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14. ABSTRACT <p><u>1. Contingency Preparedness:</u> 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.</p> <p><u>2. Rapid Identification of Matched Donors:</u> Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.</p> <p><u>3. Immunogenic Studies:</u> Increase understanding of the immunologic factors important in HSC transplantation.</p> <p><u>4. Clinical Research in Transplantation:</u> Create a platform that facilitates multicenter collaboration and data management.</p>					
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DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS
FINAL REPORT
SUBMITTED JANUARY 26, 2022

Office of Naval Research

And

The National Marrow Donor Program®

500 5th St N

Minneapolis, MN 55401

I. Heading

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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 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. 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.

RITN continued to develop the preparedness of its network of hospitals through the following activities:

- One new transplant center joined RITN: Baylor University Medical Center, Dallas, TX.
- Co-hosted the Radiation Track at the National Association of County and City Health Officials (NACCHO) annual Preparedness Summit. We were joined by the Department of Energy's Radiation Emergency Assistance Center and Training Site (REAC/TS) and the Advanced Hazmat Life Support organization in this venture to ensure radiation continues to be part of the education agenda.

- Completed development of the RITN Acute Radiation Syndrome (ARS) Cytokine Administration Triage guidelines and shipped hard copies of poster versions and pocket cards to all RITN hospitals as well as to RITN partner organizations.
- Finalized the RITN training videos and posted on the RITN website and the [RITN YouTube Channel](#) for access globally:
 - Decontamination and Care for Radiation Disaster Patients
 - Updated: Introduction to RITN
- Initiated and continued collaboration for the Department of Defense through the Uniformed Services University with the American Burn Association to assist with updating combined injury (Burn and acute radiation syndrome) treatment guidelines for use in the forward operations setting.
- Completed the creation of adult and pediatric medical orders in the Epic Electronic Medical Record System, which is scheduled to be deployed worldwide in February 2021
- 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.

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 142,179 newly registered volunteer donors between October 1, 2019 and September 30, 2021.

Modeling and analysis of registry coverage for the Warfighter

Due to potential radiation emergencies that the Warfighter may encounter, it is important to model and analyze the potential to provide warfighters with cellular therapy. In this work we created synthetic HLA haplotype frequencies based on known racial/ethnic groups of warfighters from 2017 published demographics. Then we prepare for calculation of the likelihood of finding a potential donor in the Be The Match Registry for known warfighter demographic distributions. To examine potential emergency scenarios, we created synthetic multilocus unphased genotypes (MUGs) from the warfighter HLA haplotype frequencies to identify gaps in likelihood of potential donors available for warfighter treatment.

Warfighter Study Population

We considered the population of 2,103,415 individuals in the military force reported in a 2017 demographic profile of US warfighters. There are six race groups of the warfighter- White, Native Hawaiian/Pacific Islander, Black/African American, Asian, American Indian/Alaska, and Hispanic. The number of individuals of each race group is listed in Table 1.

Note that there are 73,691 individuals in the military force reported as other/unknown race, so we did not take into account these individuals in the modeling and analysis. We also considered five age groups: 25 years or younger, 26 to 30 years, 31 to 35 years, 36 to 40 years, and 41 years or older. The percentages of the warfighter population that are in these age groups are 40.3, 20.6, 15.5, 11.0, and 12.6, respectively. As the age distribution for the individual racial/ethnic groups in the warfighter community are unspecified, we used these percentages to generate population subsets for each age group, as shown in Table 2.

Table 1. Race of the military force

Race Group	Population
White	1,487,237
Native Hawaiian/Pacific Islander	19,990
Black or African American	356,870
Asian	91,943
American Indian or Alaska	21,526
Hispanic	294,003

Table 2. Age group and population distribution of the military force

Race Group	Y25L	Y26-30	Y31-35	Y36-40	Y41G
White	599,356	306,371	230,522	163,596	187,392
Native Hawaiian/Pacific Islander	8,056	4,118	3,098	2,199	2,519
Black or African American	143,818	73,515	55,315	39,256	44,966
Asian	37,053	18,940	14,251	10,114	11,585
American Indian or Alaska	8,675	4,434	3,337	2,368	2,712
Hispanic	118,483	60,565	45,571	32,340	37,044

Be The Match Registry

According to final inventory and adult donor models in 2017, National Marrow Donor Program® (NMDP) /Be The Match maintains a registry of 18,267,161 adult donor registrants as of December 31, 2016. We considered HLA haplotype frequencies of 8 U.S. racial and ethnic groups to generate synthetic haplotype frequencies for the warfighter population.

HLA Match Definitions

We consider an HLA-matching model with high-resolution matching at HLA-A, HLA-B, HLA-C, and HLA-DRB1. We have 8/8 HLA matching when we have matches at all of these loci and we consider a single-allele mismatch at any of these loci in case of 7/8 HLA matching.

Estimating Match Rates for the Donor Race Categories

Before we estimated the match rates of the warfighter, we calculated the match rates of the 21 donor populations. Table 3 lists the detailed race groups of the 21 donor populations.

Table 3. Detailed race groups of Be The Match Registry

Race code	Detailed race/ethnic description
AAFA	African American
AFB	African
AINDI	South Asian Indian
AISC	American Indian – South or Central Am.
ALANAM	Alaska native or Aleut
AMIND	North American Indian
CARB	Caribbean Black
CARHIS	Caribbean Hispanic
CARIBI	Caribbean Indian
EURCAU	European Caucasian
FILII	Filipino
HAWI	Hawaiian or Other Pacific Islander
JAPI	Japanese
KORI	Korean
MENAF	Middle Eastern or N. Coast of Africa
Race code	Detailed race/ethnic description

MSWHIS	Mexican or Chicago
NCHI	Chinese
SCAHIS	Hispanic – South or Central American
SCAMB	Black – South or Central American
SCSEAI	Southeast Asian
VIET	Vietnamese

Estimating Match Rates for the Warfighter Race Categories

To estimate the match rates for the warfighter population, we mapped known warfighter race and ethnic groups back to BTM Registry race codes. Table 4 lists the Be The Match donor registry race groups used to create haplotype frequencies of the warfighters.

Table 4. Race groups of Be The Match Registry used to create race groups of the warfighters.

Warfighter Racial/Ethnic Group	Be The Match Registry Race code
White	MENAF + NAMER (EURCAU)
Native Hawaiian/Pacific Islander	HAWI
Black or African American	AAFA + AFB + CARB + SCAMB
Asian	AINDI + FILII + JAPI + KORI + NCHI + SCSEAI + VIET
American Indian or Alaska	AISC + ALANAM + AMIND + CARIBI
Hispanic	CARHIS + MSWHIS + SCAHIS

Adult-donor Match Likelihood for 21 donor populations

Table 5 lists the 8/8 and 7/8 match rates for the 21 donor populations. The highest and lowest match rates were found for European Caucasian and African, respectively.

Table 5. Match rates of the 21 donor populations

Race code	8/8 Match (%)	7/8 Match (%)
AAFA	22	74
AFB	18	71
AINDI	37	87
AISC	52	88
ALANAM	57	89
AMIND	62	95
CARB	21	74
CARHIS	50	91
CARIBI	41	85
FILII	48	89
HAWI	37	81
JAPI	44	89
KORI	43	88
MENAFB	52	92
MSWHIS	49	90
NAMER (EURCAU)	79	99
NCHI	45	88
SCAHIS	40	85
SCAMB	40	81
SCSEAI	32	80
VIET	48	86
AAFA	22	74

Here we identified the likelihood of finding an unrelated donor on the Be The Match registry to provide an estimate for providing cellular therapy to warfighters in the event of radiation exposure. We also identified gaps in warfighter population coverage that will assist in targeted future recruitment efforts to address deficiencies. There are some limitations of this work, and we have room for improvement. To model and analyze registry coverage, we assumed 100% adult donor availability. Availability is the percentage of donors that will agree to donate if they are a match. Sometimes donors refuse or are unable to donate despite

being a match, and this availability rate varies by population. In future we will regenerate match rates while taking into account the actual percentage of donor availability. Currently, we do not have actual HLA data and age-specific population distributions for the warfighter population. However, we can refresh this calculation upon obtaining any new HLA frequencies and actual population distributions for warfighters. We also plan to revamp our methods to redefine and re-estimate match rates, including consideration for greater mismatches and improved population detail to revisit assumptions.

Development of science and technology for rapid communication of HLA data

A virtual Data Standards Hackathon was held April 23-25, 2020. This was a global event over 48-hours. 52 people asked to be part of it, nine from NMDP, 29 from academia, registries or health organizations, and 14 from companies. Exactly half the attendees were attending their first DaSH. There were people in eight time zones, with a 16-hour spread. We used slack, GitHub and video conferencing to collaborate.

All respondents who answered the question said they wanted another virtual hackathon. It is likely that more people are interested in attending such a low-cost event than will actually have the time to code or discuss things. This is to be expected of virtual hackathons, even when not during a pandemic. The number of active attendees is about the average of all previous DaSHes. The main accomplishments during this event was to develop standards and system systems for processing electronic HLA messages for the 18th IHIW (<http://www.ihw18.org>) and enhancements to a system for automated annotation of HLA sequences as part of the Gene Feature Enumeration Project (<https://github.com/orgs/nmdp-bioinformatics/projects/1>).

A Data Standards Hackathon and symposium was held on September 16-18, 2020. The symposium involved 13 talks and was open to the public. The agenda was focused on HL7-FHIR implementation and rapid communication of HLA. These talks were attended by 52 individuals: 28 from NMDP, 5 from industry and 19 from government or academic health centers.

The hackathon was attended by 25 participants: 13 NMDP employees, 4 industry partners and 8 from government or academic health centers. The main topics of the hackathon was testing messages from industry partners and vetting a new data format for HLA antibody testing.

Oral Presentations: Title and Speaker

- | | |
|---|---------------------|
| • Data Transformation Initiative | Kristina Bloomquist |
| • Introduction to FHIR, ONC & CMS Rules | Lloyd McKenzie |
| • Roadmap to R5 | Lloyd McKenzie |
| • CIBMTR Reporting App Update | Kirt Schaper |
| • FHIR Implementation Guides: Tooling | Lloyd McKenzie |
| • HL7 Genomics Reporting IG | Bob Milius |
| • S4G Phase 3: HLA Reporting IG | Bob Milius |
| • HML Gateway | Miranda Bauer |
| • Converting Proprietary HLA format to FHIR | Bob Milius |
| • HML2FHIR Update | Bob Milius |

A manuscript entitled “[HLA Haplotype Frequency Estimation for Heterogeneous Populations Using a Graph- Based Imputation Algorithm](#)” was published in Human Immunology during this grant period. This paper describes methods, developed under this grant, to address limitations of the population genetics models upon which current donor selection algorithms are based. Specifically, the assumption that an individual’s genetic background can be linked to one population. The paper demonstrates a new method that addresses individuals who are multi-racial or where race information is unknown and allows this information to be imputed in the expectation step of the population “expectation maximization” algorithm. The result of applying this new method to multiple data sets is that this new method produces much higher likelihood values and better haplotype recovery than all evaluated EM implementations (including our own methods). This method can be applied to generating new frequencies which we believe result in a direct improvement in matching accuracy for populations that are currently underserved by this therapy.

A manuscript entitled “Excess homozygosity in HLA alleles and haplotypes at mating and population levels” was submitted to Frontiers in Immunology. This study evaluates the population genetics of HLA in the US population where we find excess homozygosity in all non-African populations and all loci. This excess can be the result of preferential mating, population substructure, and perhaps transmission imbalance in chromosome 6. In Asian populations, even stronger homophily is observed in HLA that present epitopes involved in NK cell education through KIR and the C2 and Bw4 KIR binding motifs in combination with the leader peptide of HLA-B. This finding is relevant for understanding HLA at population levels and modeling registry growth and matching since many current population genetics methods assume Hardy-Weinberg Equilibrium in the distribution of HLA genotypes. Population substructure and natural selection driven by regulation of the immune system, observable in generational transmission bias of HLA, result in substantial deviation from an equilibrium state which needs to be accounted for when analyzing HLA in US populations.

New HLA haplotype frequencies were generated from the NMDP registry database. These frequencies are the first to extend to the HLA-DPB1, -DPA1 and -DQA1 loci and are the largest cohorts analyzed to date (23.5M total, 10.4M). This data will be prepared for publication.

A manuscript entitled “[Optimal donor selection for hematopoietic cell transplantation using Bayesian machine learning](#)” was published in the Journal of Clinical Oncology Clinical Cancer Informatics describing the results of machine learning experiments to assign risk of clinical endpoints (180 day survival and acute Graft vs Host Disease) on a per donor and per patient basis. The main finding of the study is that upon re-evaluation of searches that resulted in an 8/8 allele matched adult unrelated donor transplant from the period 2015-2016 an achievable improvement was possible with 10% of patients where a risk reduction of ~5% was possible with a younger available donor. This work is being extended in the current grant period to extended to a larger and more recent cohort (2016-2018) and focusing on the 4 clinical endpoints at the 1-year milestone that constitute “Event Free Survival” (death, relapse, rejection and moderate-to-severe chronic Graft vs Host Disease).

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 >8,600 pairs for enrollment in the project and used grant funds to support approximately half of the typing costs. All selected sample pairs have shipped to the project laboratory for testing. All results were received prior to Sept. 30, 2020 and efforts to finalize the data audit were completed under the FY21 grant.

Full HLA Gene Matching Analysis

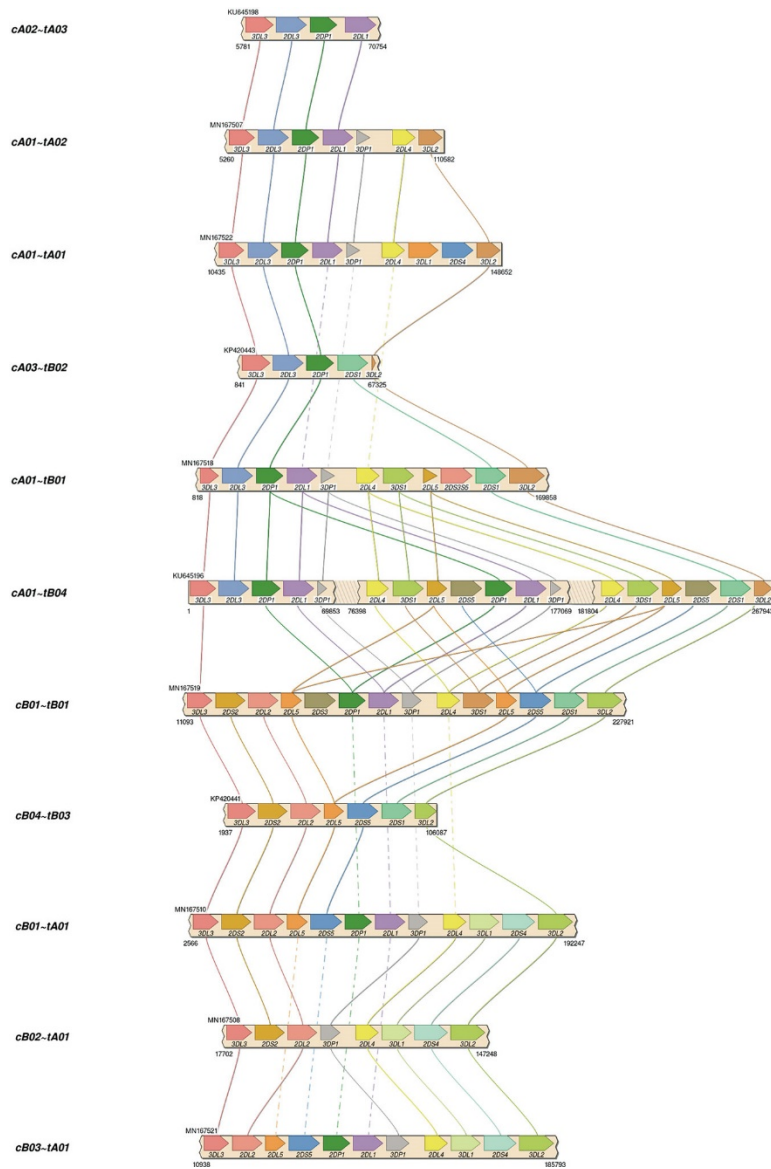
Completed the analysis for the study IB19-01: Impact of ultra-high resolution (UHR) HLA matching on the outcome of unrelated donor hematopoietic cell transplantation. The manuscript entitled, "[Impact of previously unrecognized HLA mismatches using ultrahigh resolution typing in unrelated donor hematopoietic cell transplantation](#)" was accepted and published in the Journal of Clinical Oncology.

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 $\leq 11/12$ 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.

A manuscript “[Efficient Sequencing, Assembly, and Annotation of Human KIR Haplotypes](#)” has been published in *Frontiers in Immunology*. This study was supported under this grant and is a collaboration with industry partners to deliver a new typing protocol for the highly polymorphic KIR. This method addresses the limitations inherent in “shotgun” based methods by using hybrid probe capture to sequence large (2-8k) fragments of DNA on a new sequencing platform and assembling these in a way that preserves two inherited genomic segments without ambiguity. This method has been shown to provide results that are concordant with more expensive methods for Fosmid cloning and sequencing at < 1/10th of the price. With continued support we hope to further multiplex this method to achieve another order of magnitude drop in price which will allow large research cohorts to be fully characterized at the genomic level in this highly polymorphic and structurally varying region for the first time.

The figure from the paper and depicted below, shows the genomic arrangements observed in a set of eight European and eight African donors. The variation in terms of deletions and duplications of entire chromosomal segments is substantial. Investigation of the clinical impact of this structural and allele variation, especially its role in hematopoietic stem cell transplantation, has not been possible at this scale until now.



During the grant period we completed an analysis of genomic data from 48 donor samples typed using a long-read sequencing method developed under this grant. This method had previously been shown to efficiently capture, sequence, and assemble diploid human KIR genomes on 16 individuals. This method has been adapted to a new long-read sequencing platform (PacBio Sequel) and multiplexing has been introduced to reduce costs substantially. Although analysis is ongoing, preliminary results of the KIR allele calls were found to be sufficiently concordant with previous typing results using targeted gene sequencing protocols. Based on these results, we have proposed scaling this approach to 200 samples. Scaling of this assay and analysis pipeline will provide an opportunity to evaluate the clinical impact the genomic structure and, for the first time, the intergenic and regulatory aspects of KIR which have not been evaluated clinically to date.

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

- Completed the preliminary analysis for the study entitled “GV19-01: Exploring the link between donor-engrafted clonal hematopoiesis and adverse outcomes in allogeneic hematopoietic cell transplant recipients: Pilot study”.
- The detected CHIP frequency was ~10% vs. the expected 15% rate used for the power calculations. Leaving the study underpowered.
- No associations were found between the presence of donor CHIP and any clinical outcomes in either univariate (see Table 6 below) or multivariate analysis (data not shown).
- CHIP was called at VAF >0.02 for preliminary analysis, which aligns with prior published studies of CHIP in allogeneic transplantation. The study team has been evaluating approaches to produce accurate calls at VAF <0.02. This could increase the CHIP frequency, but with no hint of any associations at the current VAF it is unclear whether this will impact the current results.
- The lack of an association between CHIP and any clinical outcomes in the present analysis and other studies has diminished enthusiasm for further investigation of CHIP as a donor selection factor.

Table 6: Univariate results of GV19-01: Exploring the link between donor-engrafted clonal hematopoiesis and adverse outcomes in allogeneic hematopoietic cell transplant recipients: Pilot Study

Outcomes	CHIP+ (N = 30)		CHIP- (N = 269)		P Value
	N	Prob (95% CI)	N	Prob (95% CI)	
Overall survival	30		269		0.882
100-day		83.3 (68.2-94.3)%		94.4 (91.4-96.8)%	
6 months		76.7 (60.2-89.8)%		85.9 (81.5-89.8)%	
1-year		76.7 (60.2-89.8)%		68.8 (63.1-74.2)%	
Disease free survival	30		267		0.898
100-day		73.3 (56.4-87.3)%		86.9 (82.6-90.7)%	
6 months		70 (52.7-84.8)%		69.7 (64-75)%	
1-year		63.3 (45.6-79.4)%		56.9 (51-62.8)%	
Relapse	30		267		0.173
100-day		13.3 (3.6-27.9)%		9.4 (6.2-13.1)%	
6 months		13.3 (3.6-27.9)%		22.1 (17.3-27.3)%	
1-year		20 (7.7-36.3)%		30 (24.6-35.6)%	
Treatment related mortality	30		267		0.165
100-day		13.3 (3.6-27.9)%		3.7 (1.8-6.4)%	
6 months		16.7 (5.6-32.2)%		8.2 (5.2-11.8)%	
1-year		16.7 (5.6-32.2)%		13.1 (9.3-17.4)%	
Chronic GVHD	30		268		0.496
100-day		0%		2.6 (1-4.9)%	
6 months		10 (1.9-23.4)%		17.2 (12.9-22)%	
1-year		NE		41 (35.2-47)%	

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 are 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.

The study protocol was finalized, a testing laboratory selected and the immunophenotyping panel established during the grant year. The study will continue under future grants.

D. Clinical Research in Transplantation

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

Observational Research

- Published a total of 174 manuscripts in peer-reviewed journals during the grant period (Oct. 1, 2019-September 30, 2021).
- Presented 12 oral and 13 poster abstracts at the American Society of Hematology Annual Meeting. A list of the presentations is provided in the table below. Complete abstracts were published in the Nov. 13, 2019 issue of Blood (https://ashpublications.org/blood/issue/134/Supplement_1).

Title	Status	Presenter
Fludarabine and Melphalan Compared with Reduced Doses of Busulfan and Flurabine Improves Transplant Outcomes in Older MDS Patients	Oral	Betul Oran
Primary Plasma Cell Leukemia Outcomes Remain Dismal Despite Novel Agents and Hematopoietic Cell Transplantation	Oral	Sagar Patel
Superior Survival with Post-Remission Pediatric-Inspired Chemotherapy Compared to Myeloablative Allogeneic Hematopoietic Cell Transplantation in Adolescents and Young Adults with Ph-Negative Acute Lymphoblastic Leukemia in First Complete Remission: Comparison of CALGB 10403 to Patients Reported to the CIBMTR	Oral	Matthew Wieduwilt
Comparison of Reduced-Intensity Conditioning (RIC) Regimens for Allogeneic Hematopoietic Cell Transplantation (alloHCT) in Non-Hodgkin Lymphomas (NHL)-a Center for International Blood & Marrow Transplant Research (CIBMTR) Analysis	Oral	Nilanjan Ghosh
Allogeneic Hematopoietic Stem Cell Transplantation for Therapy-Related Myelodysplastic Syndromes and Acute Myeloid Leukemia	Poster	Leland Metheny
Lower Hematopoietic Progenitor Cell Counts and Yields at Subsequent Donations Is Influenced By a Shorter Inter-Donation Interval between the First and Subsequent Mobilizations	Poster	Sandhya Panch
Busulfan, Melphalan, and Bortezomib Compared to Single Agent High- Dose Melphalan As a Conditioning Regimen for Autologous Hematopoietic Stem Cell Transplantation in Multiple Myeloma: Long Term Follow up of a Novel Conditioning Regimen	Poster	Patrick Hagen
Genome-Wide Association Study Identifies an Immune-Related Etiology for Severe Aplastic Anemia	Poster	Sharon Savage

De Novo and Therapy-Related Acute Myeloid Leukemia and Myelodysplastic Syndrome: Similarities and Differences in SNP-Array Detected Chromosomal Aberrations in Pre-Transplant Blood Samples	Poster	Youjin Wang
Allogeneic Transplantation for Myelodysplastic Syndrome in Adults over 50 Years Old Using Reduced Intensity/Non-Myeloablative Conditioning: Haploidentical Relative Versus Matched Unrelated Donor	Poster	Michael Grunwald
Impact of Renal Dysfunction Measured By Estimated Glomerular Filtration Rate (eGFR) on Outcomes after Allogeneic Hematopoietic Cell Transplantation (HCT)	Poster	Ajoy Dias
Comparison of Reduced-Intensity Conditioning (RIC) Regimens for Allogeneic Hematopoietic Cell Transplantation (alloHCT) for Classical Hodgkin Lymphoma (cHL): a Center for International Blood & Marrow Transplant Research (CIBMTR) Analysis	Poster	Sairah Ahmed
Tisagenlecleucel Chimeric Antigen Receptor (CAR) T-Cell Therapy for Relapsed/Refractory Children and Young Adults with Acute Lymphoblastic Leukemia (ALL): Real World Experience from the Center for International Blood and Marrow Transplant Research (CIBMTR) and Cellular Therapy (CT) Registry	Poster	Stephan Grupp
Early Broad-Spectrum Antibiotics and Risk of Acute Graft-Versus-Host Disease in Children: an analysis from the Center for International Blood and Marrow Transplantation Research (CIBMTR) and the Pediatric Health Information System (PHIS)	Oral	Caitlin Elgarten
Excellent Overall Survival and Low Incidence of Late Effects in Patients Undergoing Allogeneic Hematopoietic Cell Transplant for Sickle Cell Disease: A Report from the Center for International Blood and Marrow Transplant Research (CIBMTR)	Oral	Elizabeth Stenger
Post-Transplant Work Status of Young Adult Survivors of Allogeneic Hematopoietic Cell Transplant: A Report from the Center for International Blood and Marrow Transplant Research (CIBMTR)	Oral	Neel A. Bhatt
Post-Marketing Use Outcomes of an Anti-CD19 Chimeric Antigen Receptor (CAR) T Cell Therapy, Axicabtagene Ciloleucel (Axi-Cel), for the Treatment of Large B Cell Lymphoma (LBCL) in the United States (US)	Oral	Marcelo Pasquini
Breaking the Glass Ceiling of Age in Transplant in Multiple Myeloma	Oral	Pashna N. Munshi
Novel Prognostic Scoring System for Autologous Hematopoietic Cell Transplantation (AHCT) in Multiple Myeloma (MM)	Oral	Binod Dhakal
Tisagenlecleucel Chimeric Antigen Receptor (CAR) T-Cell Therapy for Adults with Diffuse Large B-Cell Lymphoma (DLBCL): Real World Experience from the Center for International Blood & Marrow Transplant Research (CIBMTR) Cellular Therapy (CT) Registry	Oral	Samantha Jaglowski

Does Addition of Rituximab® to BEAM Conditioning Improve Outcomes of Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Undergoing Autologous Hematopoietic Cell Transplantation (auto-HCT)?	Oral	Deepa Jagadeesh
Impact of Depth of Pretransplant Clinical Response on Outcomes of Acute Myeloid Leukemia Patients in First Complete Remission (AML-CR1) Who Undergo Allogeneic Hematopoietic Cell Transplantation (AlloHCT)	Poster	Mary-Elizabeth Percival
Cognitive Impairment Is Associated with Inferior Survival and Increased Non-Relapse Mortality in Older Allogeneic Hematopoietic Cell Transplant (alloHCT) Recipients: A Multicenter Retrospective Study	Poster	Rebecca Olin
Myeloablative Conditioning Is Preferred for Allogeneic Transplantation of Acute Myeloid Leukemia and Myelodysplastic Syndromes with Low/Intermediate but Not High Disease Risk Index	Poster	Nelli Bejanyan
Genome Wide Interaction Analysis Identifies Expression Quantitative Trait Loci Associated with Reduced Survival after Reduced Intensity Conditioning HLA-Matched Unrelated Donor Allogeneic Hematopoietic Cell Transplant	Poster	Ezgi Karaesmen

- 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](https://www.bbmt.org/issue/S1083-8791(19)X0014-2)).

<i>Title</i>	<i>Status</i>	<i>Presenter</i>
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
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

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

- Presented 24 abstracts to the 2020 American Society of Hematology Annual Meeting. All were accepted with 9 assigned to oral presentations and 15 as poster presentations. The study titles, presentation type and presenting author are noted below. Complete abstracts were published in the Nov. 5, 2020 issue of Blood (<https://ashpublications.org/blood/issue/136/Supplement%201>).

<i>Study Title</i>	<i>Presentation type</i>	<i>Presenting author</i>
A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplantation to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Advanced Myelodysplastic Syndrome: Blood and Marrow Transplant Clinical Trials Network Study 1102	Oral	Corey Cutler

Comparison of Outcomes after Haploidentical Relative and HLA Matched Unrelated Donor Transplantation with Post-Transplant Cyclophosphamide Containing Gvhd Prophylaxis Regimens	Oral	Mahasweta Gooptu
Impact of Cryopreservation of Donor Grafts on Outcomes of Allogeneic Hematopoietic Cell Transplant (HCT)	Oral	Jack Hsu
Comparison of Haploidentical Donor Hematopoietic Cell Transplantation Using Post-Transplant Cyclophosphamide to Matched-Sibling, Matched-Unrelated, Mismatched-Unrelated, and Umbilical Cord Blood Donor Transplantation in Adults with Acute Lymphoblastic Leukemia: A CIBMTR Study	Oral	Matthew Wieduwilt
Chromosomal Aberrations in Pre-HCT Blood Samples and Outcomes after Transplantation in Patients with Myelofibrosis	Oral	Youjin Wang
Expanded Comorbidity Definitions Improve Application of the Hematopoietic Cell Transplantation Comorbidity Index (HCT-CI) for Children and Young Adults with Non-Malignant Diseases Receiving Allogeneic Hematopoietic Cell Transplantation	Oral	Larisa Broglie
Superiority of Thiotepa-Containing Conditioning Regimens in Patients with Primary Diffuse Large B-Cell Lymphoma (DLBCL) of the Central Nervous System (CNS) Undergoing Autologous Hematopoietic Cell Transplantation (autoHCT)	Oral	Trent Wang
Population Distribution of GvL and GvH Minor Histocompatibility Antigens	Oral	Kelly Olsen
Allogeneic Hematopoietic Cell Transplantation (allo-HCT) in T-Cell Prolymphocytic Leukemia (T-PLL): An Analysis from the CIBMTR	Poster	Hemant Murthy
Impact of Age on the Outcomes of HCT for AML in CR1: Promising Therapy for Older Adults	Poster	Joseph Maakaron
Improving Donor Selection for Haploidentical Stem Cell Transplantation with Post-Transplant Cyclophosphamide through Selective HLA-Mis/Matching	Poster	Ephraim Fuchs
Conditioning Regimens and Outcomes after Allogeneic Hematopoietic Cell Transplant for Hyperinflammatory Inborn Errors of Immunity	Poster	Rebecca Marsh
Outcomes of Pediatric Patients with JMML Following Unrelated Donor Transplant: The Impact of Donor KIR Gene Content and KIR Ligand Matching	Poster	Hemalatha Rangarajan
Geographic Disparities of Hematopoietic Cell Transplantation in Acute Myeloid Leukemia Patients in Virginia	Poster	Joseph Mock

Prognostic Impact of a Modified European LeukemiaNet (ELN) Genetic Risk Stratification in Predicting Outcomes for Adults with Acute Myeloid Leukemia (AML) Undergoing Allogeneic Hematopoietic Stem Cell Transplantation (HCT). a Center for International Blood and Marrow Transplant Research (CIBMTR) Analysis for the CIBMTR Acute Leukemia Writing Committee	Poster	Antonio Jimenez
Meta-Analysis of Genome-Wide Association Studies of Acute Myeloid Leukemia (AML) Patients Identifies Variants Associated with Risk of 11q23/ <i>KMT2A</i> -Translocated and Core-Binding Factor (CBF) AML and Suggests a Role for Transcription Elongation in Leukemogenesis	Poster	Lara Sucheston-Campbell
BMT CTN 1803: Haploidentical Natural Killer Cells (K-NK002) to Prevent Post-Transplant Relapse in AML and MDS (NK-REALM)	Poster	Sumithira Vasu
Associations of Clinical Outcomes after Allogeneic Hematopoietic Cell Transplantation with Number of Predicted Class II Restricted mHA	Poster	Othmane Jadi
Pre-Transplant Clonal Mosaicism Is Associated with Increased Relapse and Lower Survival in Acute Lymphoblastic Leukemia Patients Undergoing Allogeneic Hematopoietic Cell Transplant	Poster	Yiwen Wang
Non-Infectious Pulmonary Toxicity after Allogeneic Hematopoietic Cell Transplantation (HCT): A Center for International Blood and Marrow Transplant Research (CIBMTR) Study	Poster	Sagar Patel
Maintenance Use Is More Important Than the Choice of Bortezomib-Based Triplet Induction in Newly Diagnosed Multiple Myeloma Patients Undergoing Upfront Autologous Stem Cell Transplantation	Poster	Surbhi Sidana
Younger HLA-Matched Unrelated Donor Allogeneic Hematopoietic Cell Transplantation (allo-HCT) for Myelodysplastic Syndromes (MDS) Is Associated with Superior Disease-Free Survival Compared to Older HLA-Identical Sibling Donors: CIBMTR Analysis	Poster	Guru Murthy

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, in May 2020 to reflect one Cellular Therapy form revision & in July 2020 to reflect one Cellular Therapy form revision.

- Enhancements to form capabilities to support data capture for COVID-19.
- Introduced new monthly security monitoring and incorporating fixes to security vulnerabilities within the month. Nineteen vulnerabilities were fixed in August and September with release in October 2020.
- 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 last of the six FormsNet Forms Definition Manager (FDM) grid conversions from the Telerik to Kendo ahead of Telerik's impending retirement in September 2020, thereby improving FormsNet security.
- Updated the FDM Mapping Tool to automate major portions of the AGNIS metadata mapping to decrease manual errors and the time to map FormsNet form revisions to AGNIS.
- Updated Formsnet 3 Donor Module to successfully interface with required changes to the option group/review section of the Protocol Deviation Form (Form 3000).
- Completed messaging and error validation enhancements, end-to-end integration testing, and bug fixing for the Infections Disease Marker (IDM) Automation project which will reduce the time it takes to clear a donor by automating the reporting of IDM results and improve any error handling should these messages fail to send as expected (will be in production by 10/15/20).
- Deployed updates to the audit tool to allow for the querying of forms in query/pending status to prepare for and maximize an audit's completeness, up-to-date accuracy, and transplant center satisfaction.
- 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, was released in May. This change has become necessary as patients can receive multiple infusion types (e.g., HCT, CT), at different centers.
- Introduced combined follow-up reporting in Formsnet3 to align follow-up data collection forms to the same timepoint when recipient has had both a hematopoietic cellular transplant and a genetically modified cellular therapy.
- Implemented a new type of data validation that uses a web service call, to ensure that a valid clinical trial study ID number is being reported.
- Made Inotuzumab Supplemental form (2541 r1 & r2) "unselectable" by the Audit Tool and completed analysis on how Audit can interface with several key fields that will no longer appear on forms (to be in production by January 2021).
- Disabled DID for Donor Forms and IDM Upload Tool to support GRID requirements and 12/15/20 deadline (Successfully developed, QA tested, regression testing is underway for 10/23 release)
- Creation and configuration of a new Enterprise Service Bus (ESB) message to communicate typing results received by CORE system for customized typing orders, so that FN3 can inform users of the status of the order and the scanned form (supports impending KeyLink retirement).
- Developed and released the following data collection forms in July 2020.

Form	Form Name	Category
2030R3	Sickle Cell Disease Pre-Infusion Data	Revised recipient form
Form	Form Name	Category
2130R3	Sickle Cell Disease Post-Infusion Data	Revised recipient form
2543R1	Gemtuzumab Ozogamicin (Mylotarg™) Supplemental	New study form
2402r5	Disease Classification	Revised recipient form
2014r4	MDS Pre-Infusion Data	Revised recipient form
2114r4	MDS Post-Infusion Data	Revised recipient form
2057r1	MPN Pre-Infusion Data	Revised recipient form
2157r1	MPN Post-Infusion Data	Revised recipient form
2400r7	Pre-Transplant Essential Data	Revised recipient form
2500r4	Recipient Eligibility Form	Revised recipient form
2532r2	BMT CTN 1702 Enrollment Form	Revised study form
2533r2	BMT CTN 1702 Donor Testing	Revised study form
2534r2	BMT CTN 1702 Monthly Update	Revised study form
2536r2	BMT CTN 1702 Off Study	Revised study form
2149r1	Respiratory Viruses	New recipient form
2450r5	Post-Transplant Essential Data	Updated for COVID-19
4000r6	Pre-Cellular Therapy Essential Data	Updated for COVID-19
2900r4	Recipient Death Data	Updated for COVID-19
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. Efforts 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 Children’s Hospital Colorado Production environment using the CIBMTR Reporting App and began exchanging:
 - Patient demographics
 - CRID assignment
 - GVHD observations
- 12 form revisions have been released in Production for AGNIS users.
- 7 form revisions have been released for external AGNIS users to test.
- Successfully updated 6 forms with COVID-19 options.
- AGNIS auto-population enhancement development has been completed.
- Testing and release efforts for resolution of an AGNIS 2804r6 production issue.
- Testing related to an AGNIS 4000r6 update needed after FN3 update for clinical trials field.
- Testing and release efforts for AGNIS maintenance release updates (field name changes, floating text updates, etc.).
- Testing and release efforts for AGNIS of two donor linking issues, initiated common validations testing and AGNIS auto-population test case preparation.
- Implementation of check-digit logic for AGNIS.
- Donor linking issue from external center was developed, tested and released for AGNIS.

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.
- Added additional checks to CIBMTR’s Critical Systems Dashboard to track the status of CIBMTR systems and reports.
- Implemented new processes to support CIBMTR’s International CPI Processes.
- Developed a data file sharing process with external partner, Emmes.
- Added additional reporting capabilities to our business intelligence suite to support CIBMTR Prospective Research team needs.
- Completed pathway to capture and store survey data from CIBMTR’s ePRO system.
- Enhanced Cord Blood Data Quality Report to include additional Cellular Therapy data.
- Began first round of Transplant Center data review for the 2020 Center Volumes Data Reporting project.
- Added new reports to the Quarterly Cord Blood Quality to highlight Cellular Therapy data and capture month to month data changes.
- 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:

- Data Operations Dashboard
 - Enhanced the DataOps dashboard to include a COVID Impacts extract which collect data from Transplant Centers on impacts to specific patient's treatment plan/infusion.
 - Introduced a new dashboard to facilitate secure, self-service file downloading.
 - DataOps dashboard currently contains files for Consecutive Transplant Audit (CTA Reports) and Transplant Center Specific Analysis reports.

Consecutive Transplant Audit (CTA reports)

- Formerly a service offered through secure email; is now offered on a self-service portal
- Reports are updated weekly

Transplant Center Specific Analysis (TCSA reports)

- Formerly a service offered through secure email; is now offered on a self-service portal
- Contains both the draft report collaborations and the final reports
- Reports are updated in the spring and winter

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.

- 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.
 - Completed loading and validation of CAR T-cell and attendant infectious disease data.
 - Completed building domain model infrastructure for enabling data extracts from the unified database.
 - Delivered first research-ready CAR T-cell data extracts out of the unified database.
 - Continued mapping of infectious disease data, transplant essential data, and new respiratory virus data to the physical data model.
 - Completed loading of new and updated data tied to Spring 2020 FormsNet revisions

- 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.
- Completed loading and validation of multiple myeloma infectious disease data into the unified database.
- Completed mapping of pre- and post- transplant essential data (TED).
- Completed data architecture design for bringing patient related outcomes data (ePRO) into the unified database.
- Delivered first production CAR T-cell data sets to our Japan partners.
- Completed design for and continued building of infrastructure required to incorporate HLA donor and recipient data into the unified database.

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 559 subjects through September 2020. No further activity was attributed to this grant.

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 was developed, and the project moved forward without support from this grant.

Publications

1. Mohty M, Malard F, Abecasis M, et al. Prophylactic, preemptive, and curative treatment for sinusoidal obstruction syndrome/veno-occlusive disease in adult patients: a position statement from an international expert group. *Bone Marrow Transplantation*. doi:10.1038/s41409-019-0705-z. Epub 2019 Oct 1. Impact factor: 4.70.
2. Solomon SR, St. Martin A, Shah NN, et al. Myeloablative vs reduced intensity T-cell-replete haploidentical transplantation for hematologic malignancy. *Blood Advances*. 2019 Oct 8; 3(19):2836-2844. doi:10.1182/bloodadvances.2019000627. Epub 2019 Oct 3. PMC6784523. Impact factor: 4.6.
3. Muhsen IN, Hashmi SK, Niederwieser D, et al. Correction: Worldwide Network for Blood and Marrow Transplantation (WBMT) perspective: the role of biosimilars in hematopoietic cell transplant: current opportunities and challenges in low- and lower-middle income countries. *Bone Marrow Transplantation*. doi:10.1038/s41409-019-0714-y. Epub 2019 Oct 15. Impact factor: 4.70.
4. Snowden JA, Saccardi R, Orchard K, et al. Benchmarking of survival outcomes following haematopoietic stem cell transplantation: A review of existing processes and the introduction of an international system from the European Society for Blood and Marrow Transplantation (EBMT) and the Joint Accreditation Committee of ISCT and EBMT (JACIE). *Bone Marrow Transplantation*. doi:10.1038/s41409-019-0718-7. Epub 2019 Oct 21. Impact factor: 4.70.
5. Bejanyan N, Kim S, Hebert KM, et al. Choice of conditioning regimens for bone marrow transplantation in severe aplastic anemia. *Blood Advances*. 2019 Oct 22; 3(2):3123-3131. doi:10.1182/bloodadvances.2019000722. Epub 2019 Oct 22. PMC6849938. Impact factor: 4.6.
6. Herr MM, Curtis RE, Tucker MA, et al. Risk factors for the development of cutaneous melanoma after allogeneic hematopoietic cell transplantation. *Journal of the American Academy of Dermatology*. doi:10.1016/j.jaad.2019.10.034. Epub 2019 Oct 22. Impact factor: 7.69.
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8. DeFilipp Z, Ancheta R, Liu Y, et al. Maintenance tyrosine kinase inhibitors following allo-HCT for chronic myeloid leukemia: A CIBMTR study. *Biology of Blood and Marrow Transplantation: Journal of the American Society for Blood and Marrow Transplantation*. 2020 Mar 1; 26(3):472-479. doi:10.1016/j.bbmt.2019.10.017. Epub 2019 Oct 25. Impact factor: 3.9.
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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.