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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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DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY RESEARCH PERFORMANCE REPORT

SUBMITTED January 14, 2022

Office of Naval Research

And

The National Marrow Donor Program®

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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:

- RITN Training committee workgroup completed the modular acute radiation syndrome (ARS) treatment just-in-time training course for healthcare providers. The purpose was to create a shorter, multi-part series to replace the current, longer (16-minute) ARS just-in-time training video. The three-part series of modules may each be used as standalone just-in-time training but are also a cohesive series, building off each other. The target audience for two of the modules are physicians, advanced practitioners, and advanced registered nurses who are not familiar with ARS and care of ARS patients, yet the material is not given on a basic medical level. The other module covers preparedness plans for emergency managers and those in the safety areas. The videos are available on the RITN YouTube Channel (https://www.youtube.com/channel/UCkd45X1DlPqeRr-u5lph6Og) as well as the RITN website (https://ritn.net/training/).
    - What to Expect…Does the Patient Have ARS? (~9 minutes)
        - This module is designed to give answers to frequently asked questions that may arise about treating patients with Acute Radiation Syndrome.
    - Treating Radiation Victims…Am I Safe? (~7 minutes)

        - This module addresses one of the most commonly asked radiation questions heard from medical staff..."Am I Safe Treating Acute Radiation Syndrome… or ARS…Patients?" And the answer is Yes!
    - Preparedness Steps…Identifying Your Resources (~8 minutes)
        - This module focuses on how to prepare for a radiological emergency before it happens.

- The Department of Health and Human Services-Assistant Secretary for Preparedness and Response's Operational Intent for FY2022 is a radiation focus. In support of this RITN developed a functional exercise (drill) kit (or an 'exercise-in-a-box') to be used by healthcare coalition members to meet this requirement. The exercise has six modules and an after-action review (hot wash), each module taking approximately 45 minutes to conduct. It is also Homeland Security Exercise and Evaluation Program (HSEEP) compliant.
    - There is no cost for hospitals to use this exercise-in-a-box to fulfill their requirements for increased preparedness for ASPR. It is important to note that this is free as hospitals are accustomed to paying for any kind of training and material.
    - The exercise-in-a-box has been added to the RITN website as well as on ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) website, and was showcased at the National Healthcare Coalition Preparedness Conference (NHCPC) in December 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.

During the past quarter, a total of 52,144 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

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

Enhance population genetics driven donor selection algorithms
During the past quarter progress haplotype frequencies for global populations (over 45M individuals) were validated to address several data quality issues. The resulting haplotype frequencies are being prepared for publication and will cover 9 HLA loci. The computational pipeline was substantially refactored to run on a supercomputer cluster in parallel which will allow this analysis to be rerun in the future.

The resulting frequencies are being prepared for publication and will be used to improve donor selection algorithms by extending predictions on the NMDP search reports to include loci previously not included in up-front matching.

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

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

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 accepted for poster 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 immunophenotyping panel was finalized and accrual was initiated for U.S. based donors. A total of 11 product samples were received and tested through December 31, 2021.

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 protocol team continued to meet regularly to finalize the study protocol that is titled, "MEASURE: **M**olecular **E**valuation of **A**ML patients after **S**tem cell transplant to **U**nderstand **R**elapse **E**vents". the protocol was submitted to and approved by the NMDP IRB in late December. A site selection questionnaire was developed and distributed to 15 candidate centers to solicit interest in participating in the study. To date, 9 centers have responded with an intent to participate in the study and have committed to enroll >250 patients per year. The protocol team planned an investigator meeting with the site principal investigators that will be held at the annual Tandem meeting scheduled for February 4, 2022 in Salt Lake City

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 107 manuscripts in peer-reviewed journals during this grant period.
- Additional research activity will be reported under a subsequent grant.

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

BMT CTN 1702: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial has accrued 1531 subjects through December 2021. A total of 144 patients were accrued in the past quarter.

Publications

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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.