009 and 2019.

The table below outlines the anticipated parameters for data collection:

Data Category	Data to be collected
Patient characteristics	• Age at ASCT • Sex • Race/ethnicity • ECOG Performance Status • Comorbidity scoring (e.g. by Charleson Comorbidity Index) • FL histology/grading • Ann Arbor stage at FL relapse • FLIPI/(FLIPI2/PRIMA-PI) at diagnosis • FLIPI/(FLIPI2/PRIMA-PI) at relapse
Treatment information	• Number of therapies prior to ASCT • Number of cycles of frontline BR • Rituximab maintenance post-BR, pre-ASCT • Type of salvage therapy after frontline BR • Mobilization regimen • Disease status at ASCT • Conditioning regimen used for ASCT
Outcome variables	• Relapse post-ASCT • Progression post-ASCT • Death post-ASCT • Death post-ASCT whilst in remission • Transformation post-ASCT

Sample requirements:
N/A. This study does not aim to collect biological samples.

Study design:
This is a retrospective observational study.
Descriptive statistics will be used to summarize patient and disease characteristics. Progression free survival (PFS) is defined as the time from transplant to the first documentation of lymphoma progression/recurrence or death due to any cause, whichever comes first. Kaplan-Meier methodology will be used to describe the estimated 2 year and median PFS for all patients. Overall survival (OS) will be described as the time from transplant to the date of death due to any cause. Kaplan-Meier methodology will be used to report the estimated 2 year and median OS for all patients.

Non-CIBMTR data source:
N/A. This study does not anticipate using a non-CIBMTR data source. However, a non-transplant cohort of FL patients with POD24 may be desirable as a comparator, and our group is currently in the process of

identifying and collating data sources that may allow the data accrued in this project to be linked in a meaningful way.

Conflicts of interest:
None

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First Auto HCT for adults (18+) with FL after frontline BR or R-CHOP with POD24 (CRF Track), 2008-2018

Characteristic	BR	R-CHOP
No. of patients	31	53
No. of centers	23	36
CCN region - no. (%)		
US	30 (97)	52 (98)
Canada	1 (3)	1 (2)
Time from diagnosis to HCT (months) - median (min-max)	29 (8-122)	37 (9-138)
Age at HCT - median (min-max)	60 (34-74)	58 (37-78)
Disease status prior to HCT - no. (%)		
CR	16 (52)	27 (51)
PR	11 (35)	23 (43)
Chemoresistant	4 (13)	3 (6)
Graft type - no. (%)		
Peripheral blood	31	53
TX year - no. (%)		
2008	0	4 (8)
2009	0	5 (9)
2013	2 (6)	2 (4)
2014	6 (19)	7 (13)
2015	3 (10)	12 (23)
2016	7 (23)	8 (15)
2017	4 (13)	12 (23)
2018	9 (29)	3 (6)
Follow-up - median (min-max)	24 (3-59)	35 (3-112)

Proposal: 1911-42

Title:
Outcomes of Allogeneic HCT in patients with Hodgkin Lymphoma in the era of Checkpoint Inhibitors: A joint CIBMTR and EBMT analysis.

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Hypothesis:
Results of allogeneic transplant for Hodgkin Lymphoma (HL) in the recent era have improved in part because prior exposure to checkpoint inhibitors improves post-transplant outcomes through decreased relapse.

Specific aims:
Assess outcomes in adult patients with Hodgkin lymphoma undergoing reduced intensity allo-HCT with or without prior exposure to checkpoint inhibitors.

General Outcomes to be examined include:
Primary objective:
- Overall Survival.

Secondary objectives:
- Engraftment (neutrophil, platelet), graft failure
- NRM
- acute GVHD (II-IV and II-IV)
- chronic GVHD
- relapse/progression
- PFS/DFS
- To identify factors predictive of outcomes with the use of CPI prior to HCT.
- To describe and identify factors predictive of response and outcomes with the use of CPI post HCT.

Scientific impact:
The approvals of new and highly effective drugs such as brentuximab vedotin (BV) and checkpoint inhibitors (CPI) have resulted in lower numbers of patients with Hodgkin lymphoma being referred for allo-HCT. However, results in the modern era suggest a significant improvement in overall survival in those patients with Hodgkin Lymphoma who undergo allo-HCT. The key points are: 1) AlloHCT remains a curative option for Hodgkin Lymphoma and may be underutilized; 2) Results in the recent era of CPI have shown remarkable outcomes of allo-HCT in HL; and 3) there is data to suggest graft source may be important and particularly haplo. Understanding factors that impact HCT outcomes including prior use of CPI, which has now become standard, will be important in optimal patient selection and choice of transplant approach. Furthermore, many experts are now advocating the use of haploidentical donors in Hodgkin lymphoma allo-HCT based on recent data showing improved survival compared to other graft sources. This would be in contrast to comparisons for all other diseases and may therefore reflect a CPI effect rather than a graft source effect. What is therefore missing is a clear analysis that separates out

the CPI effect and the haplo effect. It may be that both are important or it is just CPI, in which case haplo should not be promoted as the preferred graft but considered as one additional option.

Scientific justification:

Hodgkin lymphoma (HL) is a rare malignancy that has a bimodal distribution of incidence with most patients diagnosed between 15 and 30 years of age and another peak in those older than 55 years. It is estimated that in 2014, approximately 9,190 people were diagnosed with HL in the United States.[1] Despite high success rates with initial chemotherapy, relapse occurs in 10-20% of patients with HL and a small minority is nonresponsive to initial chemotherapy. The standard management of these patients includes high-dose chemotherapy (HDT) followed by autologous stem cell transplant (ASCT). For patients who relapse following ASCT, eligible candidates have historically been offered allogeneic SCT.[2,3] The past decade has been notable for the approval by the FDA of highly effective novel therapies in patients with HL, including brentuximab vedotin (BV) and the checkpoint inhibitors (CPI).[4-11] CPI have been investigated in large prospective trials. The Checkmate 205 study included patients who had not received brentuximab vedotin (BV), had received after an ASCT, and had received BV both pre and post ASCT [9,12]. The objective response rate was 69% overall and 65% to 73% in each cohort [9]. The median duration of response was 16.6 months (95% CI, 13.2 to 20.3 months), and median progression-free survival was 14.7 months (95% CI, 11.3 to 18.5 months). The KEYNOTE-087 study examined 3 cohorts of patients treated with pembroluzimab, patients who progressed after ASCT and BV, patients who failed salvage chemotherapy and BV, were ineligible for ASCT, and those who failed ASCT but did not receive BV [11,13]. The ORR was 69.0% (95% CI, 62.3% to 75.2%), and the CR rate was 22.4% (95% CI, 16.9% to 28.6%). ORRs were 73.9% for cohort 1, 64.2% for cohort 2, and 70.0% for cohort 3. More recently, nivolumab has been tested in the upfront setting in combination with AVD [14]. The ORR was 84% (71% to 93%), with 67% (52% to 79%) achieving CR. Additional studies are ongoing and nivolumab has also been combined with BV [15,16].

The increasing use of BV and CPIs has likely resulted in decreased utilization of allo-HCT in this patient population (A Sureda, EHA 2018). Prior studies have shown improved outcomes of allo-HCT in HL in the brentuximab era,[17] although an EBMT report showed that prior BV did not directly affect OS after HCT.[18] Interestingly recent preliminary data suggests that outcomes in patients with HL who were treated with CPI are improved compared to historical controls.[9] While there is currently limited published data regarding the use of CPI prior to or after HCT, a few preliminary studies have been reported.[9,19] Merryman et al described 39 patients, including 31 with HL, who underwent allo-HCT after prior CPI.[19] The 1-year OS and PFS were 89% (95% confidence interval [CI], 74-96) and 76% (95% CI, 56-87), respectively, whereas the 1-year cumulative incidences of relapse (CIR) and NRM were 14% (95% CI, 4-29) and 11% (95% CI, 3-23), respectively. More recently, Armand et al reported outcomes of 44 patients who proceeded to allo-HCT after treatment with nivolumab.[9] At the time of publication, the 6-month PFS estimate was 82% and the 6-month OS estimate 87%. These results are markedly better than previously published CIBMTR data, where Devetten et al reported probabilities of PFS and OS of 30% and 56% at 1 year and 20% and 37% at 2 years, respectively.[20] Finally the potential benefit of choosing a haploidentical donor over other graft sources remains controversial with conflicting data in the literature.[21,22] It is possible that the results of these studies do not correct for prior CPI use, which in part coincides with the increasing use of haploidentical HCT.

Patient eligibility population:

This study will include adult patients with Hodgkin Lymphoma who received a first allogeneic using a reduced intensity conditioning between 01/2008 and 12/2018.

Inclusion criteria:

- first allo-HCT between 2008 and 2018
- Age > 18
- Donors include MSD, MUD and HLA-haploidentical
- GVHD prophylaxis (CNI/MTX, CNI/MMF, PTCY/CNI/MMF) – exclude ex vivo T cell depletion
- Reduced intensity conditioning

Data requirements:

CIBMTR:

Utilizing data collected by CIBMTR from pre and post HCT, which includes pre-transplant essential data form #2400, post-transplant essential data form #2450, chimerism studies form #2451, selective post-transplant selective data form #2455 and 100 day post-HSCT data form #2100. The parameters to be assessed are outlined in table 1 below.

EBMT:

corresponding data to CIBMTR forms.

Table 1 Data Requirements:

Type of data	Data point	Specific data
Patient Specific	Patient specific characteristics	Age at transplant (Date of birth) Gender Race Significant comorbidities Prior autologous transplant Remission status (CR1, CR2, etc) Karnofsky performance status at transplant: ≥ 90 vs. < 90 vs. missing HCT-CI HCT-CI/age Prior use of checkpoint drug (nivolumab, pembrolizumab) and time from last dose.
Transplant Specific	Transplant date	Transplant date
	Preparative regimen used	Reduced Intensity/ non-myeloablative
	GVHD prophylaxis	Calcineurin inhibitor based (cyclosporin, tacrolimus) Sirolimus PTCY Other
	Graft characteristic	Donor-recipient HLA match
	Donor source	Sibling Unrelated Haploidentical
Outcome Measures	Engraftment	Time to absolute neutrophil count $\geq$500 cells/mm^3 for 3 consecutive laboratory readings Time to unsupported platelets $\geq$20 x 10^9 cells/L and $\geq$50 x 10^9 cells/L Donor-recipient chimerism

		Graft failure (primary and secondary)
	GVHD	Acute GVHD (aGVHD) Incidence of grade II-IV acute GVHD (aGVHD) (subset evaluating grade III-IV aGVHD) Time to aGVHD GVHD after day 100 Incidence of chronic GVHD (cGVHD) Severity of GVHD after day 100
	Mortality	Time to mortality Day 100, 6 months and 1 year mortality Treatment related mortality at 6 months and 1 year Cause of mortality
	Disease relapse	Incidence of disease relapse Time to disease relapse

Study design:

A retrospective study will be conducted utilizing CIBMTR and EBMT data. Patients will be eligible for inclusion if they are $\geq$ 18 and who received a first allogeneic HCT for Hodgkin Lymphoma using a MSD, MUD or haploidentical donor between 01/2008 and 12/2018. The objectives of this analysis are to determine outcomes in patients undergoing HCT with or without prior checkpoint exposure treatment. Descriptive tables of patient, disease-, and transplant-related factors will be created and compared for both cohorts. The tables will list median and range for continuous variables and percent of total for categorical variables. Cumulative incidence of chronic GVHD, relapse/progression, and NRM will be calculated while accounting for competing events. Probabilities of OS will be calculated using the Kaplan-Meier estimator. Multivariate analysis will be performed using Cox proportional hazards models for outcomes for chronic GVHD, relapse/progression, NRM, PFS, and OS and logistic regression for acute GVHD. A stepwise model building approach will then be used to identify the significant risk factors associated with the outcomes. Factors which are significant at a 5% level will be kept in the final model. The potential interactions between main effect and all significant risk factors will be tested. The proportional hazards assumption will be checked for the Cox model. If violated, it will be added as time-dependent covariates.

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First Allo HCT for adults (18+) with HL (CRF level), 2008-2018

Characteristic	No CPI	CPI
No. of patients	155	64
No. of centers	75	40
CCN region - no. (%)		
US	113 (73)	59 (92)
Canada	1 (1)	0
Europe	8 (5)	3 (5)
Asia	8 (5)	1 (2)
Australia/New Zealand	9 (6)	0
Mideast/Africa	2 (1)	0
Central/South America	14 (9)	1 (2)
Prior auto-HCT and/or Brentuximab - no. (%)		
No prior auto, no prior brentuximab	37 (24)	0
No prior auto, prior brentuximab	14 (9)	12 (19)
Prior auto, no prior brentuximab	51 (33)	13 (20)
Prior auto, prior brentuximab	53 (34)	39 (61)
Age at HCT - median (min-max)	35 (18-70)	32 (19-72)
Disease status prior to HCT - no. (%)		
CR	71 (46)	40 (63)
PR	51 (33)	15 (23)
Chemoresistant	29 (19)	8 (13)
Untreated	2 (1)	0
Unknown	2 (1)	1 (2)
Donor type - no. (%)		
HLA-identical sibling	55 (35)	25 (39)
Other related	44 (28)	20 (31)
Well-matched unrelated (8/8)	56 (36)	19 (30)
Graft type - no. (%)		
Bone marrow	36 (23)	15 (23)
Peripheral blood	119 (77)	49 (77)
Reported planned conditioning intensity - no. (%)		
RIC/NMA	155	64
Year of HCT - no. (%)		
2008	12 (8)	0
2009	8 (5)	0
2010	7 (5)	0
2012	5 (3)	0
2013	5 (3)	0
2014	23 (15)	0

Characteristic	No CPI	CPI
2015	14 (9)	1 (2)
2016	19 (12)	12 (19)
2017	30 (19)	24 (38)
2018	32 (21)	27 (42)
Follow-up - median (min-max)	24 (3-119)	13 (3-49)

*CPI: Nivolumab, Pembrolizumab, Ipilimumab

EBMT Selection criteria

	Excluded	N
Number of adult patients underwent 1st ALLO HCT for HL from 2008-2017 in EBMT		3487
Haplo donor, or HLA-identical sibling (MSD) or well-matched unrelated donor (WMUD, 8/8)	904	2583
Reduced intensity	742	1841
GVHD prophylaxis: exclude ex vivo T cell depletion	81	1760
CNI/MTX, CNI/MMF, PTCY/CNI/MMF	552	1208

EBMT Table 1. Baseline characteristics of CRF patients receiving a reduced intensity alloHCT for HL from 2008-2017

	No prior CKI	CKI*
Number of patients	1171	37
Number of centers	205	29
Patient age, years		
Median (range)	33 (18-72)	29 (19-57)
18- 29	461 (39)	22 (59)
30- 39	389 (33)	8 (22)
40- 49	191 (16)	5 (13)
50 – 59	95 (8)	2 (5)
≥ 60	35 (3)	0
Sex		
Male	694 (59)	28 (76)
Female	474 (40)	8 (22)
Missing	3 (0)	1 (3)
KPS		
≥ 90	878 (75)	35 (95)
< 90	235 (20)	2 (5)
Missing	58 (5)	0
Race		
White		
Black		
Asian		
Others		
Missing	1171 (100)	37 (100)
Remission status at HCT		
Sensitive	837 (71)	32 (86)
Resistant	289 (25)	2 (6)
Untreated	0	0
Unknown	45 (4)	3 (8)
Donor type		
HLA-identical sibling	475 (41)	11 (30)
Matched unrelated donor	342 (29)	7 (19)
Haploidentical donor	354 (30)	19 (51)

	No prior CKI	CKI*
GVHD prophylaxis		
CNI/MTX	447 (38)	9 (24)
CNI/MMF	399 (34)	11 (30)
PTCY/CNI/MMF	325 (28)	17 (46)
Transplant year		
2008	92 (8)	0
2009	119 (10)	0
2010	96 (8)	0
2011	110 (9)	0
2012	111 (9)	0
2013	136 (12)	0
2014	158 (13)	0
2015	144 (12)	2 (5)
2016	96 (8)	15 (40)
2017	109 (9)	20 (54)
Median follow-up of survivors (range), months	37 (0-134)	16 (0-43)

*CKI: Nivolumab, Pembrolizumab, Ipilimumab

Proposal: 1911-204

Title:
Trends in Survival post-autologous transplant in Classical Hodgkin Lymphoma.

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Hypothesis:
Due to development of multiple novel targeted and immune based therapies in Hodgkin lymphoma, post auto-HCT overall and progression free survival has improved in the contemporary time period

Specific aims:
To evaluate overall survival (OS) over the last 15 years post auto-HCT in Hodgkin Lymphoma.

- Primary outcome will be to evaluate trends in OS and progression free survival (PFS) from 2015-2019 vs 2010-2014 vs 2005-2009
- Secondary outcomes will include trends in pre-transplant rates of CR, non-relapse mortality, and relapse/progression

Scientific justification:
Hodgkin lymphoma (HL) is an aggressive, yet curable form of hematological malignancy that disproportionally impacts younger patients. Fortunately, with advanced in combination chemotherapy approaches, nearly 80% of patients with Stage III-IV classical HL will be cured with current standard of care frontline treatment options[1]. Unfortunately, while the majority of patients do well for those with relapsed or refractory disease outcomes are less favorable. The general approach to relapsed classical HL is salvage chemotherapy and in chemosensitive patients a consolidative autologous transplant. With this approach, nearly half the patients have achieved a long-term remission. To improve outcomes, recently strategies for maintenance therapy post-autoHCT with novel agents have been employed (e.g. brentuximab or pembrolizumab) resulting in improved PFS after transplant[2, 3]. Furthermore, these same agents have also been utilized to achieve a CR prior to auto-HCT which also impacts clinical outcomes post-autologous transplant[4].
To better understand improvements in clinical outcomes of autologous transplant, a trends analysis utilizing the CIBMTR database can help determine if OS/PFS and rates of CR prior to auto-HCT have improved in the more recent time periods compared to historical controls. This data will be clinically valuable and help set a standard for future clinical trials in relapsed, refractory Hodgkin lymphoma.

Patient eligibility population:
Inclusion criteria:

- Adults>18 years of age at the time of transplant from 2005-2019
- Diagnosis of classical Hodgkin lymphoma
- First autologous transplant only

Exclusion criteria:

- Prior allogeneic transplant
- Secondary malignancies

Data requirements:

- Data will be captured through CIBMTR collection forms

Demographic/patient level variables to be analyzed:

Main effect:

Report survival outcomes of patients with relapsed classical HL who undergo autologous transplant over three time periods 2015-2019 vs 2010-2014 vs 2005-2009

Patient-related:

- Age at transplant, Continuous & decades
- Gender: male or female
- Karnofsky performance status at transplant: < 90% vs. ≥ 90%
- HCT comorbidity index at transplant 0, 1, 2, and ≥ 3

Disease-related:

- Disease Risk Index
- Disease stage at diagnosis: I/II vs III/IV
- Disease assessment prior to transplant (CR vs PR vs SD vs PD)

Transplant-related:

- Conditioning Regimen

Study outcomes:

Overall survival (OS):

Time to death. Death from any cause will be considered an event. Surviving patients will be censored at the time of last follow up.

Non-relapse mortality (NRM):

Death without relapse or progression, where relapse or progression would be competing risks. Those who survive without recurrence or progression would be censored at the time of last contact.

Relapse/progression:

Progressive disease or recurrences of disease would be counted as events. Treatment related death, defined as death without relapse or progression, is the competing event. Those who survive without recurrence or progression would be censored at the time of last contact.

Progression-free survival (PFS):

Survival without recurrence or tumor progression. Recurrence of progression of disease and death would be counted as events. Those who survive without recurrence or progression would be censored at the time of last contact.

Study design:

A retrospective multicenter study will be conducted utilizing CIBMTR dataset involving patients with a diagnosis of classical HL who underwent autologous transplant for relapsed disease. Patients will be eligible if they satisfied the criteria detailed in the patient eligibility section above. The objective of this analysis is report trends in survival and relapse post-autologous transplant over time.

PFS and OS will be calculated using the Kaplan-Meier estimator. For NRM, relapse/progression will be the competing event. For relapse rate, NRM will be the competing event. Data on patients without an event will be censored at last follow up. For univariate analysis, the log-rank test will be used to identify

factors influencing survival and to compare survival among patients the three mentioned time periods. . The association between treatment groups and outcomes will be studied with multivariate Cox regression models. P values are 2 sided and values < 0.05 will be considered significant.
The other variables tested will be retained in the final multivariate model if the variable will attain the level of significance set for these analyses. Results will be expressed as hazard ratio (HR) with 95% confidence intervals (CI). Possible interactions within the treatment groups and other variables will be tested. All models will be tested regarding proportional hazard of assumptions (PHA). If the assumption will be violated, time dependent covariates will be constructed.

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First Auto HCT for adults (18+) with Classical Hodgkin Lymphoma, 2005-2018

Characteristic	N (%)
No. of patients	9108
No. of centers	301
Research patient	935 (10)
CCN region - no. (%)	
US	7261 (80)
Canada	442 (5)
Europe	365 (4)
Asia	110 (1)
Australia/New Zealand	32 (<1)
Mideast/Africa	369 (4)
Central/South America	529 (6)
Age at HCT - median (min-max)	34 (18-84)
Disease status prior to HCT - no. (%)	
CR	4505 (49)
PR	3562 (39)
Chemoresistant	842 (9)
Untreated	48 (1)
Unknown	151 (2)
Graft type - no. (%)	
Bone marrow	36 (< 1)
Peripheral blood	9072 (99)
TX year - no. (%)	
2005	28 (<1)
2006	77 (1)
2007	160 (2)
2008	827 (9)
2009	856 (9)
2010	856 (9)
2011	857 (9)
2012	829 (9)
2013	791 (9)
2014	812 (9)
2015	783 (9)
2016	723 (8)
2017	787 (9)
2018	722 (8)
Follow-up - median (min-max)	47 (2-154)