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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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Grant Award N00014-21-1-2954

DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY RESEARCH PERFORMANCE REPORT

SUBMITTED July 14, 2022

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:**
    - RITN Biennial (FY2022) Workshop "Past Informing the Present, Past Improving the Plan for a Rad/Nuc Incident" is (1) Targeted towards physicians and other healthcare providers, support staff, hospital and hospital system administrators, emergency managers, research scientists, and appropriate federal agency staff that would be involved in radiation response and treatment of patients with radiation-induced bone marrow injury; and (2) Will (a) highlight recent developments in Covid pandemic response and applicable lessons we have learned, (b) review and disseminate novel radiation countermeasures and dosimetry, (c) discuss optimizing triage and on the ground federal resources, (d) present strategies to ensure the availability and appropriate use of medical and psycho-social supportive care and resilience, and (e) explore applying telemedicine as a force multiplier for care and education.

        - Planning Committee continued to meet monthly to plan for August 4-5, 2022.
        - The call for abstracts closed after the extended deadline for submission on May 1, 2022. A total of 24 were received and accepted for presentation at the meeting.

        - General participant registration began May 2, 2022.
        - Committee members represent RITN hospitals: Dana Farber Cancer Institute, Duke University, Mayo Clinic Rochester, North Shore University Hospital, and the University of Iowa; as well as federal partners: The Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).

    - Emergency Management of Radiation Victims 1-day course (1) Has an intended audience of physicians, physician multipliers, nursing staff, administrators and coordinators from departments such as bone marrow transplant, hematology, oncology, radiation safety, nuclear medicine, and the emergency department, as well as emergency management, and first responders; and (2) Will discuss the fundamentals of radiation physics, radiation detection/measurement/identification, prevention of the spread of contamination, how to minimize radiation dose to victims and providers, and the role of medical/health physicists in caring for contaminated victims with instruction provided by the Radiation Emergency Assistance Center/Training Site (REAC/TS).
        - Due to other commitments and staffing issues, this 1-day course has been canceled.
        - Date and location for YR2023 are currently being considered.

    - Advanced HAZMAT Life Support (AHLS) for Radiological Incidents & Terrorism 4-hour course (1) Has a target audience of physicians, physician multipliers, nursing staff, administrators and coordinators from departments such as bone marrow transplant, hematology, oncology, radiation safety, nuclear medicine, and the emergency department, as well as emergency management, and first responders; and (2) Will include interactive lectures and tabletop exercises that trains healthcare professionals to evaluate and care for irradiated and radiologically contaminated patients.
        - One, half-day course has a confirmed scheduled date for the afternoon of Wednesday, August 3 (day before biennial RITN Workshop) at the Westin Alexandria Old Town.
        - Two, half-day courses are scheduled for July 20, 2022. The Region 9 Healthcare Coalition (Chicago) will be hosting in Elgin, IL.

- **Radiation disaster preparedness training:**
    - No updates at this time.

- **Hospital radiation disaster preparedness:**
    - Annual disaster readiness tabletop exercises (drills) have been scheduled for current RITN centers to participate for their annual task completion. Six dates are offered between June and August 2022 to ensure as much participation as possible from centers.
    - Additional disaster readiness exercises (drills) have resumed pre-COVID scheduling. Yet to be scheduled: one Full-scale exercise, two Functional exercises, and three Regional Tabletop exercises.
    - Work underway to assist Nebraska Medicine in streamlining the interactions they have with national specialty organizations such as RITN as well as potentially supporting them in their regional exercise (drill).

- **Hospital network growth:**
    - To ensure the appropriate growth in a direction that supports the vision and needs of the Department of Defense-Office of Naval Research as well as the Department of Health and

Human Services Assistant Secretary for Preparedness and Response plans for response to a radiological/nuclear disaster with-in the continental U.S.

- Orlando Health (Orlando, FL) joined in January of 2022.
- Due to continued staffing issues and logistic complications at hospitals due to COVID and its response, it is unlikely more new centers will join before the end of the FY2022 period.

- **Federal partnership development:**
  - Support the Gryphon Scientific's Center for Disease Control (CDC) funded project as a subcontractor to assess United States laboratory capabilities for ionizing radiation related testing.
    - Analysis has continued and the complete data is available for workgroup members.
    - RITN connected Gryphon Scientific with Spectrum Health, a RITN center. The purpose was to discuss with Spectrum about the laboratory testing component of a rad incident response to help Gryphon analyze the data in the context of a radiological incident.

- **Other projects:**
  - RITN Automated Tracking System project seeks to develop an integrated means to collect, review, report and store data related to the activity and annual task deliverables of the hospitals that are part of its' network. This system should automate where feasible all steps that are currently manually accomplished. Users of this system range from staff at RITN headquarters to staff at each individual RITN center across the United States.
    - Currently in discovery phase of project.
      - RITN and vendor meetings to give current state of tracking system.
      - Vendor finalizing mock-up system for review.
    - Scheduled completion – July 2022.

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 70,699 newly registered volunteer donors were HLA typed and added to the Be The Match Registry.

Modeling and analysis of registry coverage for the Warfighter

In the last quarter, analysis to better understand the contribution of racially and ethnically diverse donors for matching in diverse groups was performed and validated through simulations of donor registry searches

with patient-donor HLA match criteria. Population genetics-based registry models projected donor coverage for warfighters as potential patients approaches but does not reach 100% when considering HLA match levels down to 5 of 8 matching alleles.

To validate the HLA match likelihoods, we compared the results calculated using the population-based genetic model and search simulation. For both methods, 5/8-8/8 HLA match likelihoods for donors of any age, the difference in HLA match likelihood results between the population-based genetic model and search simulation ranges from 2.2-7.6% at the 8/8 HLA match level. In the meantime, the results differ by 1.2-9.1% for 8/8 HLA match likelihoods including a DPB1 TCE match/permissive mismatch. Results of the modeling were presented as a poster abstract presentation at the 2022 Tandem meeting in April. This modeling aids in preparation for coverage of potential donor sources to warfighters of diverse race and ethnic backgrounds in case of radiation emergencies.

Development of science and technology for rapid communication of HLA data

This quarter, hackathons were held during the 18th International HLA and Immunogenetics workshop. These collaborative hands-on working sessions brought researchers and developers from around the world together to discuss and implement standards and services for handling HLA and other immunogenetic data. HLA and other immunogenetic data was communicated from laboratories in HML (Histoimmunogenetics Markup Language) format, from research and inventory reference files, or from transplant center facing user interfaces. This data is then parsed and compared against existing reference data or assigned/translated to further feature annotation in order to provide rapid handling and communication of HLA data across datasets for downstream use.

Further validation and computational efficiencies were introduced in the last quarter for data in higher volumes in addition to the added features associated with version control so that entries could be uniquely identified and cross-referenced. An initial aggregate matching tool is planned for launch in the next quarter. This workflow allows for rapid communication of HLA data to promote both research studies that rely on HLA information and the operational matching of patients and donors.

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

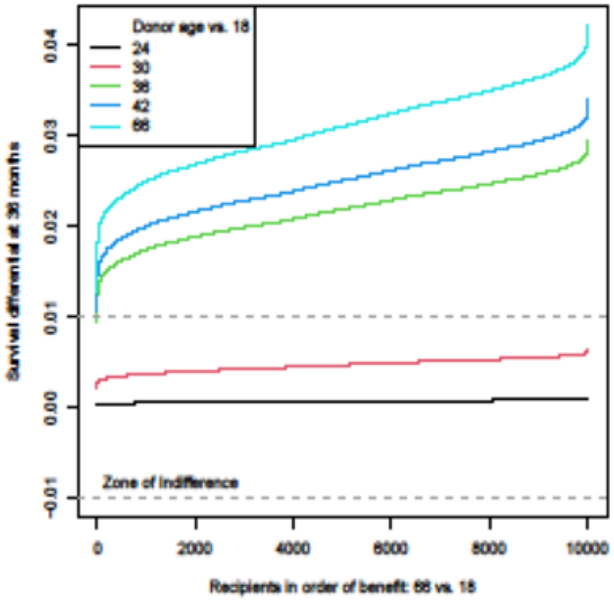
Machine learning models for censored time-to-event and multiple competing risk statistical and machine learning models were explored for prediction of event-free survival after allogeneic stem cell transplant. Event-free survival is defined as survival where the patient does not experience any significant adverse events including graft rejection, moderate or severe chronic graft versus host disease, or relapse. Our objectives are to develop methods for optimizing donor selection to improve overall survival (OS) and event-free survival (EFS) and quantify the potential benefit in patient outcomes from doing such donor optimization.

To optimize donor selection, we first needed to build a flexible prediction model that could be used to predict patient specific outcomes over a range of potential donors, while also quantifying the uncertainty in such predictions. Since there were limited methods available to serve this purpose, we first developed a novel Bayesian machine learning model called Nonparametric Failure Time Bayesian Additive Regression Trees (NFT BART), which can flexibly handle complex time to event survival outcomes and provide prediction uncertainty measures. A manuscript describing this novel biostatistical approach was submitted

to a top five biostatistics journal known as Biometrics; the manuscript was invited for a revision and resubmission, and a revised draft is in process. Next, we built prediction models for OS and EFS as a function of patient, disease, transplant, and donor characteristics, using this NFT BART model applied to a cohort of all 8/8 matched unrelated donor transplants between 2016 and 2019. These models allow for patient specific predictions for any potential donor. After examining the variable importance of each donor characteristic, we identified that donor age and donor gender are the only variables with a measurable impact on OS or EFS outcomes.

A summary of the patient specific impact of donor age on overall survival at three years is shown in the following waterfall plot, where the *x* axis denotes each individual patient in the dataset (sorted by donor age), and the *y* axis shows the predicted difference in two-year survival for each of several donor ages relative to an 18 year-old donor. Future work will apply this model to a pool of potential donors for patients extracted from the NMDP donor search archive, to examine the achievable benefit from optimizing the donor selection over donor age and gender.

Figure 1: Patient-specific impact of donor age on Overall patient survival at three years.



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

The NMDP/CIBMTR maintains a research repository of peripheral blood samples from transplant donors (pre-donation) and recipients (pre-transplant). These samples are routinely genotyped through the ongoing Donor/Recipient Pair project to ensure sample identity and enhance the immunogenetic data available for histocompatibility research. This sample inventory and upgraded data are critical for expanding and optimizing research scenarios for evaluation of the role of HLA and other immunogenetic factors in HCT.

Last quarter, the Immunobiology Project Research data was successfully migrated from a legacy database (Sybase) to the new test results storage location (Core database) where it will benefit from built-in validation and supported data storage and retrieval methods. Query tools were also migrated to Microsoft SQL Server. Finally, the audit of related sample group typings (486 pairs of patients and related donor typings) was completed.

Transplantation practices are constantly evolving, and the DRPP will continue enroll the most recent related and unrelated transplant pairs to ensure that changes in practice can be evaluated using quality-controlled high resolution HLA data. Strategic selection of pairs for testing and optimization of practices associated with data storage and management will be conducted in next quarter to ensure that investigators have timely access to robust, high-quality data to analyze the impact of matching as either the focus of or as a variable in NMDP/CIBMTR-approved research studies.

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.

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 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 plans to launch 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, 15 centers have committed to participate in the study and combined plan to enroll >250 patients per year. Four of 15 sites have received local IRB approval for the protocol with 4 additional sites currently under review. All sites have initiated submission of regulatory documents required for participation. The protocol team held an investigator meeting with the site principal investigators at the annual Tandem meeting in Salt Lake City on April 26. Site initiation visits are currently being scheduled with several planned for early next quarter. The study is expected to open for enrollment in August 2022.

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 this grant 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.

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 accrual continued for U.S. based donors. A total of 165 product samples were received and tested through June 30, 2022. Testing costs are covered under a previous year grant while staff support is funded under this grant. The DKMS laboratory continued efforts to establish the standardized immunophenotyping panel for testing of Germany based donors. The study team met several times to finalize plans for concordance testing between the U.S. and DKMS laboratories. Concordance testing using known controls supplied by the NMDP testing laboratory will be performed in the next quarter. Accrual of German donors has begun on a limited basis and will be expanded following successful completion of the concordance evaluation to ensure that data is being consistency captured in both the U.S. and German laboratories. Testing of German donors will be fully funded by DKMS.

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

With pre-transplant whole genome sequencing results from a cohort of 494 patients with MDS and their respective donors, we sought to identify the contribution of genomic factors beyond HLA to the prediction of overall survival outcomes following allogeneic HCT. Previously we identified a number of genomic factors that correlated well with transplant overall survival outcomes in this cohort and used random survival forest modeling to build prediction models first with the foundation of the known revised international prognostic scoring system data (base model) on these patients. After adding other known clinical patient data (clinical model = base model + MDS type, hypomethylating agent treatment, chemo data) and then adding previously selected genomic candidates, we were able to obtain a striking increase of almost 0.2 in the concordance index for prediction of overall survival in patients with MDS.

This quarter, further analyses were conducted on a more a comprehensive set of genomic variants. When these additional variants were combined with the previously identified genomic candidates and evaluated the machine-learning prediction models produced an even higher concordance (~0.8) for prediction of overall survival in patients with MDS. Further datasets will be needed to validate these findings. These preliminary results show promise for the evaluation of the contribution of genomic features to transplant outcomes for patients with MDS. A manuscript that focuses on the characterization of mortality risk in patients with MDS including identification of biomarker candidates, pattern cluster analysis, and prediction model building for transplant outcomes with genomic data over baseline clinical information was submitted to the Journal of Clinical Oncology. Additional planned analyses include the characterization of donor genome contributions and further development of a structural variant pipeline. These efforts support the analysis and discovery of additional factors that play a role in patient transplant outcomes.

D. Clinical Research in Transplantation

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

Observational Research

- Published 20 manuscripts in peer-reviewed journals during the last quarter (see publications below).
- A total of 23 abstracts were presented at the 2022 BMT Tandem Annual Meeting originally scheduled to be held Feb. 2-6 in Salt Lake City, UT. The meeting was recently postponed and rescheduled for April 23-26 due to current pandemic surge. Presentation titles and type are detailed in the table below. Abstracts were published in a supplemental issue of the Transplantation and Cellular Therapy Journal.
- A total of 384 proposals were received for consideration within the 15 CIBMTR Working Committee meetings to be held at the 2022 annual Tandem BMT Meeting. A total of 92 were accepted for presentation in the various working committee meetings. A total of 20 proposals were selected for activation in the 2022-2023 academic year (July 1, 2022-June 30, 2023). All proponents were informed of the decisions about proposal acceptance and/or rejection during the past quarter. Work will begin on the newly approved proposals during the next quarter.

Table 1: CIBMTR presentations at 2022 BMT Tandem Annual Meeting – presentation dates/times pending revised schedule for postponed meeting.

Title	Status
Outcomes of Allogeneic Hematopoietic Cell Transplantation in Blastic Plasmacytoid Dendritic Cell Neoplasm: A CIBMTR Analysis	Poster
A Pilot Study Exploring the Link between Donor-Engrafted Clonal Hematopoiesis and Outcomes of Allogeneic Hematopoietic Cell Transplantation from Older Matched Sibling Donors	Poster
Improved Overall Survival of Patients Treated with Abatacept in Combination with a Calcineurin Inhibitor and Methotrexate Following Allogeneic Hematopoietic Stem Cell Transplantation: Analysis of the Center for International Blood and Marrow Transplant Research Database	Poster

Title	Status
Effect of Autograft CD34 + Dose on Outcome in Pediatric Patients Undergoing Autologous Hematopoietic Stem Cell Transplant for Central Nervous System Tumors.	Poster
Impact of CD34+ Cell Dose on Outcome Among Children Undergoing Autologous Hematopoietic Stem Cell Transplant for High-Risk Neuroblastomas.	Poster
Single HLA Class I Mismatches with High Peptide Divergence in the Graft-Versus-Host Direction Are Associated with Inferior Survival after 9/10 HLA-Matched UD-HCT: A Retrospective Study from the CIBMTR	Poster
Return to School Practices after Hematopoietic Cell Transplantation: A Survey of Transplant Centers in the United States	Poster
What Do Patients Think about Palliative Care? A National Survey of Hematopoietic Stem Cell Transplant Recipients	Poster
Enhancing Administrative Claims Data to Identify and Address Barriers to Treatment: NMDP Search and CMS Medicare Claims Merged Dataset	Poster
Humoral Immunogenicity of Sars-Cov-2 Vaccination in the First Year after Hematopoietic Cell Transplant or Chimeric Antigen Receptor T Cell Therapy: A CIBMTR and BMT CTN Study	Poster
The Use of Search Summary Score Tool for Rapid Unrelated Bone Marrow Search Assessment	Poster
A Tool to Assess Functional HLA-DPB1 Variation in Transplantation	Poster
Unrelated Donor Registry HLA Match Likelihoods in the Mismatched Setting	Poster
A report from the National Marrow Donor Program: Neither COVID-19, nor cryopreservation, prevented allogeneic product infusion.	Poster
Impact of Bortezomib-Based Vs. Lenalidomide Maintenance Therapy on Outcomes of Patients with High-Risk Multiple Myeloma	Oral
A refined model of HLA-DP permissiveness improves stratification of acute graft-versus-host disease risks after unrelated hematopoietic cell transplantation: a retrospective study from the CIBMTR	Oral

Title	Status
Mutation Analysis in Patients with High-Risk Myelodysplastic Syndrome Receiving Allogeneic Hematopoietic Cell Transplantation Based on Biological Donor Availability: Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Study 1102.	Oral
Trends in Late Mortality Amongst Two-Year Survivors of Pediatric and Young Adult Allogeneic Hematopoietic Cell Transplantation for Acute Leukemias: On Behalf of the CIBMTR Late Effects Working Committee	Oral
Chimeric Antigen Receptor t-Cell (CAR-T) Therapy Recipients and Worsening Financial Impact over Time: A Mixed Methods Longitudinal Study	Oral
Impact of Donor Socioeconomic Status on Recipient Outcomes Following Hematopoietic Cell Transplantation	Oral
Racial and Ethnic Diversity on Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Trials – We Can Do Better.	Oral
Haploidentical Versus Matched Unrelated Donor Transplants for Lymphomas Using Post-Transplant Cyclophosphamide: A Joint CIBMTR/EBMT Study	Oral
Cryopreservation of Allogeneic Hematopoietic Cell Grafts Did Not Adversely Impact Early Post-Transplant Survival during the First Six Months of the COVID-19 Pandemic	Oral

Research data collection and systems enhancements

During the past quarter, CIBMTR has continued support for electronic data submission initiatives, production FormsNet Recipient, FormsNet Donor, and AGNIS customers, as well as Data Warehouse users. Progress has been made on the following critical projects to upgrade our technology supporting the program:

Simplify Data Acquisition
To acquire timely, high quality, data with less administrative burden to current and new partners/patients.

FormsNet (FN3)
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:

- Five new cellular therapy reporting tracks with a planned July release. Tracks will incorporate center reporting preferences and research consent to determine whether follow up will be requested, and how often, for non-DLI cellular therapy infusions.
- Added collection fields within FN3 for supporting Data Transformation Initiative, with a planned July release
- Enhancements for external users: 1) Ability for users to reset forms that are in LTF (Lost to Follow-up) or SUR (Survival) status, planned for July release

- New internal tool User Interface (UI) features to support reprocessing multiple forms at a single time, with a planned July release.

- FormsNet3 Forms Definition Manager (FDM): Completed several proactive security vulnerability updates revealed by new scans

- FDM/AGNIS Mapping Tool:
    - Configured tool to connect to new Cancer Data Standards Registry and Repository (caDSR) API
- FormsNet3 Donor:
    - Enhanced Infectious Disease Marker (IDM) functionality to parse Multiple Recipient IDs (RID)
    - Removed Donor E-Signature to support organizational goal of LDAP retirement
- Audit Tool:
    - Retired LDAP dependence for Audit Tool
    - Made 13 forms auditable in tool; updated logic so new forms default to "auditable"
- Audit Migration to Formsnet3:
    - Created Question Tree functionality in FN3 to reduce manual work, increase data quality, reporting capabilities, and configurability for the future
- Developed and released the following data collection forms in April 2022.

Form	Form Name	Category
2058R1	Thalassemia Pre-Infusion Data	New form
2158R1	Thalassemia Post-Infusion Data	New form

Electronic data submission/AGNIS
CIBMTR continued support for electronic data submission initiatives and production AGNIS customers. Effort focused on support for CIBMTR form revision updates to existing forms. The team has developed and enhanced implementations to lower AGNIS submission burdens and increase AGNIS customer satisfaction by:

- Completed additional steps to reuse existing AGNIS modules when supporting form revisions and other Forms Builder reports enhancements
- Enhanced AGNIS reports (e.g., 9000) to help support external users when they are testing new AGNIS forms.
- Recent AGNIS and other electronic data submission accomplishments:
- The AGNIS team continues to release forms for centers to use in data submission to the CIBMTR as well as address questions or issues raised by centers and their vendors.
- Two AGNIS forms were released to production:
    - 2402r6 Pre-TED Disease Classification
    - 2400r8 Pre-Transplant Essential Data

Automated data exchange using electronic data collection systems that interface directly with source health and laboratory records
CIBMTR has continued to update its reporting application to exchange additional discrete electronic data records. Using the data extracted directly from data collection systems at partner centers, CIBMTR successfully expanded capabilities to populate additional laboratory data points on 26 forms at both pre-

infusion and post-infusion time points. These added capabilities provide partner transplant centers with improved time savings and eliminate the potential of manual data entry errors. Enhancements to the CIBMTR Reporting app have been made to harness updates to data interoperability standards. These updates provide the ability to expand the data types to be exchanged via the Reporting app.

Simplify Data Analysis
Collect & analyze more data more frequently without increasing the burden on centers.

Integrated Data Warehouse (IDW)
CIBMTR continued to increase the capabilities of the IDW, which is the Operational Data Warehouse utilized for delivery of key data to stakeholders. Accomplishments include:

- Incorporated ongoing forms revisions into the warehouse
- Continued enhancing processes to support CIBMTR's Domestic and International CPI Processes.
- Continued enhancing study information and visualizations to support our Prospective Research team.
- Began review of requirements for 2022 Center Volumes Data Reporting project.
- Provided ePRO data for use in Data Back to Centers (DBtC) dashboard.

Unified Domain Model (UDM)
Continuing the 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.

- Continued transitioning HCT data from the Research Database to the Unified Domain Model (UDM) including delivery of 17 new data extracts directly from UDM and initial development of a relapse-specific data domain.
- Continued delivery of monthly and quarterly CAR T-cell data sets to our Japan (JDCHCT) and pharmaceutical partners.
- Continued refinement and delivery of Periodic Safety Update Reports (PSUR) for two CAR T-cell therapies.
- Provided quarterly Stem Cell Therapeutic Outcomes Data required for the HRSA SCTOD quarterly report.
- Completed development and delivery of the Center Specific Analysis data extract, making it available directly from UDM. The extract includes incorporation of COVID infection data
- Completed mapping of newly created Thalassemia forms and all high-prioritized disease forms
- Continued development of adding human leukocyte antigen data (HLA) data to the UDM

Enhance Data Sharing and Visualization
Deliver data visualization and analytic tools that will enable stakeholders to more efficiently interact with data to identify relevant trends and patterns.

- Enhanced the Data Back to Centers (DBtC) dashboard and Data Back to Centers Download (DBtC-Download) to leverage the extracts produced from UDM and the HCT Centralization project
- Created additional reports in new Business Intelligence tool, Looker, to support CIBMTR Prospective Research team needs. Enhanced Business Intelligence reports to support ePRO Data Quality efforts.

- Business Intelligence Data Sharing- Continued 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.
- This quarter, CIBMTR has released a version of the HLA Save extract. This extract has been developed on CIBMTR's new UDM data platform. This delivery has dramatically transformed the production of this important data set. The HLA Save extract contains the best match grade information (HLA typing and computed match grade scores) for every transplant known to the CIBMTR. This includes all NMDP facilitated transplants, non-NMDP facilitated un-related transplants, related transplant and autologous transplants. The extract for this quarter contains ~174,000 cases from 1999 to 2022, and the technical changes that have occurred have reduced the preparation time from 3-4 weeks down to less than one day. In the past, the process involved 7-8 people performing tasks, and the new process needs only a single person to do the technical work, and a single person to check the automated QA results. Our new platform will allow for new service integrations, new match grade computations, and much better integration with patient outcomes.

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.