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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 15th, 2020

Office of Naval Research

And

The National Marrow Donor Program®

500 5th St N

Minneapolis, MN 55401

I. Heading

PI: Steven Devine, M.D.

National Marrow Donor Program

N00014-20-1-2705

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 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:

- Updated the Cytokine Triage Guidelines and circulated for additional comments
- Continued collaboration with the American Burn Association to develop advanced practice guidelines for the combined care of patients by RITN and burn centers.
- Coordinated with the DOD to present about Acute Radiation Syndrome patient care at the Brooke Army Medical Center as part of the Armed Forces Radiobiology Research Institute (AFRRI) Medical Effects of Ionizing Radiation (MEIR) Course.
- Drafted adult and pediatric medical orders in the Epic Electronic Medical Record system.
- Supported Gryphon Scientific CDC funded project to assess United States laboratory capabilities for ionizing radiation related testing.
- Continued to develop the Hospital Radiation Morbidity Toolkit as part of the CDC grant awarded to RITN.

- Held RITN Executive Committee strategic planning meeting in Washington D.C. on February 25 to review past successes, projects underway, to evaluate current structure, and priorities for continued success of RITN.

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.

Supported HLA typing of 37,533 newly registered volunteer donors.

Modeling and analysis of registry coverage for the Warfighter

This project seeks to model the potential availability of donors for scenarios where they may be needed for the warfighter. Planning has continued during the past quarter with contacts at the DoD Donor Center and Uniformed Services University. The parameters of the model have been refined based on a call with Lt Col Lien Sencha a radiologist with Military Medical Operations.

Development of science and technology for rapid communication of HLA data

A data standards hackathon was held in January focusing on public validation services. This event involved 19 people from NMDP and 4 partner academic/registry organizations (CHORI, UCSF, Stanford and DKMS). This effort leveraged tools developed under earlier years of this grant and will form the basis of the validation process for the 18th International Workshop for HLA and Immunogenetics https://www.ihiw18.org/. A virtual hackathon has been planned in April (23-25) that will continue this work with more involvement from the commercial vendors. This hackathon will be "virtual" and will include a component to support data collection for a number of projects trying to link HLA and COVID-19 infection.

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

The EFI (European Federation for Immunogenetics) conference was postponed due to the coronavirus pandemic. The abstracts to present work supported under this grant will be presented 1-year later (in April 22-25, 2021).

A report entitled "Choosing an optimal hematopoietic stem cell donor with Bayesian Additive Regression Trees (BART)" has been reviewed by the CIBMTR stats committee and is being prepared for publication. The dataset for the 2nd phase of this study has been distributed to the collaborators at the Medical College of Wisconsin which will be used for the analysis of factors affecting the prediction of event free survival.

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 selected >4,000 pairs for enrollment in the project. The sample pull is in process at the NMDP Biorepository and will be shipped for testing in April 2020. Pairs are being prioritized based on needs of the CIBMTR observational research program. Results are expected by the end of next quarter.

Full HLA Gene Matching Analysis

- Completed the preliminary analysis for the study IB19-01: Impact of ultra-high resolution (UHR) HLA matching on the outcome of unrelated donor hematopoietic cell transplantation. Summary of findings:
    a. UHR matching was not associated with the primary outcome of overall survival in the T cell deplete, T cell replete or full cohort.
    b. 12/12 UHR matching was associated with lower aGVHD2-4 compared to <=11/12 UHR matched.
    c. TCE non-permissive mismatch was associated with worse aGVHD2-4 than matched: HR=1.26 (1.10,1.45), P=0.0007.
    d. The combination of TCE and CMV 'TCE_CMV' was associated with OS, TRM, DFS and relapse in various models (full cohort, TCD and T replete). Although highly statistically significant they are not consistent with hypothesized biologic mechanisms.
    e. The HLA-DPB1 TCE effect was weaker than previously observed in CIBMTR studies (Pidala et al Blood 2014) HR 1.2 vs. 1.08 for permissive vs. non-permissive mismatching. A post-hoc power calculation suggests that a sample size of N=21,267 would be required to detect a difference at the 0.05 significance level with 80% power. Study team reviewing differences between the Pidala and current cohort to identify factors that could have influenced the impact of DPB1-TCE matching.

- Full gene sequence analysis and UHR match scoring was initiated on a cohort of 1402 donor/recipient transplant pairs with 1-3 high resolution mismatches at HLA-A, -B and/or -C. The goal of the analysis is to evaluate the sequence associations across the full HLA haplotype. We hypothesize that high resolution mismatches associate with distinct UHR sequences across the HLA haplotype. The high-resolution mismatched cohort is summarized below and analysis is in process:

HLA mismatch category	Sample size	Percentage of total population
HLA-A	N=681	48.57%
HLA-B	N=272	0.86%
HLA-C	N=319	1.50%
HLA-A,-B	N=12	2.00%
HLA-A, -C	N=28	19.40%
HLA-B, -C	N=69	4.92%
HLA-A, -B, -C	N=21	22.75%

Develop and mature typing protocols for the highly polymorphic KIR.

- A meeting was held with collaborators on this project to assess the current results and develop a strategy for how to proceed with the development of this method. A manuscript has been prepared and submitted and is under revision. A cohort of 48 samples have been selected for typing under this project expanding on the first two phases of 8 and 12 samples.

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

- Completed development of a CIBMTR Graft Versus Host Disease Working Committee protocol for evaluation of donor clonal hematopoiesis of indeterminate potential (CHIP) on HCT outcomes. The study is titled "GV19-01 "Exploring the link between donor-engrafted clonal hematopoiesis and adverse outcomes in allogeneic hematopoietic cell transplant recipients: Pilot study".
- CHIP testing of N=300 donor samples for evaluation in the pilot project was completed in March and sequence analysis is in process with the clinical correlation analysis anticipated next quarter. Testing is funded through an in-kind donation from an industry partner. Navy funds will be used to support the pilot analysis and additional CHIP testing on a larger cohort.

D. Clinical Research in Transplantation

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

Observational Research

- Published 21 manuscripts in peer-reviewed journals.
- Reviewed 98 proposals for consideration at the Transplant and Cellular Therapy Annual Meeting working committee sessions and accepted 31 for activation during the 2020-2021 academic year. The Working Committee study approval distribution is noted below:

Working Committee	TOTAL
Acute Leukemia	**4**
Cellular Immunotherapy for Cancer	**4**
Chronic Leukemia	**2**
Donor Health and Safety	**1**
Graft Sources and Manipulation	**2**
Graft vs Host Disease	**2**
Health Services and International Studies	**1**
Immunobiology	**2**
Infection and Immune Reconstitution	**1**
Late Effects and Quality of Life	**2**
Lymphoma	**2**
Non-Malignant Diseases	**1**
Pediatric Cancer	**2**
Plasma Cell Disorders and Adult Solid Tumors	**3**
Regimen Related Toxicity and Supportive Care	**2**
TOTAL	**31**

- Presented 14 oral and 8 poster abstracts at the Transplant and Cellular Therapy Annual Meeting. A list of the presentations is provided in the table below. Complete abstracts were published in the March 2020 issue of Biology of Blood and Marrow Transplant (https://www.bbmt.org/issue/S1083-8791(19)X0014-2).

Title	***Status***	***Presenter***
Higher Total Body Irradiation (TBI) Dose-Intensity in Fludarabine (Flu)/TBI-Based Reduced-Intensity Conditioning (RIC) Regimen Is Associated with Inferior Survival in Non-Hodgkin Lymphoma (NHL) Patients Undergoing Allogeneic Hematopoietic Cell Transplantation (alloHCT).	**Oral**	Mehdi Hamadani
MLL-Rearranged AML Is Associated with Poor Outcomes As Compared to Patients with Intermediate- and Adverse-Risk Disease: A CIBMTR Study of 3779 Adult Patients	**Oral**	Kamal Menghrajani
Long-Term Follow up of BMT CTN 0901, a Randomized Phase III Trial Comparing Myeloablative (MAC) to Reduced Intensity Conditioning (RIC) Prior to Hematopoietic Cell Transplantation (HCT) for Acute Myeloid Leukemia (AML) or Myelodysplasia (MDS) (MAvRIC Trial)	**Oral**	Bart L. Scott
Impact of Genetic Mutations on the Outcomes of Allogeneic Hematopoietic Cell Transplantation in Patients with Acute Myeloid Leukemia with Antecedent Myeloproliferative Neoplasm	**Oral**	Vikas Gupta
Prognostic Impact of Pre-Transplant Chromosomal Aberrations Detected By SNP-Array in Patients Undergoing Unrelated Donor Hematopoietic Cell Transplant for Acute Myeloid Leukemia	**Oral**	Youjin Wang
Title	***Status***	***Presenter***
Development of the Renal Adjusted Hematopoietic Cell Transplant Comorbidity Index (RA-HCT-CI) Using Different Levels of Renal Dysfunction According to Estimated Glomerular Filtration Rate (eGFR)	**Poster**	Nosha Farhadfar
Hematopoietic Cell Transplantation (HCT) Followed By Solid Organ Transplantation (SOT) and SOT Followed By HCT: A Descriptive Analysis of Patients Undergoing Sequential Transplantation in the United States	**Poster**	Meera Gupta
Hematopoietic Cell Transplantation (HCT) Predictions for the Year 2023	**Poster**	Nosha Farhadfar
Acute Graft-Versus-Host Disease Is Less Severe and Associated with Lower Non-Relapse Mortality after Haploidentical Transplantation with Post-Cyclophosphamide Prophylaxis	**Oral**	Rima M. Saliba

A Qualitative Study of State Medicaid Coverage Benefits for Allogeneic Hematopoietic Cell Transplantation (alloHCT) for Patients with Sickle Cell Disease (SCD)	**Oral**	Tatenda G. Mupfudze
Transplant Physicians' Attitudes on Candidacy for Allogeneic Hematopoietic Cell Transplantation (HCT) in Older Patients: The Need for a Standardized Geriatric Assessment (GA) Tool	**Oral**	Asmita Mishra
Evaluation of Tumor Vaccine Generation in a Phase II Multicenter Trial of Single Autologous Hematopoietic Cell Transplant (AutoHCT)Followed By Lenalidomide Maintenance for Multiple Myeloma (MM) with or without Vaccination with Dendritic Cell/ Myeloma Fusions (DC/MM fusion vaccine): Blood and Marrow Transplant Clinical Trials Network (BMT CTN) 1401	**Oral**	David E. Avigan
Transplantation Using Bone Marrow from a (very) HLA Mismatched Unrelated Donor in the Setting of Post-Transplant Cyclophosphamide Is Feasible and Expands Access to Underserved Minorities	**Poster**	Bronwen Shaw
Comparison of Haploidentical Related Donor with Post-Transplant Cyclophosphamide (PTCy) and Umbilical Cord Blood (UCB) Transplantation after Myeloablative Conditioning for Hematological Malignancy	**Poster**	John E. Wagner
Title	***Status***	***Presenter***
Incidence and impact of Non-CMV herpes viral infection in Haploidentical and Matched Sibling Donors receiving Post-transplant Cyclophosphamide (PTCy): A CIBMTR Analysis.	**Poster**	Anurag K. Singh
BMT CTN 1803: Trial to Investigate If Haploidentical Natural Killer Cells (CSTD002) Prevent Post-Transplant Relapse in AML and MDS (NK-REALM)	**Poster**	Sumithira Vasu
Incidence and Impact of Cytomegalovirus Infection in Haploidentical and Matched-Related Donors Receiving Post-Transplant Cyclophosphamide (PTCy): A CIBMTR Analysis	**Oral**	Scott R. Goldsmith
Feasibility of Centralized Electronic Patient-Reported Outcome (ePRO) Collection By an Outcome Registry, a CIBMTR Study of Patients on the Centers for Medicaid & Medicare Coverage with Evidence Development (CMS CED) Myelodysplasia Protocol	**Oral**	Bronwen Shaw

Incidence and Impact of Community Respiratory Viral Infection (CRV) in Haploidentical and Matched Sibling Donors receiving post-transplant Cyclophosphamide (PTCy): A CIBMTR analysis	**Oral**	Randy Taplitz
HLA Genotyping Does Not Predict Outcomes in Hematopoietic Cell Transplantation (alloHCT)	**Oral**	Charlotte Story
Results of Blood and Marrow Transplant Clinical Trials Network Protocol 1101 a Multicenter Phase III Randomized Trial of Transplantation of Double Umbilical Cord Blood Vs. HLA-Haploidentical -Related Bone Marrow for Hematologic Malignancy	**Oral**	Claudio G. Brunstein

Research data collection and systems enhancements

During the grant year, 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 January 2020 to reflect four Cellular Therapy form revisions.
- Began priority work on updating FormsNet to support data capture for COVID-19 and to provide Centers a better customer experience by changing the way follow-up data is collected when there are multiple infusion types.
- Investigations towards more modular (domain-based) data capture, to decrease form burden and increase re-use of modules- is on hold until the fall timeframe given other higher priority items.
- Created and updated tools to enhance efficiencies, including mapping and error handling enhancements to the Infectious Disease Marker (IDM) Upload Tool and the FormsNet Forms Definition Manager (FDM) Mapping Tool.
- Completed successful configuration of FormsNet to manage automated donor reimbursement for the costs of donation and collection, Medical and Associated Expense Solution (MAAES)
- Completed nine Formsnet Forms Definition Manager (FDM) grid conversions from the Telerik to Kendo ahead of Telerik's impending retirement.
- Completed the work to support the Multi-Center reporting/viewing functionality. This functionality, which provides centers the ability to see all forms completed for a patient regardless of which center reported the data, will be released in April. This change has become necessary as patients can receive multiple infusion types (e.g., HCT, CT), at different centers.
- Developed and released the following data collection forms in January 2020:

Form	Form Name	Category
2000R5	Recipient Baseline Data	Revised recipient form
2400R6	Pre-Transplant Essential Data	Revised recipient form
2402R4	Disease Classification	Revised recipient form
2450R5	Post-Transplant Essential Data	Revised recipient form
2004R5	Infectious Disease Markers	Revised recipient form
2005R7	Confirmation of HLA Typing	Revised recipient form
2006R5	Hematopoietic Cellular Transplant (HCT) Infusion	Revised recipient form
2016R4	Plasma Cell Disorders (PCD) Pre-Infusion Data	Revised recipient form
2116R4	Plasma Cell Disorders (PCD) Post-Infusion Data	Revised recipient form
2500R3	Recipient Eligibility Form	Revised recipient form
2542R1	Mogamulizumab Supplemental Data	New study form
4000R6	Cellular Therapy Essential Data Pre-Infusion Form	Revised cellular therapy form
4003R3	Cellular Therapy Product	Revised cellular therapy form
4006R4	Cellular Therapy Infusion	Revised cellular therapy form
4100R5	Cellular Therapy Essential Data Follow-Up Form	Revised cellular therapy form

- FormsNet2 server decommissioning was completed by January 2020.

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
- Investigations and pilots into the acquisition of discrete / structured data elements outside of the forms context; such as acquisition of structured laboratory data from source systems.

- 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:

- Successfully connected OSU Production environment using the CIBMTR Reporting App and began exchanging:
    - Patient demographics
    - CRID assignment
    - GVHD observations
- 3 form revisions have been released for external AGNIS users to test.

Integrated Data Warehouse (IDW) and Unified Data 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
- Incorporated additional metric capture capability into the CIBMTR's Data Quality Dashboard
- Developed a Critical Systems Dashboard to track the status of CIBMTR systems and reports
- Implemented new processes to support CIBMTR's International CPI Processes
- Added additional reporting capabilities to our business intelligence suite to support operational needs
- Enhanced Cord Blood Data Quality Report to include additional Cellular Therapy data

- Business Intelligence Data Sharing- Continue 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. Recent accomplishments include:

  Web Portal (website) Improvement
    - Added Multi-Factor Authentication (MFA) for enhanced security
    - Revamped the look and feel of customer portal pages for a better user experience

  Center Performance Analytics (CPA):
    - Expanded CPA to include many international sites
    - Introduced a new File Archive tab which will present files related to the CPA
    - Added Raw TCSA files to the File Archive converting manual processes into a self-service model for our customers.

  Data For 'Request For Information' (Data for RFI):
    - Data for RFI annual updates are due to be released in April, development, preparation, testing, and validation are ongoing.

  Survival Calculator
    - Annual refresh of Survival Calculator has been completed and published for the users.

Annual refresh of the Center Volumes Data Report has been completed and is ready to be published.

- Unified Domain Model- in 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
    - Loaded cellular therapy data into the data warehouse, and validated 95% of the extract data.
    - Continued mapping of transplant essential data to the physical data model.
    - Continued building infrastructure for enabling data extracts from the unified database and validated with first extract for use in cellular therapy.
    - Completed loading of new and updated FormsNet cellular therapy data tied to Winter 2020 FormsNet revisions.
    - Completed conceptual mapping of Multiple Myeloma forms in anticipation of upcoming contractual obligations.
    - Created project plans for using new data warehouse for upcoming working committee studies and anticipated partnerships with vendors.

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 406 subjects through March. As of March 20, 2020, the study has been placed on a temporary, but indefinite, accrual hold in response to the 2019 COVID-19 public health emergency.

Rapid mobilization and collection of stem cells for HCT will decrease time to transplant and simplify the logistics of product harvest.

- Initiated preliminary discussions to plan a prospective trial to evaluate the safety and efficacy of same day stem cell mobilization using experimental agents. A draft protocol will be developed in the next quarter.