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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 July 13, 2023

Office of Naval Research

And

The National Marrow Donor Program®

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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) which was hosted and completed April 11, 2023.
    - Additional hospitals:
      - Corewell Health (Grand Rapids, MI) - hosted and completed June 4 and June 5, 2023

- University of Wisconsin (Madison, WI) - will be hosted and completed July 26, 2023
- Orlando Health, (Orlando, FL) - will be hosted and completed August 7, 2023
- Temple University (Philadelphia, PA) - will be hosted and completed September 7, 2023

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

- **Hospital radiation disaster preparedness**
  - Additional exercises were to be created and conducted, helping to prepare additional hospitals and hospital coalitions. However, continued IT support for the SharePoint Portal was requested. The Portal was created last fiscal year for an integrated means to collect, review, report and store data related to hospital radiation disaster preparedness.

- **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

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

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

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

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

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

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 23 manuscripts in peer-reviewed journals during the last quarter (see publications below).

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

4. Hamadani M, Gopal AK, Pasquini MC, et al. Allogeneic Transplant and CAR-T Therapy After Autologous Transplant Failure in DLBCL: A Noncomparative Cohort Analysis. Blood Advances. doi:10.1182/bloodadvances.2021005788. Epub 2021 Oct 21. Impact Factor: 6.79

5. Cusatis R, Flynn KE, Vasu S, Pidala J, Muffly L, Uberti J, Tamari R, Mattila D, Mussetter A, Bruzauskas R, Chen M, Leckrone E, Myers J, Mau L-W, Rizzo JD, Saber W, Horowitz M, Lee SJ, Burns LJ, Shaw B. Adding centralized electronic patient-reported outcome data collection to an established international clinical outcomes registry. Transplantation and Cellular Therapy. 2022 Feb 1; 28(2):112.e1-112.e9. doi:10.1016/j.jtct.2021.10.016. Epub 2021 Oct 29. PMC8915447. Impact Factor: 5.60

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

7. Fuchs EJ, McCurdy SR, Solomon SR, et al. HLA informs risk predictions after haploidentical stem cell transplantation with post-transplantation cyclophosphamide. Blood. doi:10.1182/blood.2021013443. Epub 2021 Nov 1. Impact Factor: 22.11

8. Zou J, Wang T, He M, Bolon YT, et al. Number of HLA mismatched eplets is not associated with major outcomes in haploidentical transplantation with post-transplantation cyclophosphamide: A Center for International Blood and Marrow Transplant Research Study. Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2021.11.001. Epub 2021 Nov 11. Impact Factor: 5.60

9. O' Donnell PV, Brunstein CG, Fuchs EJ, et al. Umbilical cord blood or HLA-haploidentical transplantation: Real world outcomes vs randomized trial outcomes. Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2021.11.002. Epub 2021 Nov 11. Impact Factor: 5.60

10. Sidana S, Kumar S, Fraser R, et al. Impact of induction therapy with VRD vs. VCD on outcomes in patients with multiple myeloma in partial response or better undergoing upfront autologous stem cell transplantation. Transplantation and Cellular Therapy. doi:DOI: 10.1016/j.jtct.2021.10.022. Epub 2021 Nov 12. Impact Factor: 5.60

11. Martin PJ, Levine DM, Storer BE, Zheng X, Jain D, Heavner B, Norris BM, Geraghty DE, Spellman SR, Sather CL, Wu F, Hansen JA. A model of minor histocompatibility antigens in allogeneic hematopoietic cell transplantation. Frontiers in Immunology. 12:782152. doi:10.3389/fimmu.2021.782152. Epub 2021 Nov 18. PMC8636906. Impact Factor: 6.42

12. Tan CR, Estrada-Merly N, Landau H, et al. A second autologous hematopoietic cell transplantation is a safe and effective salvage therapy in select relapsed or refractory AL amyloidosis patients. Bone Marrow Transplantation. doi:10.1038/s41409-021-01527-z. Epub 2021 Nov 20. Impact Factor: 5.48

13. Meyers G, Hamadani M, Martens MJ, et al. Lessons learned from early closure of a clinical trial for steroid-refractory acute GVHD Bone Marrow Transplantation. doi:10.1038/s41409-021-01529-x. Epub 2021 Nov 23. Impact Factor: 5.48

14. Luznik L, Pasquini M, Logan B, et al. Randomized Phase III BMT CTN Trial of Calcineurin Inhibitor-Free Chronic Graft-Versus-Host Disease Interventions in Myeloablative Hematopoietic Cell Transplantation for Hematologic Malignancies. Journal of Clinical Oncology. doi:10.1200/JCO.21.02293. Epub 2021 Dec 2. Impact Factor: 44.54

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16. Epperla N, Hamadani M. Double-refractory Hodgkin lymphoma: tackling relapse after brentuximab vedotin and checkpoint inhibitors. Hematology / the Education Program of the American Society of Hematology. 2021 Dec 10; 2021(1):247-253. doi:10.1182/hematology.2021000256. Epub 2021 Dec 10. Impact Factor: 3.06

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18. Iqbal M, Savani BN, Hamadani M. New indications and platforms for CAR-T therapy in lymphomas beyond DLBCL. EJHaem. 2022 Jan 1; 3(Suppl 1):11-23. doi:10.1002/jha2.323. Epub 2022 Jan 1. Impact Factor: 2.99

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22. Kim S, Kim J-K, Ahn KW. A calibrated Bayesian method for the stratified proportional hazards model with missing covariates. Lifetime Data Analysis. doi:10.1007/s10985-021-09542-4. Epub 2022 Jan 16. Impact Factor: 1.58

23. Murthy HS, Ahn KW, Estrada-Merly N, et al. Outcomes of allogeneic hematopoietic cell transplantation in T-cell prolymphocytic leukemia: a contemporary analysis from the Center for International Blood and Marrow Transplant Research. Transplantation and Cellular Therapy. 2022 Feb 8; 6(3):920-930. doi:10.1016/j.jtct.2022.01.017. Epub 2022 Jan 23. Impact Factor: 5.60

24. Hu Z-H, Wang H-L, Gale RP, et al. Correction to: A SAS macro for estimating direct adjusted survival functions for time-to-event data with or without left truncation. Bone Marrow Transplantation. doi:10.1038/s41409-021-01533-1. Epub 2022 Feb 1. Impact Factor: 5.48

25. Savani M, Ahn KW, Chen Y, et al. Impact of conditioning regimen intensity on the outcomes of peripheral T-cell lymphoma, anaplastic large cell lymphoma and angioimmunoblastic T-cell lymphoma patients undergoing allogeneic transplant. British Journal of Haematology. doi:10.1111/bjh.18052. Epub 2022 Feb 2. Impact Factor: 6.99

26. Mei M, Hamadani M, Ahn KW, et al. Autologous hematopoietic cell transplantation in diffuse large B-cell limphoma after 3 or more lines of prior therapy: evidence of durable benefit. Haematologica. doi:10.3324/haematol.2021.279999. Epub 2022 Feb 3. Impact Factor: 9.94

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Results of the BMT CTN 1302 Trial Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2022.07.007. Epub 2022 Jul 12. Impact Factor: 5.60

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