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14. ABSTRACT

1. Contingency Preparedness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors: Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

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Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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a. REPORT	b. ABSTRACT	c. THIS PAGE			Jeffery Auletta, M.D. - Sr Vice President and Chief Scientific Director
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Grant Award N00014-20-1-2832

DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY RESEARCH PERFORMANCE REPORT

SUBMITTED October 15th, 2021

Office of Naval Research

And

The National Marrow Donor Program®

500 5th St N

Minneapolis, MN 55401

I. Heading

PI: Jeffrey Auletta, M.D.

National Marrow Donor Program

N00014-20-1-2832

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

II. Scientific and Technical Objectives

The main goal of all activities funded through this grant is to develop, test and mature the ability of the NMDP Coordinating Center and NMDP contracted network sites network sites to address contingency events wherein civilian or military personnel are exposed to marrow toxic agents, primarily ionizing radiation or chemical weapons containing nitrogen mustard. As a result of prior efforts in this regard a solid foundation has been established. The proposed new activities will continue to enhance and expand our capabilities in each of the four focus areas. Contingency preparedness activities will continue to integrate NMDP's role with federal, state and local agencies.

An accident, a military incident, or a terrorist act in which a number of individuals are exposed to marrow toxic agents will result in injuries from mild to lethal. But the extent of individual injuries and the likelihood of recovery in many cases will not be apparent until days or weeks after the event. Casualties will be triaged by first responders, and those with major marrow injuries who will need aggressive medical support and may be ultimately candidates for hematopoietic cell transplantation (HCT) will need to be identified. While these patients are being supported, HCT donor identification activities will be initiated because it will not be initially clear which ones may ultimately require HCT. NMDP-approved transplant centers will provide a uniform and consistent clinical foundation for receiving, evaluating and caring for casualties. NMDP Coordinating Center will orchestrate the selection and testing necessary to rapidly identify the best available donor or cord blood unit for each patient utilizing its state-of-the-art communication infrastructure, sample repository, laboratory network, and human leukocyte antigen (HLA) expertise. NMDP's on-going immunobiologic, bioinformatics and clinical research activities promote studies to advance the science and technology of HCT transplantation to improve outcome and quality of life for the patients.

Importantly, most individuals with near-lethal marrow toxic injuries will recover their own marrow function provided they receive intensive supportive care from the medical professionals that are part of the contingency response community.[1] These professionals can save the lives of persons with severe marrow suppression using the knowledge and skills practiced every day to treat patients undergoing HCT coordinated through the NMDP.

III. Approach

A. Contingency Preparedness

HCT teams are uniquely positioned to care for the casualties of marrow toxic injuries. The NMDP manages a network of centers that work in concert to facilitate unrelated HCT. The Radiation Injury Treatment Network (RITN), comprised of a subset of NMDP's network centers, is dedicated to radiological disaster preparedness activities and develops procedures for response to marrow toxic mass casualty incidents.

B. Development of Science and Technology for Rapid Identification of Matched Donors
Disease stage at the time of transplantation is a significant predictor of survival, decreasing the time to identify the best matched donor is critical. Methods are under development to rapidly provide the best matched donor for HCT.

C. Immunogenetic Studies in Transplantation
Improving strategies to avoid and manage complications due to graft alloreactivity is essential to improve the outcomes of HCT. Research efforts are focused on strategies to maximize disease control while minimizing the toxicity related to alloreactivity in HCT.

D. Clinical Research in Transplantation
Clinical research creates a platform that facilitates multi-center collaboration and data management to address issues important for managing radiation exposure casualties. Advancing the already robust research capabilities of the NMDP network will facilitate a coordinated and effective contingency response.

IV. Updates

A. Contingency Preparedness

Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event.

During this quarter RITN continued to develop the preparedness of its network of hospitals through the following activities:

- COVID response continues to prevent full engagement in RITN activities.
- RITN and the Radiation Emergency Assistance Center/Training Site (REAC/TS) developed a new 2.5-day in-person training course which targets a new audience (healthcare coalition members). The course includes lecture, hands on demonstrations, skill practice, and an exercise. The pilot courses are tentatively scheduled for September in the cities of Philadelphia and San Francisco and attendance will be offered to local hospital coalition members. Due to increased COVID travel and in-person meeting restrictions in San Francisco, CA and Philadelphia, PA, these courses have been postponed until spring 2022.
- RITN FY2022 Workshop Planning Committee continues planning for the August 2022 Workshop. The call for abstracts is tentatively set for fall of 2021 and registration beginning in the spring of 2022. Committee members represent RITN hospitals: Dana Farber Cancer Institute, Duke University, Mayo Clinic Rochester, North Shore University Hospital, and the University of Iowa) as well as federal partners: the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).

- RITN Training committee workgroup completed the modular acute radiation syndrome treatment just-in-time training course for healthcare providers. The videos will be available on the RITN YouTube Channel as well as the RITN website in late October 2021.
- Completed the development of five virtual educational training sessions for RITN hospitals and partners in lieu of the semi-annual RITN Workshop that would typically be held in summer 2021. Sessions 1, 2, 4, and 5 were held in May, June, August, and September of 2021, respectively. Session 3 has been postponed until further notice.
    - Session 3 - July: NDMS/RITN Patient Movement: From Incident to RITN Center
        - July 28, 2021
        - John Koerner and Andrew McBrearty
    - Session 4 - August: COVID-19 Cohort Management Program (CCMP): An Adaptable Model For Outpatient Surge Management
        - August 24, 2021
        - Memorial Sloan Kettering Cancer Center staff
    - Session 5 - September: Chernobyl: 35 Years Later
        - September 22, 2021
        - Dr. Alla Shapiro
- Continued supporting the Gryphon Scientific's Center for Disease Control (CDC) funded project to assess United States laboratory capabilities for ionizing radiation related testing. As the closing of the survey (September 2021), 1,298 labs completed and submitted the survey (1,000 was the target minimum). Analysis has begun and the preliminary data is available for workgroup members.
- Completed the development of the Hospital Radiation Morbidity Toolkit as part of the CDC grant awarded to RITN. Developed an After-Action Report (AAR) of the use of the tool by 72 hospitals to validate it worked, identify any necessary modifications, implemented 73 modifications, and submitted the AAR with updated tool to CDC.
- Completed all seven sessions of the annual exercise for RITN centers. This year's exercise is testing a newly created post-improvised nuclear device (IND) morbidity data form for the CDC.
- All 72 active RITN centers completed their annual tasks (one center inactive due to staffing for FY2021). Task completion included updating administrative information, emergency communications testing, reviewing and submitting their Standard Operating Procedures and marrow toxic injury consent forms, participate in the annual exercise, and complete educational training.
- In September 2021, representatives from Grady Health System, Emory, the U.S. Centers for Disease Control (CDC) and RITN conducted a tabletop exercise to address laboratory surge following an improvised nuclear device (IND) detonation in a distant city. The primary strengths and opportunities for improvement discovered during this exercise are listed in this executive summary below.

- Primary Strengths
  - Grady's laboratory capabilities include enough equipment, supplies, staff and throughput capability to meet the testing demand as defined in this scenario.
  - Grady has a laboratory surge plan in place to call back additional staff in the event of an emergency.
  - CDC indicated that they could provide resources to Grady for radiation surveys, if necessary. In addition, they could utilize up to 18 radiation portal monitors (RPMs) from the State of Georgia.
  - There are potential capabilities to share laboratory testing information through EPIC and other electronic medical record products that interface with EPIC.
  - Supply chain impacts could be mitigated through vendor relationships and proximity to Atlanta.
- Primary Opportunities for Improvement
  - There is a need to identify just-in-time training capabilities at Grady for staff to provide them basic radiation awareness.
  - There is a need to further coordinate with local and state public health authorities to determine how large-scale processing sites will be established for self-evacuated patients.
  - Grady should consider keeping a roster of retired laboratory professionals in the event there is a need to call them back to volunteer for laboratory surge emergencies.
  - While Grady does keep an approximate 30-day supply of laboratory consumables on-hand, it should be considered that impacts on the supply chain and increased demand nationwide will likely result in a shortage.
  - Additional planning and coordination should occur between Grady and Emory to discuss the process and resources for human leukocyte antigen (HLA) typing in this scenario.

- The Assistant Secretary for Preparedness and Response (ASPR) is requiring healthcare coalitions to conduct a radiation-based exercise in fiscal year 2022. This was seen as an opportunity to increase awareness of RITN by creating a 'functional exercise-in-a-box' for coalitions to use as a template to conduct such an exercise.

  The purpose of the exercise is to address the operational elements of the receipt, triage, and care of radiation-injury and acute blast/burn injury casualties in accordance with existing RITN, Health Care Coalition, and individual hospital/agency plans. The exercise will evaluate key actions to respond to a medical surge following an 10kT improvised nuclear device (IND) detonation in a distant location where patients are transported to hospitals around the nation primarily through the National Disaster Medical System (NDMS).

  The exercise-in-a-box will be added to the RITN website, on ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) website, and at the National Healthcare Coalition Preparedness Conference (NHCPC) in late 2021.

B. Development of Science and Technology for Rapid Identification of Matched Donors

Expand the genetic diversity of the registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies.

No activity to report this quarter.

Modeling and analysis of registry coverage for the Warfighter

Forward deployed Warfighters are a higher risk of exposure to marrow toxic injuries due to ionizing radiation or marrow toxic chemical agents. As such, it is important to model and determine the likelihood that Warfighters will have a suitably matched unrelated donor (defined as 8/8 or 7/8 matched for HLA-A, B, C and DRB1) on the NMDP/Be The Match Registry to support lifesaving HCT or cellular therapy. Our prior results indicated that most warfighters will have suitable adult donors though there is not an optimal match for many warfighters.

Previously, we identified the likelihood of finding an unrelated donor on the Be The Match registry to provide an estimate for providing HCT or cellular therapy to warfighters in the event of radiation or marrow toxic chemical exposure. We also identified gaps in warfighter population coverage that will assist in targeted future recruitment efforts to address deficiencies.

To address the gaps in warfighter population coverage at the 8/8 or 7/8 level, we consider the increasing body of evidence for advances in post-HCT immune modulation that allow for safe and effective HCT despite a greater number of HLA mismatches between the donor and potential patient. To this end, we have defined new scenarios to re-estimate match rates specific to different race and ethnic groups that consider HLA-A, B, C, and DRB1 high resolution matching at 8/8 7/8, 6/8, 5/8, and 4/8 HLA alleles. These will take into consideration the larger potential donor pool at higher levels of mismatches and will be adjusted for known donor age and availability statistics. These modeling efforts will evaluate less stringent HLA matching criteria to expand access for warfighters and allow for rapid identification of suitable donors for HCT and cellular therapy.

This quarter, additional progress was made to update the donor registry population under consideration in the model with 2020 registry characteristics. Registry data was reapportioned based on known population ratios and adjusted for demonstrated donor availability. Through the application of a population-based genetic model, match likelihoods for 21 race/ethnic groups for donors of any age and less than or equal to 35 years of age were considered. Preliminary results demonstrate the potential for available donor coverage, when allowing for HLA match levels to 5/8 to reach >99%. An abstract describing the results of the analysis was submitted for presentation at the 2022 BMT Tandem Meeting scheduled for February 2022 in Salt Lake City, Utah.

Development of science and technology for rapid communication of HLA data

Tool Development
Development and improvement of tools continues for handling HLA data toward the rapid communication, identification, and evaluation of matched donors in transplantation. In the last quarter, additional updates were made to py-ard (https://github.com/nmdp-bioinformatics/py-ard), a Python-based HLA annotation and conversion tool, to handle refresh of multiple allele codes in the intake process, smart sort for genetic group and expression character expansions, reinstall the reference IMGT database and perform database status checks. This tool has matured the point where it provides a standard HLA pre-processing filter for any downstream analysis of HLA including clinical outcomes studies.

We held a 2-day hackathon Sept 2-3, 2021. This event involved seven employees of NMDP and focused on developing an open-source software package called py-ard (https://github.com/nmdp-bioinformatics/py-ard) for normalization and conversion of HLA data between different resolutions.

The main accomplishments of the events were:

- Development of a roadmap to achieve a 1.0.0 release of the software https://github.com/nmdp-bioinformatics/py-ard/projects/2
- Production of several intermediate releases (0.6.7, 0.6.8, 0.6.9) including functionality to deal with P-group and G-group alleles
- During the hackathon the team achieved successful generation of a global file of 45,235,309 human subjects from 50 with normalized HLA data for haplotype frequency analysis.

During the past quarter we co-authored a paper summarizing challenges with commercial adoption of an XML data standard, developed by NMDP, for the reporting of HLA genotyping based on Next-Generation Sequencing (NGS).
https://www.sciencedirect.com/science/article/abs/pii/S019888592100210X

Use of population genetics and machine learning to automate the donor selection process

Machine Learning-based prediction of overall survival
Improvements were made to the machine learning pipeline for patient overall survival outcomes following allogeneic HCT. New research into the representation and interpretation of feature importance and variable encoding were pursued. The contribution of molecular matching data at different levels will be added in future models. Analyses were also performed at different stages of the patient journey and for different donor types.

To contrast with One-Hot Encoding process for treatment of variables, Weight of Evidence (WoE) encoding methodology for data preprocessing was applied to the dataset for categorical variables and label encoding for ordinal variables. An in-depth assessment and classification of variables based on prior physician or clinician-based knowledge is under way to bring new perspective to interpretation of machine-learned results. SHAP (Shapley Additive Explanation) results were explored for interaction across variables.

Enhance population genetics driven donor selection algorithms
During the past quarter progress was made in several aspects toward the goal of improving population genetics driven donor selection algorithms.

1. Global populations: HLA haplotype frequencies were generated for a global file of 45,235,309 human subjects from 50 different countries. This data will allow improved matching and modeling of HLA of populations for these countries.
2. Higher resolution: HLA haplotype frequencies were generated at the 3rd and 4th field of resolution. This will allow more accurate matching and modeling and will facilitate clinical decision making based on variants that are outside of the antigen-recognition-domain of most previous work.
3. Additional loci: HLA haplotype frequencies have been extended to cover 9 HLA loci which will allow clinical decision making, prediction and modeling based on genes which are typically not typed (e.g. HLA-DQA1 & HLA-DPA1)
4. Multi-racial individuals: A paper was published "**HLA haplotype frequency estimation for heterogeneous populations using a graph-based imputation algorithm"** (**https://www.sciencedirect.com/science/article/abs/pii/S0198885921001750**). This novel multi-racial EM implementation considers race as a Bayesian prior, enabling integration of HLA information from multiple single-race population groups, and for the first-time including individuals with ambiguous or mixed ethnic backgrounds. This multi-racial EM produces much higher likelihood values and better haplotype recovery than all evaluated EM implementations when tested on real datasets of US donor registry HLA typings as well as simulated multi-racial datasets of ambiguous HLA typings.

C. Immunogenetic Studies in Transplantation

Evaluate HLA disparity and impact on HCT by adding selected pairs to the Donor/Recipient Pair project utilizing sample selection criteria that optimize the new data generated by the typing project.

Donor Recipient Pair Project

The study team continued to audit typing results generated in the prior grant year. Case selection for the next typing cohort was completed in late summer 2021 and a total of 2497 donor/recipient transplant pairs (2010 using unrelated donors and 487 using related donors) shipped for typing. Complete results are anticipated early next quarter.

Develop and mature typing characterization of immunogenetic regions from underserved populations to improve matching and transplant outcomes for more diverse patients

An assessment was performed on the donor recruitment HLA typing performed on 160k donors requested for confirmatory typing between 2010 and 2020. In general, donors of color were found to have less complete typing at recruitment. An association was found between missing or incomplete HLA typing and compromised quality of match predictions for diverse patients. In general, prediction quality for AFA (African American) and API (Asian Pacific Islander) groups were impacted the most. Further analysis is being pursued to generate solutions for upgrading the typing and characterization of immunogenetic regions to improve matching and transplant outcomes for more diverse patients.

Determine the frequency and risks associated with donor clonal hematopoiesis of indeterminate potential in HCT.

Evaluating the impact of donor clonal hematopoiesis of indeterminate potential (CHIP) on HCT outcomes

Completed the analysis for the study entitled "GV19-01: Exploring the link between donor engrafted clonal hematopoiesis and adverse outcomes in allogeneic HCT: Pilot study. The study found no associations between donor CHIP and any outcomes. An abstract describing the results of the pilot study was submitted for presentation at the 2022 BMT Tandem Meetings. The lack of an association between CHIP and outcomes resulted in a reevaluation of this line of inquiry under this grant. Funds allocated for this effort have been reassigned to address the more pressing topics noted below.

Evaluation of Unrelated Donor Peripheral Blood Stem Cell (PBSC) Graft Composition and Impact on Allogeneic HCT Outcomes

While allogeneic HCT offers potentially curative therapy to patients with a variety of benign and malignant diseases, both acute and chronic GVHD continue to plague the field and often limit the longevity and quality of life for patients. The composition of PBSC grafts has been evaluated in multiple studies to attempt to discern associations between various cellular subsets and outcomes. The BMT CTN 0201 randomized trial of bone marrow versus PBSC found that PBSC grafts were associated with a higher risk of cGVHD and worse quality of life following unrelated donor HCT compared to BM. A correlative study of graft immunophenotype failed to identify any associations between PBSC graft composition and outcomes. However, the PBSC cohort included only 147 evaluable products limiting the power to evaluate various cellular subsets. The association between PBSC graft immunophenotype and outcomes remains unclear.

The primary aim of this study is to evaluate PBSC graft stem cell and associated immune cell composition and to determine at 12-months of follow-up how either the comprehensive graft cellular composition profile or specific graft composition elements influences the primary outcomes of time to neutrophil engraftment and overall survival. Secondary outcomes of interest include, but not limited to, incidence of acute and chronic GVHD, primary disease relapse, TRM, and DFS.

Analyses include:

- Stem cell subset composition (not just number) influences time to engraftment and immune reconstitution
- Both conventional and novel unconventional T cell subsets within the graft influence GVHD, relapse, infection and immune reconstitution after transplant
- Natural killer cells have a role in transplant biology and number and phenotype in the donor graft influence GVHD, relapse, infection and immune reconstitution after transplant.
- The myeloid/antigen presenting cell compartment of the graft influences infection risk and immune reconstitution, thus play a role in long term patient outcome

The secondary aims of this study are:

- Explore potential associations of favorable PBSC graft composition features that may be predicted by analysis of peripheral blood samples at time of unrelated donor work-up such that these biomarkers could be incorporated into donor selection algorithms.
- Evaluate graft composition association with >12-month outcomes for overall survival, primary disease relapse, DFS and the incidence of late transplant effects including, but not limited to, chronic GVHD, diseases of the cardiovascular, pulmonary, and endocrine systems, dysfunction of the thyroid gland, bone diseases and the development of secondary primary malignancies.

- Establish a cohort of pre-transplant recipient and pre-donation adult unrelated donor biologic samples (whole blood, plasma, viable PBMC and viable donor PBSC graft mononuclear cells) collected prospectively from donors and patients enrolled on this study. This important biospecimen resource will be critical for the support of additional protocol team defined allogeneic HCT related correlative studies that will extend the knowledge gained from the primary study.

During the past quarter the study team met several times via video conference call to discuss the test performance for the immunophenotyping panel. Several adjustments were defined to address antibody performance to enhance detection and characterization of cellular subsets. Work is now underway to harmonize testing procedures between the U.S. and Germany based laboratories. This project will continue under a subsequent grant.

A national framework for introducing measurable residual disease testing into the clinical care of AML patients undergoing allogeneic transplantation

While allogeneic HCT is a curative therapy for many patients with acute myeloid leukemia (AML), the risk of relapse even after achieving a cytomorphological complete remission (CR) is the most common form of treatment failure and death. Transplant-related morbidity and mortality is a major obstacle for the effective use of alloHCT, resulting in the potential under- or over-utilization of conditioning regimen intensity to prevent AML relapse. The presence of residual leukemic burden, known as measurable residual disease (MRD), prior to transplant is associated with worse outcomes after transplantation. AML MRD testing is not standardized, and no clear path to translate findings from research laboratories to clinical transplant settings currently exists.

Planning continued on a project designed to address this issue by developing a coordinated national framework to 1) allow collection of leftover initial AML diagnosis material from patients who have received alloHCT in US centers, 2) prospectively collect samples from AML patients after unrelated donor alloHCT to determine optimal timing and method for post-alloHCT MRD monitoring and 3) implement findings from phases 1 and 2, together with a central reference laboratory, to allow local centers to perform standardized MRD testing pre or post alloHCT. This would allow both selection of conditioning intensity, but also inform post-transplant maintenance and allow patient selection for novel clinical trials. During the past quarter the study team continued efforts to develop the study protocol with a focus on the testing schema and frequency of assessments. The protocol is nearly complete and will be submitted for IRB review/approval next quarter.

Even when patient and donor are HLA matched, post-transplant complications occur, therefore, other loci may play a role

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Evaluation and identification of whole genome donor-recipient pair variation and omics patterns that affect HCT outcomes

While matching donors and transplant recipients on HLA and other well-studied loci is known to improve transplant outcomes, much remains to be explored with regards to whole genome factors and effects of mutations and other variation. We recently completed a multi-omics pilot study on a cohort of transplant recipients with Myelodysplastic Syndromes (MDS). Since then, we have followed up with the whole genome sequencing of an additional 500 pairs of donors and transplant recipients with MDS with funding from a prior Navy grant.

Somatic genomic variation analysis has been completed on the cohort both for single nucleotide polymorphisms across the whole genome and for structural variants from the whole-genome sequencing

data. Analysis of recurrent MDS transplant outcomes prognostic genes demonstrated high consistency in results across cohorts. This quarter, additional supervised and unsupervised clustering methodologies were applied to the variants to identify distinct results groupings that may or may not associate with patient transplant outcomes. Preliminary results identified major groups, including those that contain TP53 and other genomic mutations, that correlated to worse transplant outcomes. Further confirmation of candidate genes through supplemental validation methods are under way. Study results were summarized in 2 abstracts that were submitted to the American Society of Hematology Annual Meeting and will be presented next quarter.

D. Clinical Research in Transplantation

Conduct clinical outcomes research using the CIBMTR research database and repository.

Observational Research

- Published 25 manuscripts in peer-reviewed journals during the last quarter for a total of 90 publications this grant period.
- A total of 32 abstracts were submitted and accepted for presentation at the 2021 American Society of Hematology Annual Meeting to be held in person and virtually this December in Atlanta, GA. Presentations dates and type are detailed in the table below for 30 of 32 abstracts. The presentation status is still pending for 2 abstracts and will be updated next quarter.

2021 CIBMTR ASH Presentations	
Title	**Status**
Saturday, December 11, 2021	
Single HLA Class I Mismatches with High Peptide Divergence in the Graft-Versus-Host Direction Are Associated with Inferior Survival after 9/10 HLA-Matched UD-HCT: A Retrospective Study from the CIBMTR	**Oral**
Efficacy and Long-Term Outcomes of Autologous Stem Cell Transplant (ASCT) for Patients with POEMS Syndrome (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Protein, Skin Changes): A CIBMTR Analysis	**Oral**
Haploidentical Vs. Matched Unrelated Donor Transplants Using Post-Transplant Cyclophosphamide for Lymphoma: A Joint CIBMTR/EBMT Study	**Oral**

Deleterious Germline Variants Are Present in Patients with Myelodysplastic Syndrome of All Ages Treated with Related Allogeneic Stem Cell	**Oral**
The Impact of Pre-Apheresis Health Related Quality of Life on Peripheral Blood Progenitor Cell Yield and Donor's Health and Outcome: Secondary Analysis of Rdsafe and BMT CTN 0201	**Poster**
Sunday, December 12, 2021	
Health-Related Quality of Life in a Biologic Assignment Trial of Reduced Intensity Hematopoietic Cell Transplantation Based on Donor Availability in Patients Aged 50-75 with Advanced Myelodysplastic Syndrome	**Oral**
Real-World Efficacy and Safety Outcomes for Patients with Relapsed or Refractory (R/R) Aggressive B-Cell Non-Hodgkin's Lymphoma (aBNHL) Treated with Commercial Tisagenlecleucel: Update from the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry	**Oral**
The Impact of Somatic Mutations on Allogeneic Hematopoietic Cell Transplantation in Chronic Myelomonocytic Leukemia: A Center for International Blood and Marrow Transplant Research (CIBMTR) Analysis	**Oral**
Late Effects after Allogeneic Hematopoietic Cell Transplantation Among Children and Adolescents with Non-Malignant Disorders: A Report from the Center for International Blood and Marrow Transplant Research (CIBMTR)	**Oral**
Prompt CR Plus Consolidation Therapy Yields Improve Survival after Allogeneic Transplantation for AML Patients Receiving Myeloablative, but Not Reduced-Intensity Conditioning: A CIBMTR Analysis	**Oral**
Real-World Outcomes of Axicabtagene Ciloleucel (Axi-cel) for the Treatment of Large B-Cell Lymphoma (LBCL): Impact of Age and Specific Organ Dysfunction	**Oral**
Lessons from an Ongoing, Multi-Center Trial Involving Biospecimen Collection for Prospective Microbiome and Immune Profiling in Patients Undergoing Reduced Intensity Conditioning Allogeneic HCT	**Poster**
The Incidence and Impact of Clostridioides Difficile Infection (CDI) on Outcomes after Allogeneic Hematopoietic Cell Transplant (alloHCT) – a CIBMTR Study	**Poster**
COVID-19 in Pediatric Hematopoietic Cell Transplant Recipients: A CIBMTR Study	**Poster**
Cryopreservation of Allogeneic Hematopoietic Cell Grafts Did Not Adversely Affect Early Post-Transplant Survival during the First Six Months of the COVID-19 Pandemic	**Poster**
A Refined Model of HLA-DP Permissiveness Improves Stratification of Acute Graft-Versus-Host Disease Risks after Unrelated Hematopoietic Cell Transplantation: A Retrospective Study from the CIBMTR	**Poster**

Bacterial Prophylaxis in Patients with Acute Gvhd; Who Is at Risk for Bloodstream Infections?	**Poster**
Monday, December 13, 2021	
Peri-Transplant Alemtuzumab Levels Predict Risk of Secondary Graft Failure and Inversely Impact CXCL9 Levels after RIC HCT (A Correlative Biology Study to BMT-CTN 1204 RICHI)	**Oral**
Donor Socioeconomic Status As a Predictor of Altered Immune Function and Treatment Response Following Hematopoietic Cell Transplantation for Hematologic Malignancy	**Oral**
Racial and Socioeconomic Disparities in Long-Term Outcomes in ≥ 1 Year Allogeneic Hematopoietic Cell Transplantation Survivors: A CIBMTR Analysis	**Poster**
Impact of Allogeneic Hematopoietic Cell Transplantation (HCT) As Consolidation Following CD19 Chimeric Antigen Receptor (CAR) T Cell Therapy for Treatment of Relapsed Acute Lymphoblastic Leukemia (ALL)	**Poster**
Identification of Novel Prognostic Biomarkers DDX11 and CHD1 of Allogeneic Hematopoietic Cell Transplantation Outcomes for Patients with MDS: A CIBMTR Comprehensive Genomic Screening	**Poster**
Genomic Subgroups Impact Post-Transplant Survival in Patients with Myelodysplastic Syndrome: A CIBMTR Analysis	**Poster**
Impact of Center Experience with Donor Type and Treatment Platform on Outcomes: A Secondary Analysis BMT CTN 1101	**Poster**
Impact of HLA Molecular Mismatch on Haploidentical Hematopoietic Stem Cell Transplantation: A Center for International Blood and Marrow Transplant Research Study	**Poster**
Trends in Allogeneic Hematopoietic Cell Transplantation Utilization and Estimated Unmet Need Among Medicare Beneficiaries with Acute Myeloid Leukemia	**Poster**
Improved Overall Survival of Patients Treated with Abatacept in Combination with a Calcineurin Inhibitor and Methotrexate Following 7/8 HLA-Matched Unrelated Allogeneic Hematopoietic Stem Cell Transplantation: Analysis of the Center for International Blood and Marrow Transplant Research Database	**Poster**
Major ABO Incompatibility Significantly Influences the Survival and Outcomes after Allogeneic Hematopoietic Cell Transplantation in Leukemia – CIBMTR Analysis	**Oral**
Impact of Autologous Hematopoietic Cell Transplant (HCT) Followed By Dendritic Cell/Myeloma Fusion Vaccine with Lenalidomide Maintenance in Increasing Multiple Myeloma (MM) Immunity (BMT CTN 1401)	**Oral**
Superior Outcomes with Fludarabine-Busulfan (Flu/Bu) Based Conditioning for Allogeneic Hematopoietic Cell Transplantation in Myelofibrosis - a Comparative Analysis By CIBMTR	**Oral**

Research data collection and systems enhancements
During the past quarter, CIBMTR has continued support for electronic data submission initiatives, production FormsNet Recipient, FormsNet Donor, and AGNIS customers, as well as Data Warehouse users.

FormsNet
Continued the quarterly releases of recipient form revisions to be current with existing treatment practices, as well as implemented revisions of forms to support the cellular therapies registry. Completed and in-process enhancements within Data Capture applications include:

- The Japanese multi-language support, allowing FormsNet system and forms to display in a language other than English, was updated in July 2021 to reflect three Cellular Therapy form revisions.

- Form Due Dates were updated to support CIBMTR's updated CPI policy. The Recipient Center Forms Due page was also updated to better suit the needs for users to run their own reports and metrics.

- Updates were made to the Consent Tool, including the ability for users to view and respond to queries.

- Continued monthly security monitoring and incorporating fixes to security vulnerabilities within the month.

- Infectious Disease Marker (IDM) Tool:
    - Successful testing and support for IDM Lab VRL's migration to Corepoint
    - CMP Status Date/Time Enhancement

- Formsnet Forms Definition Manager (FDM): Cross-form validation improvements and security vulnerability fixes

- AGNIS Mapping Tool (FDM): Hidden form mapping and clear filters enhancements

- FormsNet 3 Donor: Required updates to 715, 730, and 731 Donor forms were released to production on September 30th (715) and July 23rd (730/731).

- Made updates to support data collection for gene therapy infusions as a new type of HCT. Required forms will be similar to those for HCT, but with additional follow up visits through 15 years and a new product form (to be released in October 2021).

- Developed and released the following data collection forms in July 2021.

Form	Form Name	Category
2100R7	Post-Infusion Follow-Up	Revised recipient form
4000R8	Cellular Therapy Essential Data Pre-Infusion	Revised recipient form
4100R7	Cellular Therapy Essential Data Follow-Up	Revised recipient form
3500R2	Subsequent Neoplasms	Revised recipient form

Electronic data submission/AGNIS
CIBMTR continued support for electronic data submission initiatives and production AGNIS customers. Effort focused on development of new AGNIS instances of CIBMTR disease specific forms, and support for CIBMTR form revision updates to existing forms. The team is in process of completing communication, educational and technical project implementations to lower AGNIS submission burden and increase the client-base including but not limited to:

- Increasing the reuse of existing AGNIS modules when supporting form revisions and other Forms Builder reports enhancements
- Additional AGNIS reports and enhancements to the AGNIS test environments to help support external users when they are testing new AGNIS forms.

Recent AGNIS and other electronic data submission accomplishments:
- Updated CIBMTR Reporting App (CRA) functionality to introduce time-saving efficiencies for end users
- Expanded CRA usage to twelve centers
- The AGNIS team continues to release forms for centers to use in data submission to the CIBMTR as well as address questions or issues raised by centers and their vendors.
- Two AGNIS forms were released to production and five for external testing.
    - Form 2815r1 (for an AGNIS implementation of the Consent Tool) is now available for testing by external centers and vendors.
- A new website was created and released to replace the legacy website used by external centers and vendors for the development of AGNIS.

Integrated Data Warehouse (IDW) and Unified Domain Model (UDM)
CIBMTR continued to increase the capabilities of the IDW and UDM. Accomplishments include:
- Integrated Data Warehouse (IDW) – Operational Data Warehouse utilized for delivery of key data to stakeholders.
- Incorporated ongoing forms revisions into the warehouse.
- Enhanced processes to support CIBMTR's Domestic and International CPI Processes.
- Created reports in new Business Intelligence tool, Looker, to support CIBMTR Prospective Research team needs.
- Completed Cord Blood Bank requests to the Cord Blood Data Quality Report.
- Enhanced a pathway to capture and store survey data from CIBMTR's ePRO system.

- Created new Business Intelligence reports to support ePRO Data Quality efforts.
- Business Intelligence Data Sharing- Continued expansion of business intelligence tool capabilities. Adding to the existing suite of external Business Intelligence data sharing applications including the introduction of more data, dimensions and measures, stakeholder groups, and continuing data quality initiatives.

Center Volumes Data Reports

- Phase one of the annual CVDR update has been completed successfully.

Data Operations Dashboard

- Released a new environment for sharing data within the DataOps dashboard called 'Data Requests'. This new environment securely shares Observational Study data with the transplant centers.

Unified Domain Model- continuing the process of building this single source of truth of data that will contain high quality, validated data readily available to researchers for immunobiology, outcomes, and other types of analyses

- Continued delivery of monthly and quarterly CAR T-cell data sets to our Japan and pharmaceutical partners
- Delivered 4 Periodic Safety Update Reports (PSUR) for two CAR T-cell therapies. Continued transitioning HCT data from the Research Database to the Unified Domain Model and delivered the first set of Stem Cell Therapeutic Outcomes Data required for the HRSA SCTOD quarterly report.
- Delivered 15 new data extracts combining data from the new Unified Domain Model database with older data from the Research Database, as we work toward sunsetting the Research Database.
- Continued work on adding human leukocyte antigen data (HLA) data to the Unified Domain Model

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Support for the Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial

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BMT CTN 1702: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial has accrued 1346 subjects through September 2021. A total of 137 patients were accrued in the past quarter.

Publications

1. Bejanyan N, Zhang M, Bo-Subait K, et al. Myeloablative conditioning for allogeneic transplantation results in superior disease-free survival for acute myeloid leukemia and myelodysplastic syndromes with low/intermediate, but not high disease risk index: A CIBMTR study: Superior DFS with MAC compared to RIC HCT in AML/MDS with low/intermediate risk DRI. Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation. doi:10.1016/j.bbmt.2020.09.026. Epub 2020 Oct 1. Impact factor: 3.9

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3. Gupta V, Kim S, Hu Z-H, et al. Comparison of outcomes of HCT in blast phase of BCR-ABL1-MPN with de novo AML and with AML following MDS. Blood Advances. 2020 Oct 13; 4(19):4748-4757. doi:10.1182/bloodadvances.2020002621. Epub 2020 Oct 2. PMC7556156. Impact factor: 4.6

4. Kim S, Logan B, Riches M, et al. Tatistical methods for time-dependent variables in hematopoietic cell transplantation studies. Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation. doi:10.1016/j.bbmt.2020.09.034. Epub 2020 Oct 2. Impact factor: 4.7

5. Fahadfar N, Burns LJ, Mupfudze T, et al. Hematopoietic Cell Transplantation Predictions for the Year 2023 Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation. doi:10.1016/j.bbmt.2020.10.006. Epub 2020 Oct 9. PMC7546661. Impact factor: 3.9

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9. Hong S, Brazauskas R, Hebert KM, et al. Community health status and outcomes after allogeneic hematopoietic cell transplantation in the United States. Cancer. doi:10.1002/cncr.33232. Epub 2020 Oct 21. Impact factor: 5.7

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12. Shah NN, Ahn KW, Litovich C, et al. Is autologous transplant in relapsed DLBCL patients achieving only a PET+ PR appropriate in the CAR-T cell era? Blood. doi:10.1182/blood.2020007939. Epub 2020 Oct 29. Impact factor: 17.5

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21. Cornell RF, Fraser R, Costa L, et al. Bortezomib-based induction is associated with superior outcomes in light chain amyloidosis patients treated with autologous hematopoietic cell transplantation regardless of plasma cell burden. Transplantation and Cellular Therapy. 2021 Mar 1; 27(3):264.e1-264.e7. doi:10.1016/j.jtct.2020.11.018. Epub 2020 Dec 21. Impact factor: *See below

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* The American Society of Blood and Marrow Transplant was renamed as The American Society of Transplant and Cellular Therapy in 2020. The change led to an update to the name of the society journal from Biology of Blood and Marrow Transplant (Impact Factor: 3.9) to the Journal of Transplant and Cellular Therapy resulting in a reset of the impact factor.