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14. ABSTRACT <p>1. <u>Contingency Preparedness</u>: 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.</p> <p>2. <u>Rapid Identification of Matched Donors</u>: Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.</p> <p>3. <u>Immunogenic Studies</u>: Increase understanding of the immunologic factors important in HSC transplantation.</p> <p>4. <u>Clinical Research in Transplantation</u>: Create a platform that facilitates multicenter collaboration and data management.</p>					
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Grant Award N00014-23-1-2057

DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS
QUARTERLY RESEARCH PERFORMANCE REPORT
SUBMITTED January 12, 2024

Office of Naval Research

And

The National Marrow Donor Program® d/b/a NMDP

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I. Heading

PI: Jeffrey Auletta, M.D.

National Marrow Donor Program

N00014-23-1-2057

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 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 immunobiology bioinformatics and clinical research activities promote studies to advance the science and technology of HCT transplantation and directly translate research results to improve outcomes 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. 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 with marrow toxic injuries, such as Acute Radiation Syndrome (ARS), from exposure to ionizing radiation or chemicals. The NMDP manages a network of hospitals that work in concert to facilitate unrelated HCT. The Radiation Injury Treatment Network (RITN), comprised of a subset of NMDP's network centers as well as non-NMDP network centers, is a national network of medical centers with expertise in the management of bone marrow failure and works with partners from other medical specialties to assist with managing ARS and its health-related consequences in response to marrow toxic mass casualty incidents.

B. Development of Science and Technology for Rapid Identification of Matched Donors
Rapid progression to successful transplantation following a marrow toxic exposure or disease diagnosis affects survival. Decreasing the time to identify the optimal donor is critical. Methods are under development to rapidly identify and provide the optimal 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 focus on strategies to maximize success of HCT while minimizing the toxicity related to alloreactivity between the donor graft and the recipient.

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

Activity under this grant is complete and will continue under a subsequent award.

B. Development of Science and Technology for Rapid Identification of Matched Donors
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Expand the genetic diversity of the registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies

During the past quarter, a total of 51,379 newly registered volunteer donors were HLA typed and added to the Be The Match Registry.

Modeling and analysis of registry coverage for the Warfighter

Activity under this grant is complete and will continue under a subsequent award.

Development of science and technology for rapid communication of HLA data

Activity under this grant is complete and will continue under a subsequent award.

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

Activity under this grant is complete and will continue under a subsequent award.

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

Activity under this grant is complete and will continue under a subsequent award.

Development of a national framework to standardize measurable residual disease evaluation in the clinical care of patients receiving allogeneic transplant for acute myeloid leukemia

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.

A multicenter prospective observational study was launched in 2022 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 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 protocol team continued to meet regularly to manage the IRB approved and [ClinicalTrials.gov](https://clinicaltrials.gov) registered study protocol entitled, “MEASURE: Molecular Evaluation of AML patients after Stem cell transplant to Understand Relapse Events”. To date, 18 centers have committed to participate in the study and combined plan to enroll >250 patients per year. Seventeen of 18 sites have received local IRB approval for the protocol. All sites have initiated submission of regulatory documents required for participation. Sixteen sites have fully opened the study and have enrolled a total of 103 patients through December 2023.

Determine the impact of peripheral blood stem cell graft composition on the outcome of hematopoietic cell transplantation

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. The study will evaluate approximately 2,100 PBSC products over a 3-year accrual period with 1,100 collected in the U.S. through the NMDP and an additional 1,000 collected in Germany for U.S. based patients through the DKMS. The U.S. testing will be supported through the ONR (prior grant years and the current) and DKMS will support testing of German collected products. Data will be merged with CIBMTR collected clinical outcomes for analysis and correlation with clinical outcomes.

During the past quarter accrual continued for U.S. based donors. A total of 568 product samples were received and tested through December 31, 2023, with 65 tested in the last quarter. Preliminary analyses focused on graft composition correlation with donor characteristics and the impact of cryopreservation are underway. Initial results were presented as oral abstracts to the 2023 ASH annual meeting and abstracts submitted to the 2024 EBMT annual meeting:

- MAIT Cell Frequencies within PBSC Grafts Are Associated with Donor CMV Serostatus and Age: An Initial Analysis from the DKMS and NMDP Graft Composition Study

- Cryopreservation Changes the Immune Effector Cell Composition of Peripheral Blood Stem Cell Grafts: An Analysis from the DKMS and NMDP Graft Composition Study

Determine the impact of non-HLA genes and gene expression on allogeneic cell transplantation

Activity under this grant is complete and will continue under a subsequent award.

D. Clinical Research in Transplantation

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

Observational Research

- Published 13 manuscripts in peer-reviewed journals during the last quarter (see publications below).
- A total of 38 abstracts were presented at the 2023 American Society of Hematology (ASH) annual meeting to be held in San Diego, CA, December 9-12, 2023. Presentation title and type [oral (N=28) or poster (N=11) abstract] are listed in the table 1 below. Abstracts were published in a supplement to the journal [Blood](#) in November 2023.

Table 1. Presentations at the 2023 ASH Annual Meeting

Title	Presentation type
Real-World Evidence in the United States (US) of the Impact of Bridging Therapy Prior to Axicabtagene Ciloleucel (Axi-Cel) for the Treatment of Relapsed or Refractory Large B-Cell Lymphoma (R/R LBCL)	Oral
The Composite Health Risk Assessment Model (CHARM) to Predict 1-Year Non-Relapse Mortality (NRM) Among Older Recipients of Allogeneic Transplantation: A Prospective BMT-CTN Study 1704	Oral
Multicenter, Real-World Study in Patients with R/R Large B-Cell Lymphoma (LBCL) Who Received Lisocabtagene Maraleucel (liso-cel) in the United States (US)	Oral

Rabbit Antithymocyte (rATG) Exposure and Outcomes after Hematopoietic Cell Transplantation: A Real World Experience from BMT CTN 1202	Oral
Real-World Outcomes of Brexucabtagene Autoleucel (Brexu-cel) for Relapsed or Refractory (R/R) Mantle Cell Lymphoma (MCL): A CIBMTR Subgroup Analysis of High-Risk Characteristics	Oral
Long-Term Outcomes after Unrelated Marrow Transplantation for Aplastic Anemia with Optimized Cyclophosphamide Dose (BMT CTN 0301)	Oral
Age-Related Differences in Utilization of Allogeneic HCT for Acute Myeloid Leukemia in California: Results of a Population-Based, Novel Linked Dataset	Oral
Out-of-Pocket Costs and Financial Hardship Among Participants of the BMT CTN 1102 Study	Oral
Predictors of Cytokine Release Syndrome and Neurotoxicity in Patients with Large B-Cell Lymphoma and Their Impact on Survival	Oral
Impact of Publicly Reported Center Specific Analysis on Patient Selection Practices for Hematopoietic Stem Cell Transplantation	Oral
Factors Associated with Treatment Receipt in Medicare Beneficiaries Diagnosed with Acute Myeloid Leukemia	Oral
Donor Hematopoietic Cell Telomere Length and Magnitude of Post-HCT Shortening Predict Survival in Early Stage Leukemia and Myelodysplastic Syndrome	Oral
Large-Scale Post-Transplant TCR Deep Sequencing Reveals a Major T Cell Diversity Bottleneck with Post-Transplant Cyclophosphamide with Implications for Both Efficacy and Toxicity: Results of the BMT CTN 1801 Study	Oral
Measurable Residual IDH2 before Allogeneic Transplant for Acute Myeloid Leukemia	Oral
Ibrutinib Added to Standard Conditioning and As Consolidation Therapy Following Autologous Hematopoietic Stem Cell Transplantation (AutoHCT) for Relapsed/Refractory Activated-B-Cell Subtype Diffuse Large B-Cell Lymphoma (ABC-DLBCL): Primary Analysis of the US Intergroup Double-Blind Randomized Phase III Study Alliance A051301/BMT-CTN 1201	Oral

Machine Learning Validates Risk Biomarkers of Chronic Graft-Versus-Host Disease in 936 Patients from BMT CTN 0201 & 1202 Cohorts	Oral
Chimeric Antigen Receptor (CAR) T Cell Infusion for Large B Cell Lymphoma in Complete Remission: A Center for Internation Blood & Marrow Transplant Research (CIBMTR) Analysis	Oral
Autologous Transplant (auto-HCT) Is Associated with Improved Clinical Outcomes Compared to CAR-T Therapy in Patients (pts) with Large B-Cell Lymphoma (LBCL) Achieving a Complete Remission	Oral
CD33 CAR T-Cells (CD33CART) for Children and Young Adults with Relapsed/Refractory AML: Dose-Escalation Results from a Phase I/II Multicenter Trial	Oral
Post-Transplant Cyclophosphamide Eliminates Disparity in GvHD-Free, Relapse-Free Survival and Overall Survival between 8/8 Matched and 7/8 Mismatched Unrelated Donor Hematopoietic Cell Transplantation in Adults with Hematologic Malignancies	Oral
Patient-Reported Outcomes of BMT CTN 1703: A Randomized Phase III Study for GVHD Prophylaxis - A Quality of Life Evaluation	Oral
Post-Hoc Analysis of Measurable Residual Disease from BMT-CTN 1506/Morpho: FLT3-ITD Variant Allele Frequency and Survival Are Highly Correlated	Oral
Real World Outcomes with Idecabtagene Vicleucel (Ide-Cel) CAR-T Cell Therapy for Relapsed/Refractory Multiple Myeloma	Oral
MAIT Cell Frequencies within PBSC Grafts Are Associated with Donor CMV Serostatus and Age: An Initial Analysis from the Dkms and NMDP Graft Composition Study	Oral
Real-World Outcomes of Brexucabtagene Autoleucel (brexu-cel) for Relapsed or Refractory (R/R) Adult B-Cell Acute Lymphoblastic Leukemia (B-cell ALL): Evidence from the CIBMTR Registry	Oral
Cryopreservation Changes the Immune Effector Cell Composition of Peripheral Blood Stem Cell Grafts: An Analysis from the DKMS and NMDP Graft Composition Study	Oral
Hematopoietic Stem Cell Transplantation for Fanconi Anemia: Outcome and Prognostic Factors for Survival and Subsequent Neoplasms	Oral
Reduced Intensity Haploidentical Bone Marrow Transplantation in Adults with Severe Sickle Cell Disease: BMT CTN 1507	Oral

Comparative Effectiveness of Axicabtagene Ciloleucl Vs Historical Standard-of-Care in Patients with Relapsed or Refractory Follicular Lymphoma: An Analysis of CIBMTR and SCHOLAR-5 Data	Poster
HLA-DRB1 Hed Is Associated with Improved Survival and Decreased Relapse in Patients with Hematologic Malignancies Following Allogeneic Hematopoietic Stem Cell Transplant	Poster
Monoallelic Pathogenic Variants in Hemophagocytic Lymphohistiocytosis Genes Are Uncommon and Not Associated with Hematopoietic Cell Transplantation Outcomes in Severe Aplastic Anemia	Poster
Caregiver Perspectives on Housing, Finances and Employment Post-Allogeneic Hematopoietic Cell Transplant	Poster
Persistence of FLT3-TKD in Blood Prior to Allogeneic Transplant Is Associated with Increased Relapse and Death in Adults with AML in First Remission	Poster
Durable Efficacy and Manageable Safety in Patients Age \geq 75 Years with Relapsed/Refractory Large B-Cell Lymphoma Treated with Tisagenlecleucl in the Real-World Setting	Poster
Real-World Tisagenlecleucl Outcomes in Richter-Transformed Chronic Lymphocytic Leukemia: A Center for International Blood & Marrow Transplant Research (CIBMTR) Analysis	Poster
Is the Youngest Donor Always the Best Choice to Optimize Outcomes for Matched Unrelated Allogeneic Transplant? Improving Precision Using Novel Statistical Methodology	Poster
Measurable Residual IDH1 before Allogeneic Transplant for Acute Myeloid Leukemia	Poster
Measurable Residual FLT3-ITD before Allogeneic Transplant for Acute Myeloid Leukemia	Poster
Prediction of Graft-Versus-Host Disease (GVHD) in Recipients of Hematopoietic Cell Transplant(alloHCT) from a Single Mismatched Unrelated Donor Using a Highly Multiplexed Proteomics Assay: MHC-Pepseq	Poster

Research data collection and systems enhancements

Activity under this grant is complete and will continue under a subsequent award.

Conduct clinical trials on the use of HLA mismatched graft sources to expand access to all patients in need of allogeneic cell transplantation

Activity under this grant is complete and will continue under a subsequent award.

Publications

1. Cusatis R, Balza J, Uttke Z, et al. Patient-reported cognitive function among hematopoietic stem cell transplant and cellular therapy patients: A scoping review. *Quality of Life Research*. doi:10.1007/s11136-022-03258-0. Epub 2022 Oct 6. Impact Factor: 4.14
2. Olson TS, Frost BF, Duke JL, et al. Pathogenicity and impact of HLA class I alleles in aplastic anemia patients of different ethnicities. *Journal of Clinical Investigation Insight*. 2022 Nov 22; 7(22):e163040. doi:10.1172/jci.insight.163040. Epub 2022 Oct 11. PMC9746824. Impact Factor: 9.48
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5. Cusatis R, Martens MJ, Nakamura R, et al. Health-related quality of life in reduced intensity hematopoietic cell transplantation based on donor availability in patients aged 50-75 with advanced myelodysplastic syndrome: BMT CTN 1102 *American Journal of Hematology*. doi:10.1002/ajh.26768. Epub 2022 Oct 17. Impact Factor: 10.05
6. Vasu S, Holtan S, Shimamura A, et al. Bringing patient and caregivers voices to the clinical trial chorus: A report from the BMT CTN patient and caregiver advocacy task force. *Transplantation and Cellular Therapy*. doi:10.1016/j.jtct.2022.10.016. Epub 2022 Oct 22. Impact Factor: 5.60
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8. Hong S, Zhao J, Wang S, et al. Health-related quality of life outcomes in older hematopoietic cell transplant (HCT) survivors. *Transplantation and Cellular Therapy*. doi:10.1016/j.jtct.2022.11.016. Epub 2022 Nov 22. Impact Factor: 5.60
9. Schoettler M, Carreras E, Cho B, et al. Harmonizing definitions for diagnostic criteria and prognostic assessment of transplant associated thrombotic microangiopathy: A report on behalf of the European Society for Blood and Marrow Transplantation (EBMT), American Society for Transplantation and Cellular Therapy (ASTCT), Asia-Pacific Blood and Marrow Transplantation Group (APBMT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). *Transplantation and Cellular Therapy*. doi:10.1016/j.jtct.2022.11.015. Epub 2022 Nov 25. Impact Factor: 5.60
10. Friend B, Broglie L, Logan B, et al. Adapting the HCT-CI definitions for children, adolescents, and young adults with hematologic malignancies undergoing allogeneic hematopoietic cell transplantation. *Transplantation and Cellular Therapy*. doi:10.1016/j.jtct.2022.11.019. Epub 2022 Nov 25. Impact Factor: 5.60

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12. Putta S, Young BA, Levine J, et al. Prognostic biomarkers for hepatic veno-occlusive disease/sinusoidal obstruction syndrome (VOD/SOS) in myeloablative allogeneic hematopoietic cell transplantation: Results from the BMT CTN 1202 study. *Transplantation and Cellular Therapy*. doi:10.1016/j.jtct.2022.11.024. Epub 2022 Nov 26. Impact Factor: 5.60
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