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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.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY RESEARCH PERFORMANCE REPORT

SUBMITTED April 14, 2023

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

N00014-21-1-2954

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

- **Radiation disaster and countermeasure research education**
  - Radiation Emergency Assistance Center/Training Site (REAC/TS) training courses
    - REAC/TS training course sponsorship has been canceled as different training opportunities were created which have the option for wider audience participation.
      - Sponsoring physicians, advanced practitioners, health physicists, and other applicable RITN hospital staff to attend hands-on training course in Oak Ridge, TN at the REAC/TS facility.
        - Radiation Emergency Medicine is a 3-day course.
        - Advanced Radiation Emergency Medicine is a 4.5-day course.
        - Health Physics in Radiation Emergencies is a 4.5-day course.
      - The goal is to have participants share their knowledge with colleagues after attending the applicable course.
  - Advanced HAZMAT Life Support Radiological Incidents & Terrorism courses
    - Four additional RITN hospitals will host two 4-hour sessions on radiological incidents and terrorism.
    - This is in addition to the one RITN hospital in the FY2023 budget (West Virginia University Hospital, Morgantown, WV).

- Additional hospitals:
    - Corewell Health (Grand Rapids, MI)
    - University of Wisconsin (Madison, WI)
    - Orlando Health, (Orlando, FL)
    - Temple University (Philadelphia, PA)

- **Radiation disaster preparedness training**
    - Activity under this section is complete.

- **Hospital radiation disaster preparedness**
    - Additional exercises will be created and conducted, helping to prepare additional hospitals and hospital coalitions.

- **Hospital network growth:**
    - Activity under this section is complete and will continue under a subsequent award.

- **Federal partnership development:**
    - Activity under this section is complete

- **Other projects:**
    - Activity under this section is complete.

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

During the past quarter, a total of 14,070 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 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. Thirteen of 18 sites have received local IRB approval for the protocol. All sites have initiated submission of regulatory documents required for participation. Eight sites have fully opened the study and have enrolled 13 patients.

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 365 product samples were received and tested through March 31, 2023, with 71 tested in the last quarter. Testing costs are covered under a subsequent grant while staff support is funded under this grant. Testing of German donors will be fully funded by DKMS Testing costs are covered under this grant while staff support is funded under a subsequent grant.

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

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 14 manuscripts in peer-reviewed journals during the last quarter (see publications below).
- A total of 21 abstracts were presented at the 2023 BMT Tandem Meetings of the CIBMTR and American Society for Transplant and Cellular Therapy held February 15-19 in Orlando, FL. Presentation titles and type are detailed in table 1 below. Abstracts were published in a supplement to the Journal of Transplant and Cellular Therapy.

Table 1. CIBMTR presentations at 2023 BMT Tandem Meetings

Title	Status
Posttransplant Cyclophosphamide-Based Transplantation from Haploidentical Donors Has Similar Outcomes As Unrelated Donor Transplantation in Myelofibrosis: A Center for International BMT Research (CIBMTR) Study	Oral
Comparison of Allogeneic Hematopoietic Cell Transplantation Outcomes from Younger Matched Unrelated Donor Versus Older Sibling Donor for Acute Myeloid Leukemia	Oral
Younger Matched Unrelated Donors Confer a Decreased Relapse Risk As Compared to Older Sibling Donors for Adult B-Cell ALL Patients Undergoing Allogeneic Hematopoietic Cell Transplantation	Oral
Associations of Minor Histocompatibility Antigens with Clinical Outcomes Following Allogeneic Hematopoietic Cell Transplantation	Oral
Improved Relapse-Free Survival (RFS) for Pediatric and Young Adult Patients with Relapsed or Refractory (R/R) B-Cell Acute Lymphoblastic Leukemia (B-ALL) and Low or Intermediate Preinfusion Disease Burden Treated with Tisagenlecleucel: Results from the CIBMTR Registry	Oral
Shared Graft Versus Leukemia Minor Histocompatibility Antigens in Discovery-BMT	Oral

Title	Status
HLA Evolutionary Divergence Does Not Predict Relapse and Survival Following Allogeneic Hematopoietic Stem Cell Transplant for Myeloid and Lymphoid Malignancies	Poster
Impact of Public Reporting of Center-Specific Analysis Scores on Hematopoietic Cell Transplant Center Volumes	Poster
Access: A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Hematopoietic Cell Transplantation with Post-Transplantation Cyclophosphamide for Patients with Hematologic Malignancies	Poster
An Exploration of Unrelated Donor Existence for Patients Who Received Haploidentical Hematopoietic Cell Transplants	Poster
Association between Patient-Reported Social Determinant of Health Outcomes and a Social Genomics Profile in Allogeneic Hematopoietic Cell Transplantation: A Center for International Blood and Marrow Transplant Research (CIBMTR) Analysis	Poster
Can You Spare 100 Days? The Allogeneic Hematopoietic Cell Transplant Caregiver Requirement	Poster
Can You Spare 100 Days? Allogeneic Hematopoietic Cell Transplant Caregiver Requirements from the Perspective of Recipients and Caregivers	Poster
Does Race/Ethnicity Impact Umbilical Cord Blood Transplant in a Contemporary Era?	Poster
Delayed CD4+ T Cell Recovery after Allogeneic Hematopoietic Cell Transplantation Is Associated with Decreased Overall Survival in Adult but Not Pediatric Recipients	Poster
Patient-Reported Outcomes in Long-Term Survivors of Autologous Hematopoietic Cell Transplantation (AHCT) for Hodgkin (HL) and Non-Hodgkin Lymphoma (NHL): Secondary Analysis from Two Multicenter Randomized Controlled Trials (RCT) of Hematopoietic Cell Transplant Survivorship Interventions	Poster
Ph-Positive ALL Patients Who Are Treated with Tyrosine Kinase Inhibitors Have Similar Post-Transplant Survival As Ph-Negative Patients	Poster
Ongoing Risk of Unrelated Donors Testing Positive for COVID-19 Following Medical Clearance and Impact on Operations: A Report from the National Marrow Donor Program	Poster
Trends in Utilization of Autologous and Allogeneic Hematopoietic Cell Transplantation in Racial/Ethnic Minorities	Poster
Disease-Specific Overall Survival Prediction after Allogeneic Hematopoietic Cell Transplantation	Poster
A Retrospective Analysis of Genotype Copy Number (GCN) in Unrelated Donor Transplants and Future Implications for Mismatched Transplants	Poster

Publications

1. Pasvolsky O, Yeshurun M, Fraser R, et al. Maintenance therapy after second autologous hematopoietic cell transplantation for multiple myeloma. A CIBMTR analysis. Bone Marrow Transplantation. doi:10.1038/s41409-021-01455-y. Epub 2021 Oct 4. Impact Factor: 5.48

2. Bhatt VR, Wang T, Chen K, et al. Chronic Graft-Versus-Host Disease, Non-Relapse Mortality and Disease Relapse in Older versus Younger Adults Undergoing Matched Allogeneic Peripheral Blood Hematopoietic Cell Transplantation: A CIBMTR Analysis. Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2021.10.002. Epub 2021 Oct 9. Impact Factor: 5.60

3. Cancio M, Hebert K, Kim S, et al. Outcomes in hematopoietic stem cell transplantation for congenital amegakaryocytic thrombocytopenia. Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2021.10.009. Epub 2021 Oct 17. Impact Factor: 5.60

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6. Phelan R, Im A, Hunter RL, Inamoto Y, et al. Male-specific late effects in adult hematopoietic cell transplantation recipients: a systematic review from the Late Effects and Quality of Life Working Committee of the Center for International Blood and Marrow Transplant Research and Transplant Complications Working Party of the European Society of Blood and Marrow Transplantation. Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2021.10.013. Epub 2021 Oct 29. Impact Factor: 5.60

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