

October 07, 2016

Lt. Brian Andrews-Shigaki
Office Warfighter Performance S&T Dept
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: Final Technical Report with SF298 by the National Marrow Donor Program®

Reference: Grant #N00014-14-1-0028 between the Office of Naval Research and the National Marrow Donor Program

Dear Lt. Andrews-Shigaki,

In accordance with the requirements of the Referenced Office of Naval Research Grant, the National Marrow Donor Program® (NMDP) hereby submits the required Final Technical Report for the period of October 01, 2013 through September 30, 2015. Delivery of this report completes all actions required under the referenced Grant.

Should you have any questions regarding the performance of activity under this Grant, you may contact our Chief Medical Officer – Dennis Confer, MD directly at 763-406-3425.

Please direct any contractual questions pertaining to the Grant to my attention at 763-406-3403 or to cabler@nmdp.org.

Sincerely,

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REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Service, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188) Washington, DC 20503.

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1. REPORT DATE (DD-MM-YYYY) 07-10-2016		2. REPORT TYPE Final Technical Report		3. DATES COVERED (From - To) Oct 2013 – Sep 2015	
4. TITLE AND SUBTITLE Development of Medical Technology for Contingency Response to Marrow Toxic Agents – Final Technical Report with SF298 October 01, 2013 to September 30, 2015				5a. CONTRACT NUMBER N/A	
				5b. GRANT NUMBER N00014-14-1-0028	
				5c. PROGRAM ELEMENT NUMBER N/A	
6. AUTHOR(S) Spellman, Stephen				5d. PROJECT NUMBER N/A	
				5e. TASK NUMBER Project 1, 2, 3, 4	
				5f. WORK UNIT NUMBER N/A	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) National Marrow Donor Program 500 N. 5 th St. Minneapolis, MN 55401-1206				8. PERFORMING ORGANIZATION REPORT NUMBER N/A	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Office of Naval Research 875 N. Randolph St. Arlington, VA 22203-1995				10. SPONSOR/MONITOR'S ACRONYM(S) ONR	
				11. SPONSORING/MONITORING AGENCY REPORT NUMBER N/A	
12. DISTRIBUTION AVAILABILITY STATEMENT Approved for public release; distribution is unlimited					
13. SUPPLEMENTARY NOTES N/A					
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. Immunogenetic 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					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES 99	19a. NAME OF RESPONSIBLE PERSON Dennis L. Confer, MD – Chief Medical Office
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (Include area code) 763-406-3425

National Marrow Donor Program N00014-14-1-0028
DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC
AGENTS
FINAL BENEFITS REPORT
October 1, 2013 – September 30, 2015



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I. Heading

PI: Dennis L. Confer, M.D.

National Marrow Donor Program

N00014-14-1-0028

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

II. Scientific and Technical Objectives

The main objective of this grant is to develop, test and mature the ability of the National Marrow Donor Program® (NMDP) to address contingency events wherein civilian or military personnel are exposed to marrow toxic agents, primarily ionizing radiation or chemical weapons containing nitrogen mustard. NMDP's on-going immunobiologic and clinical research, performed in close collaboration with independent investigators from nearly all U.S. academic medical centers, promote studies to advance the science and technology of hematopoietic cell transplantation (HCT) to improve outcomes and quality of life for patients. The Office of Naval Research funding plays key roles in advancing the success of HCT and the large number of innovative treatment approaches leading to continual improvements that make possible development of optimal care plans for potential casualties. An accident, a military incident, or terrorist act in which a number of individuals are exposed to marrow toxic agents will result in injuries from mild to lethal. Casualties will be triaged by first responders, and those with major marrow injuries who may ultimately be candidates for HCT will need to be identified. HCT donor identification activities will be initiated for all potential HCT candidates. 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 process 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.

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.

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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. Concise Accomplishments

- a. Contingency Preparedness
 - i. Held a fullscale radiological exercise in Boston that involved >10 organizations. The exercise involved the use of a terminal at Boston Logan Airport to simulate the receipt and triage of casualties for transfer to the Dana-Farber Cancer Institute.
 - ii. Conducted a regional tabletop exercise in New York City led by the Memorial Sloan-Kettering Cancer Center. The exercise had a broad focus that engaged a community of responders to plan for receipt of 5,000 radiological casualties from Chicago.
 - iii. Implemented Operational Continuity Plan in response to winter storm
- b. Development of Science and Technology for Rapid Identification of Matched Donors
 - i. Supported the HLA typing of 83,099 newly recruited donors (48% minority race/ethnicity).
 - ii. Optimal HLA matching manuscript published in Blood (Pidala et al)
 - iii. Provided 20 products to the NIH transplant center
- c. Immunogenetic Studies in Transplantation
 - i. Completed HLA and KIR typing on >2,600 unrelated and related donor/recipient transplant pairs from the CIBMTR Research Repository

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- ii. Completed genotyping of >1,100 unrelated donor/recipient pairs for the Clinical Ancestry study
- d. Clinical Research in Transplantation
 - i. Completed planning work to move to development of the RITN data collection forms.
 - ii. Published 170 peer-reviewed manuscripts during the grant period.

V. Expanded Accomplishments

Contingency Preparedness

Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event.

During the grant period, the NMDP continued to advance the RITN through the following activities:

- Coordination and funding of radiological incident exercises:
 - o Regional tabletop in NYC (MSKCC hosted)
 - o Fullscale exercise in Boston (DFCI conducted)
 - o 3 web based tabletop exercises
 - o Annual RITN tabletop exercise conducted by 57 hospitals
- Released Referral Guidelines
- Collaborated with REMM.nlm.gov on an update of acute radiation syndrome treatment guidelines
- Conducted hospital readiness site assessments
- G-CSF distribution project with ASTHO and CDC
- Development of web based data collection forms for incorporation into FormsNet
- Became a member of the National Alliance for Radiation Readiness (NARR)
- RITN awareness project with NACCHO
- Sponsored two mobile REAC/TS advanced medical training courses

Each item will be discussed in depth below.

Hospitals are eligible to join RITN if they participate in both the NMDP Network of treatment centers and the NDMS. The NDMS is comprised of over 1,800 accredited hospitals across the nation that have agreed to receive trauma casualties following a disaster. The program is managed by the Department of Health and Human Services. RITN conducts targeted recruitment on an annual basis with a goal of expanding the network. During 2014, four new transplant centers joined RITN; resulting in a total composition of: 61 transplant centers, 6 donor centers, and 7 cord blood banks (Figure 1). The new centers that joined RITN were:

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1. Univ. of Colorado-Aurora (CO)
2. Northwestern University (IL)
3. Emory University (GA)
4. North Shore University (NY)

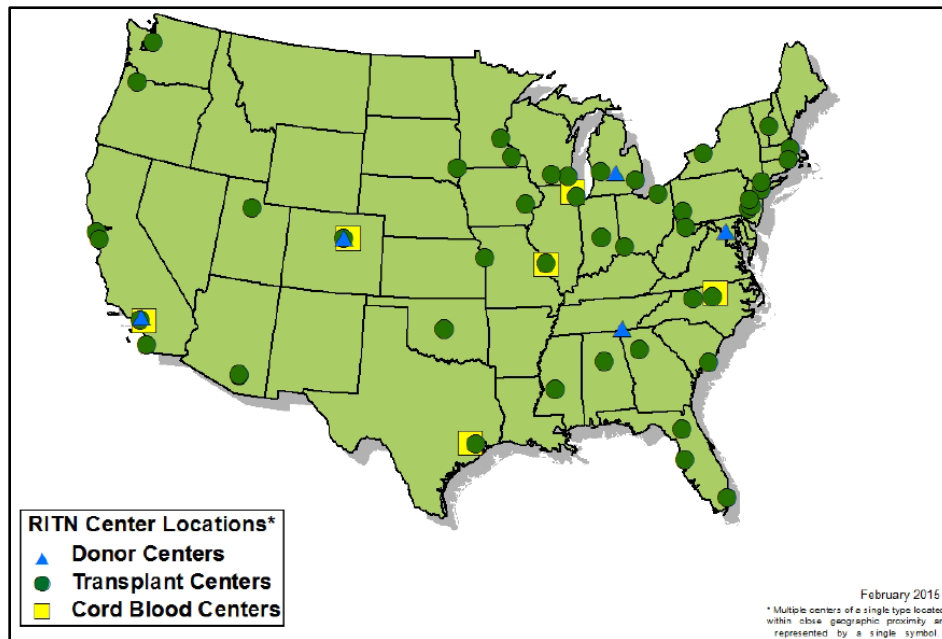


Figure 1. Location of RITN Centers

RITN centers were asked to continue to develop their level of preparedness during the grant period. Tasks included communications drills, updating of standard operating procedures, outreach to local public health and emergency management contacts, a tabletop exercise and training of staff.

During 2014, 98% of RITN centers completed all of their required annual tasks (Figure 2). This is consistent with the performance during the previous grant period.

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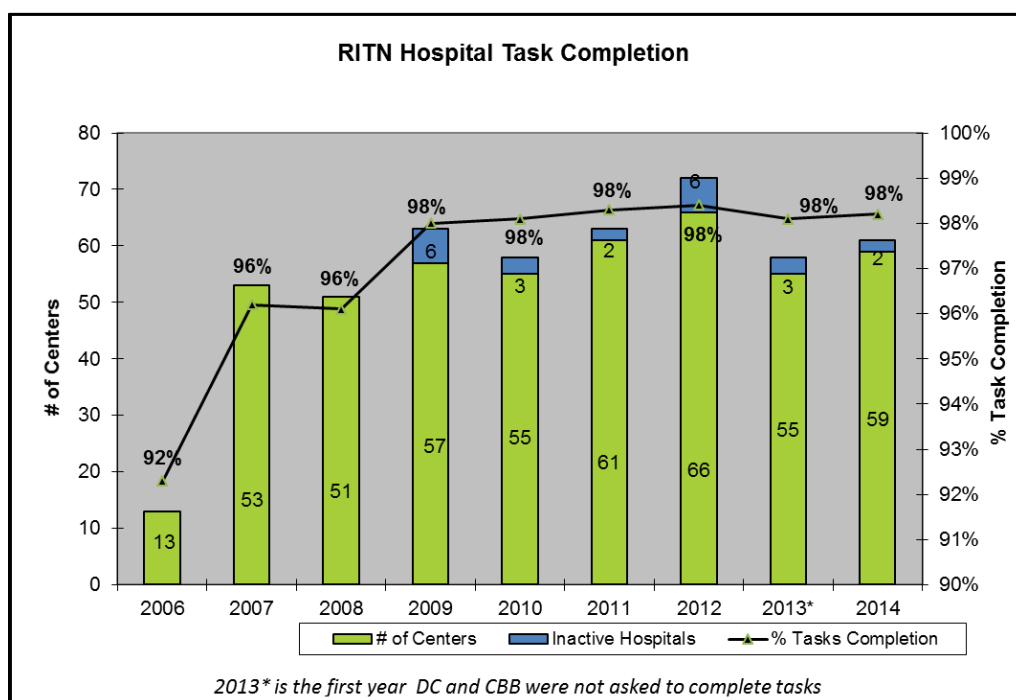


Figure 2. RITN Center task completion by year

RITN Exercise Program: RITN coordinates or provides support for many radiological exercises each year; these include fullscale, functional, regional tabletop and tabletop exercises (the intensity and effort required decreases accordingly from fullscale to tabletop). RITN has facilitated more than 434 exercises since initiation in 2006 (see Figure 3 for breakdown by type). During the grant period Dana-Farber Cancer Institute held a fullscale radiological exercise in Boston and Memorial Sloan Kettering Cancer Center conducted a regional tabletop exercise. Both were great successes.

The exercise in Boston involved over ten organizations from as far away as Alaska:

1. Dana Farber/Brigham & Women's Cancer Center
2. Dana Farber/Boston Children's Cancer and Blood Disorders Center
3. Boston Children's Hospital
4. Brigham & Women's Hospital
5. National Marrow Donor Program/Radiation Injury Treatment Network
6. Fairbanks Memorial Hospital

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7. Massport Logan Airport
8. Fallon Ambulance Service
9. Boston Public Health Commission
10. Boston University Healthcare Emergency Management
11. Veteran's Administration

This involved the use of a terminal at Boston Logan Airport to simulate the receipt and triage of casualties for movement to Dana Farber where the following day the casualties were received, in processed and treatment plans were determined. Gaps were identified and are included in the after [action review posted on the RITN website](#).

The Exercise in New York City involved 15 entities:

1. Brookhaven National Laboratories
2. New York City Department of Health and Mental Hygiene
3. Fire Department of New York
4. Health and Human Services-Assistant Secretary for Planning and Response
5. National Marrow Donor Program/Radiation Injury Treatment Network
6. Mount Sinai Hospital
7. North Shore Health System
8. New York State Department of Health
9. New York City Office of Emergency Management
10. New York Presbyterian Hospital
11. New York University
12. Langone Medical Center
13. New York Regional EMS Council
14. Greater New York Hospital Association
15. Department of Veterans Affairs

This exercise had a broad focus that asked the community of responders how they would receive 5,000 radiological casualties from Chicago. Many gaps were identified and are in the after [action review which is also posted on the RITN website](#).

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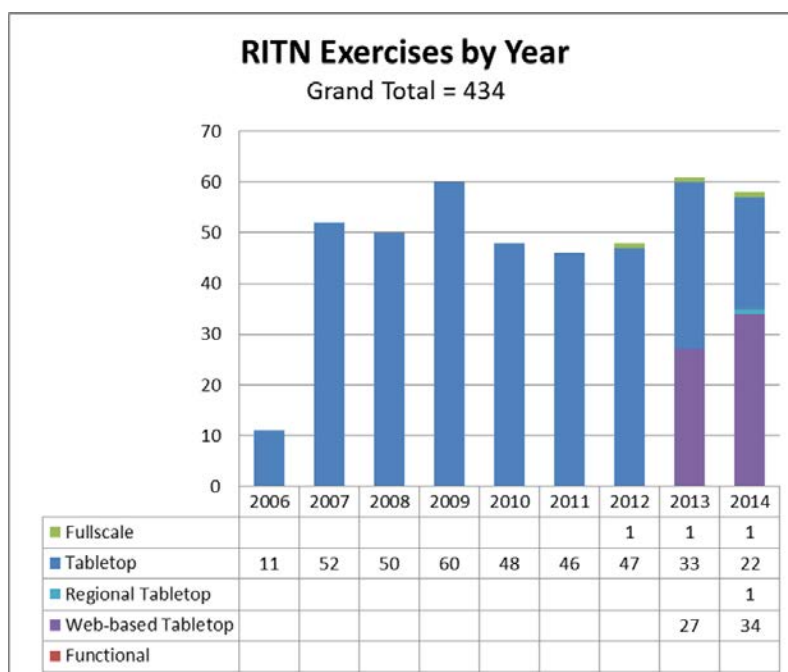


Figure 3. Number of RITN centers participating in exercises from 2006-2014.

Tabletop exercises: The 2014 tabletop exercise presented the detonation of a 1Kt improvised nuclear device resulting in the receipt of 100 casualties with ARS. For the second year a facilitated webinar based tabletop was offered to RITN hospitals; once again the format was very well received. The number of RITN centers participating in tabletop exercises annually is summarized in Figure 3.

Table 1. List of annual RITN tabletop exercise scenarios and level of patient surge.

Summary of RITN Tabletop Exercise Scenarios		
Year	Scenario	Max Victims
2006	Radiological Exposure Device (RED) placed on public train system	650 identified as having some level of ARS. 50 patients to each center
2007	Train derailment spills multiple chemicals, produces vapor cloud which exposes a crowd of 15,000	5,000 (mostly children and senior citizens)
2008	IND was detonated and 300,000 victims were triaged	5,000 victims required RITN assistance

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2009	10-kiloton nuclear device detonated in a major metropolitan center	12,000 patients with high radiation dose in the 200-600 rad range. 300 patients to each center
2010	Detonation of a surface burst 10-kiloton nuclear device in major metropolitan center	20,000 patients with high radiation dose in the 200-600 rad range. 500 patients to each center
2011	National Disaster Medical System (NDMS) flow and integration	Not specified
2012	1 kT IND detonated 500 miles away from RITN center, 20 patients to prioritize using provided casualty cards	20 casualty cards w/ limited bed availability provided
2013 w/ Webinar Option	Radiological exposure devices placed on mass transit vehicles in multiple US cities	4,500 casualties nationwide; 300 patients and 140 family members are sent to each RITN center
2014 Primarily Webinar	Detonation of a 1kT IND	100 patients from a large metropolitan area 500 miles away

The results from the tabletop exercise included questions about the hospital's triage process, integration into local hospital coalitions, coordination with the hospital's public information officer and integration with the regional poison control center. These questions raised awareness of the importance of each of these areas as well as highlighted areas for improvement for many hospitals. Results from four of the exercise questions are below; two about the triage process (Figure 4) and two about integration into the local healthcare coalition (Figure 5). A well-developed triage process and integration with the local healthcare coalition are essential to mount an effective response. These responses showed that even though over 80% of RITN hospitals have an established triage process less than 65% have tested this process in an exercise. However, the level of integration into the local healthcare coalition is impressive; the vast majority (79%) have coordinated with the coalition and even conducted exercises to ensure an effective response.

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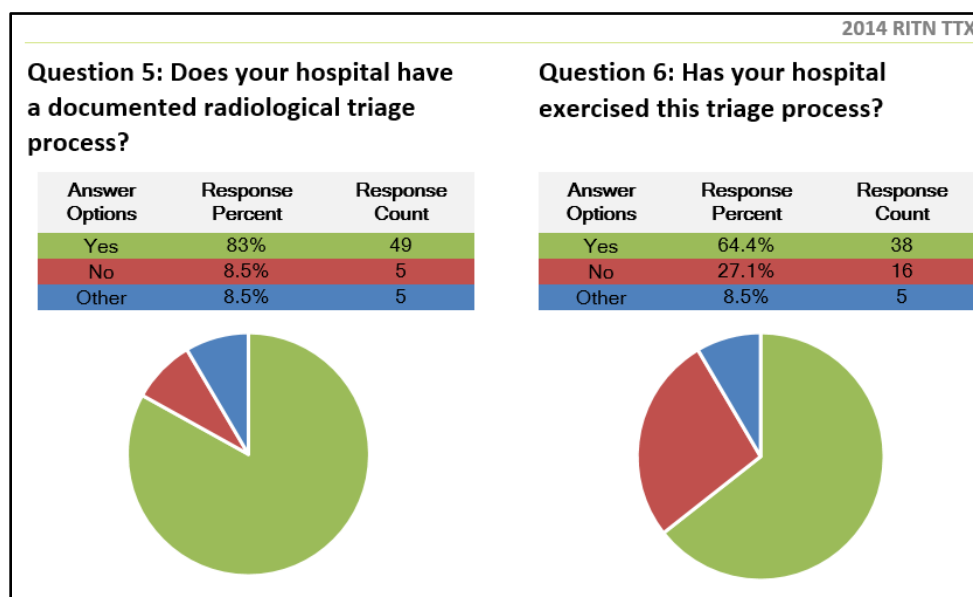


Figure 4. 2014 Tabletop exercise responses regarding the triage process.

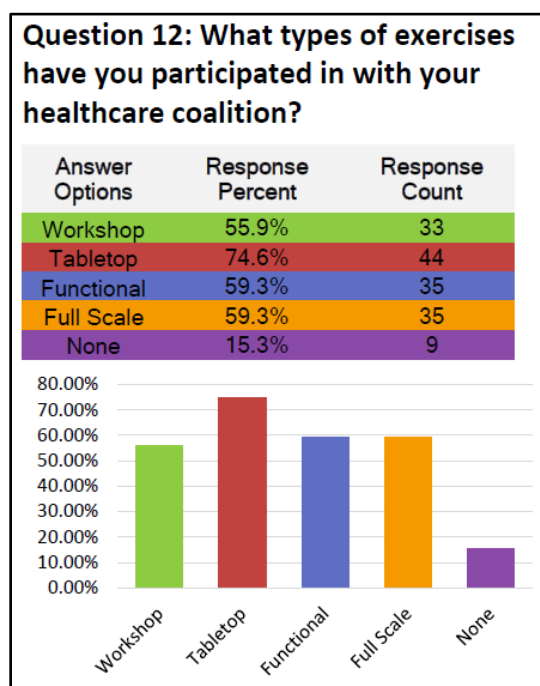


Figure 5. 2014 Tabletop exercise responses regarding integration with the local healthcare coalition.

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Training tasks: Training options have expanded as RITN has grown. As shown in Figure 6, centers can now choose between conducting Basic Radiation Training, sending a physician to the REAC/TS training, conducting an Acute Radiation Syndrome Medical Grand rounds session, and having a site assessment conducted. In addition, centers can conduct community outreach and education using the RITN Overview Presentation. All of these materials, except REAC/TS training, are available unrestricted, through the RITN website. The RITN web based training catalog includes:

1. Introduction to RITN
2. RITN Concept of Operations
3. GETS 101
4. Satellite telephone 101
5. Basic Radiation Training
6. Non-medical Radiation Awareness Training

The online learning management system allows RITN center staff to complete the full course at their own pace and receive an electronic certificate of completion after meeting all the course objectives including knowledge assessments. Since 2006 RITN has had a hand in the disaster response training or education of over 11,000 medical staff affiliated with RITN hospitals.

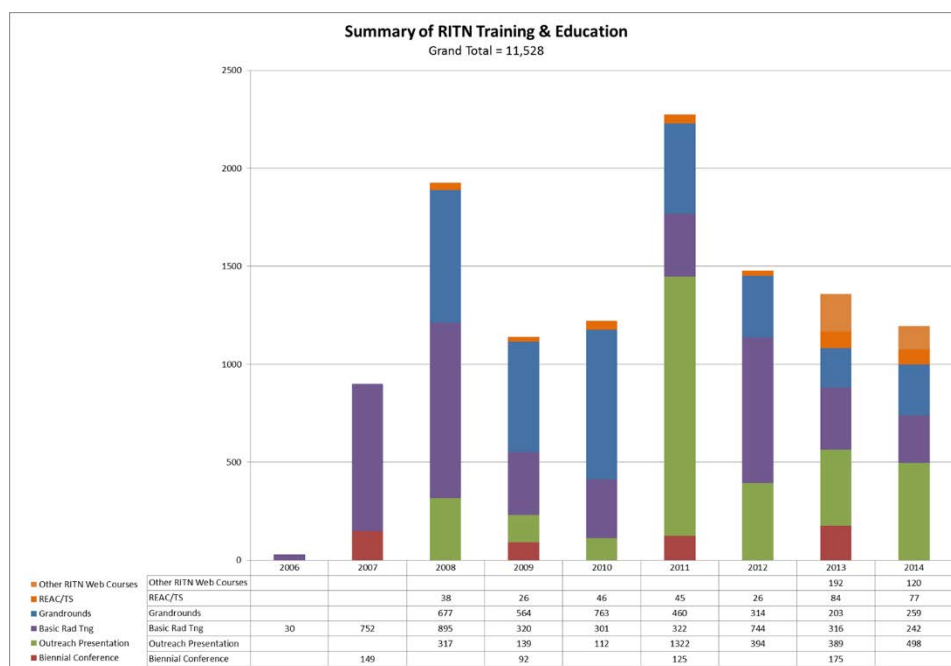


Figure 6. RITN center staff training accomplished by year.

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In 2011, RITN initiated the Site Assessment program where a RITN Control Cell staff member reviewed existing documentation at multiple RITN transplant centers using a standardized checklist (Figure 7). Areas evaluated included Casualty Processing, Outpatient Treatment of Casualties, Inpatient Treatment of Casualties, Coordination with City, State and Regional Assets, and Documentation.

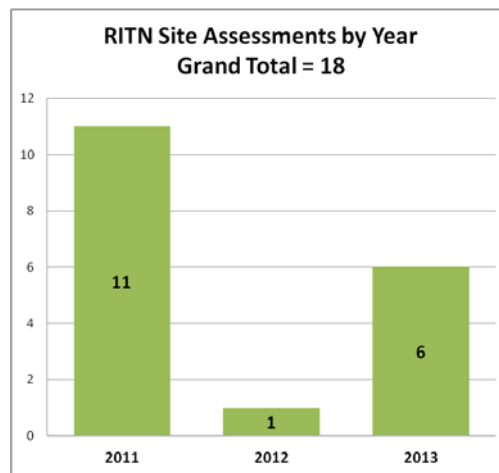


Figure 7. RITN center site assessments by year.

The Site Assessment Checklist formed the basis for revisions to the standard operation procedure (SOP) template and all centers updated their local SOPs using the new template.

The RITN continuously seeks to formalize the partnerships developed with federal agencies and organizations.

Memoranda of Understanding (MOU) are established with the following groups to collaborate on preparedness efforts:

- ASBMT since 2006
- Department of Health and Human Services – Office of the Assistant Secretary for Preparedness and Response (HHS-ASPR) since 2007
- AABB-Disasters Task Force since 2008
- New England Center for Emergency Preparedness (NECEP) since 2010

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- European Group for Blood and Marrow Transplantation - Nuclear Accident Committee (EBMT-NAC) since 2011

Additionally, the RITN maintains and develops informal relationships to increase awareness about RITN worldwide through close interaction with:

- Biomedical Advanced Research and Development Authority (BARDA)
- Health Resources and Services Administration (HRSA)
- World Health Organization - Radiation Emergency Medical Preparedness and Assistance Network (WHO-REMPAN)
- Radiation Emergency Assistance Center and Training Site (REAC/TS)
- Armed Forces Radiobiology Research Institute (AFRRI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institutes of Health (NIH) - National Library of Medicine (NLM) - Radiation Emergency Medical Management (REMM)
- American Hospital Association (AHA)
- American Burn Association (ABA)
- Association of State and Territorial Health Officials (ASTHO)
- National Association of City and County Health Officials (NACCHO)
- Veteran's Administration Health System
- Centers for Medical Countermeasures Against Radiation (CMCR)
- National Security Council staff
- National Alliance for Radiation Readiness (NARR)

RITN receives at no cost, access to Health Care Standard® (HCS®) software through a partnership with the developer Global Emergency Resources. This software allows the RITN to consolidate participating hospitals Capability Reports and to communicate situation status updates to the network through a web based interface. Annual tests are conducted to ensure that users are familiar with the system and that it is capable of receiving and consolidating submitted data. This system allowed RITN to collect the bed availability and on-hand G-CSF quantities throughout the network.



The Assistant Secretary for Preparedness and Response from the Department of Health and Human Services has been a partner since the foundation of RITN. This partnership is formalized

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through an MOU and is prominently displayed on the Department of Health and Human Services website for Public Health Emergencies on the Chemical, Biological, Radiological, Nuclear and Explosive Branch page, (<http://www.PHE.gov/about/oem/cbrne>, and Figure 8):



Figure 8. Chemical, Biological, Radiological, Nuclear and Explosive Branch webpage noting the partnership with RITN.

NMDP's critical functions must remain operational during contingency situations that directly affect the Coordinating Center.

Operational Continuity Planning (OCP) is essential for world-class organizations to meet the myriad of 21st century emergencies; this is evident by the visibility of many standards, such as ISO 22301:2012 which specifies requirements to plan, establish, implement, operate, monitor,

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review, maintain and continually improve a documented management system to protect against, reduce the likelihood of occurrence, prepare for, respond to, and recover from disruptive incidents when they arise. The Operational Continuity Plan is comprised of plans, systems, and processes for resuming NMDP operations in the shortest time possible following a severe operational disruption. OCP focuses on increasing the resiliency of the staff essential to conduct recovery operations, the facilities required to house these staff members, and the specialized long lead time equipment needed to connect these staff members to our data center from remote locations.

The OCP mitigates the effect of the many incident categories that may adversely impact NMDP operations. The OCP does not specifically plan for each possible hazard to the organization, rather it has a broad scope with a flexible and scalable response to allow for a successful activation in response to various catastrophic impacts ranging from fires, flooding, pandemics, extended evacuations (due to building damage, local chemical spill, or other hazards making the facilities unusable), to extended service outages such as water, electricity or sewer services. The OCP does not include NMDP Data Center incidents, as these are covered by the Information Services department through the Disaster Recovery program. NMDP continues to annually test its OCP to validate functionality with the continually changing information system environment as well as the growing organization structure and operational complexity.

During the performance period, the NMDP responded to an incident that required a partial activation of the OCP. In January 2014 Winter Storm Ion required office closures and the relocation of KitMaker services. Following the storm a formal after action review was conducted where nine areas of improvement were identified and tasked out to be corrected by the appropriate staff. As of May 2015 all nine issues have been addressed or deferred due to immediate barriers to implementation that will be resolved through the upcoming move to the new headquarters in late 2015. These areas ranged from simple messaging changes, to training of staff on the use of remote access systems, to expediting the distribution of laptops to staff that were scheduled to be issued a laptop later that year. A full list of the issues as well as the status is below:

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Issue/Area for Improvement	Corrective Action	Comments	Status
Initial e-mail notification did not contain all pertinent HR information.	Incorporate HR staff into the development of emergency messages.	SOPs were updated to include HR contacts.	Completed
Supervisors were unable to contact staff.	Supervisors should be granted access to contact information within Vista for assigned staff.	30OCT14 Updates being made to Vista to allow supervisors access to numbers	Completed
4. Using the term "closed" created confusion as to the current status of NMDP operations.	Remove any language containing "closed" from future ENS messages and instead provide specific information about any impacts to NMDP operations or job functions.	SOPs were updated.	Completed
Some users were unable and/or unaware with how to connect through VPN.	Develop additional job aids to assist staff in connecting through VPN.	Job aids available through the Service Center.	Completed
	Conduct training for staff on how to connect through the VPN.	Training will be self paced using job aids that are post on insideNMDP.	Completed
	Supervisors should encourage staff to regularly test their issued equipment remotely.	This task is an on going process that the EP Team is developing into all BCP exercises.	Completed
Not all staff selected to work remotely are issued laptops.	Departments are encouraged to identify staff that currently do not have laptops and develop an implementation strategy in coordination with IT.	Through FY15 laptop issue in preparation for move to new facility; 85% of staff assigned to critical tasks have laptops assigned, remaining 15% will have laptops on hold by IT for incidents.	Completed
Some departments still rely on traditional fax machines.	Departments are encouraged to review how RightFax can be implemented within their operations.	IT conducted a meeting with department stakeholders to educate about RightFax. As part of transisiton to new facility RightFax numbers will be assigned to all staff who require faxes.	Deferred until move to new facility
	Conduct training and develop job aids for new RightFax users.	Job aid available on insideNMDP through the Technology Tools and Resources page.	Completed

Other OCP support activities included an update of the NMDP plans to meet the requirements specified in [ISO standard 22301:2012](#) (Societal security -- Business continuity management systems). The emergency communications system components (satellite telephones, GETS cards, and the mass telephonic alert system) were maintained and tested. The Operational Continuity Steering Committee reviewed changes and additions to the Critical Task List at their annual meeting. The committee is co-chaired by the Chief Medical Officer and the Strategic

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Development Officer and seated by the Chief Information Officer; Chief Financial Officer; Senior VP, Legal, Risk and Network Affairs; and the Senior VP, Operations.

Development of Science and Technology for Rapid Identification of Matched Donors

Increasing the resolution and quality of the HLA testing of volunteers on the Registry will speed donor selection.

In 2014, NMDP donor centers (including Department of Defense (DoD)) and recruitment groups recruited 191,016 minority race and 197,626 Caucasian donors, for a total of 388,642 U.S. donors added to the registry. Navy funding supported the HLA typing of 83,099 donors (excluding DoD) of this culturally diverse group (48% minority).

Advancing technology improved performance and pricing

The NMDP typing strategy maximizes the use of funds by utilizing new typing methodologies that deliver a higher resolution of results at a lower cost than previous methods. The overall goal is to ensure that new donors are listed on the registry with the best possible resolution and number of loci tested. This is particularly critical during times of a contingency where well HLA-characterized adult donors can be readily matched to patients in need of HCT for ARS.

- Since April 2014, all new donors are typed at minimum of HLA-A, B, C, DRB1, DQB1, and DPB1.

Two-Step recruitment at live drive registration

In order to further our understanding of donor personal commitment and its effect on downstream donor availability, the NMDP piloted a 2-step donor recruitment study. The hypothesis is that those who pro-actively take a second activation step will be more committed to being on the registry and available if called. Several thousand live drive recruits were asked to take an additional step to activate their membership, in order to have their sample typed and to be listed on the registry. Much like credit card activation, the new recruit was required to call in to an automated phone line, text in an activation confirmation, or enter an activation confirmation online.

Results show that approximately 45% of those who attended a 2-Step live drive followed through with the activation step. While this is a relatively low follow-through rate, those that do follow through have demonstrated high levels of commitment when called on behalf of a patient. Availability rate when called for Confirmatory Typing is approximately 71% for 2-Step donors, similar to the availability rate of ~76% for a control group of donors who registered via online registration (DIY), and higher than the availability rate of ~48% for a control group of donors who attended a standard live drive.

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DNA storage methods transition to frozen buccal swab model

Be The Match Registry member samples stored at the Biorepository provide the basis for Customized Typing requested on behalf of patients, for rapid testing in the event of a national disaster, and for prospective registry upgrade typing. The transition from controlled room temperature storage to frozen storage at -30°C has been designed to preserve the long-term utility of this valuable resource.

Baseline time point samples, both at controlled room temperature and short-term frozen (-30°C), have been tested at two labs for DNA quantity and quality, and typing at HLA-A, B, C, DRB1, DQB1, DPB1 by 3 methods:

- High resolution SBT (sequence-based typing) with Sanger methodology
- High resolution SBT with long range NGS (next generation sequencing) methodology
- Intermediate resolution with SSO (sequence specific oligonucleotide) methodology

Baseline results indicate similar DNA quantity and quality from both frozen and room temperature swabs, and HLA concordance with SBT and SSO HLA typing methodologies. However, with the long range NGS methodology, there were a few discrepancies and some amplification failures observed with the frozen samples (rate of 3.74%) that were not observed with the room temperature cohort. This elevated rate of problematic loci for the frozen samples could be inherent to the longer amplicons being tested, which may be more fragile after a freeze/thaw cycle. Therefore additional baseline samples were shipped in a frozen state to retain their integrity until the lab began testing the samples, as opposed to the samples undergoing a thaw cycle during ambient shipping conditions en-route to the lab. While analysis of the additional samples indicate continued problems for amplifying Class II loci with the long range NGS approach, the problems are equally present for both the controlled room temperature as well as the frozen-shipped-frozen swabs.

The one year time point of the study is currently undergoing testing at the laboratories, with a cohort of the buccal swab samples stored for slightly more than one year at frozen conditions (-30°C) and a cohort of control samples stored at room temperature. The samples that were stored frozen were shipped to the typing laboratories on dry ice to preserve their frozen state until the lab was ready to extract the DNA and amplify.

Enhancing Non-HLA data for selected donors

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ABO/Rh at Recruitment by DNA-based testing

Due to recent advances in testing methodology (primarily due to Next-Generation Sequencing), it became feasible to explore adding ABO/RhD as another locus that could be tested from the same sample at the same time as recruitment HLA testing. The NMDP made sets of 1000 blind samples available to two laboratories for validation testing. A high degree of concordance between genetic ABO/RhD result and known serological ABO/Rh was seen for both sets (>97% concordance). DNA-based ABO/RhD testing on a portion of recruitment samples began in August, 2014. As of October 01, 2014, all recruitment samples receive ABO/RhD testing along with HLA testing.

Quality of HLA typings improved

The NMDP's comprehensive quality control program has supported the successful increase in the quality of HLA typing received through the contract laboratory network. Blind Quality Control (QC) samples are added to each weekly shipment of new donor recruitment samples. These QC samples comprise 2.5% of each shipment and are indistinguishable from the other samples. With the help of this grant, there are more than 700 QC Masters in active rotation, representing over 95% of common well-documented (CWD) HLA alleles.

In previous years, the majority of QC swabs are created by the Biorepository staff from expanded B-Lymphoblastoid cell line (B-LCL) vials chosen from the CIBMTR Research Repository. In an effort to decrease the cost and increase the sustainability of the QC program, alternate sources of material that would yield more cost-effective types of QC swab samples were investigated.

Purified genomic DNA absorbed onto cotton-tipped swabs ("DNA swabs") has proven to be successful and cost-effective alternative QC sample type. This approach has great potential to expand allelic coverage and diversity of HLA in the QC program, by utilizing stored NMDP volunteer QC donor blood and Registry donors with desirable HLA types.

- All recruitment and customized typing laboratories were able to successfully and accurately type blind purified QC DNA swabs.
- 233 existing volunteer QC donors with stored repository blood aliquots were selected for DNA extraction and creation of DNA swabs.
- A total of 299 sample lots were added through DNA extraction for creation of DNA swabs.

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NGS data evaluation from QC DNA swabs

NMDP maintains a robust blind quality control program for all third party contracted immunogenetic testing. Most of the current QC sample inventory has been tested by Sanger SBT or targeted exon NGS methods. The overall goal of the project was to establish an inventory of QC samples lots that had been well characterized by long range or whole gene NGS sequencing and determine if there were any limitations for the sample type with the methodology applications.

A cohort of 200 master lots from the QC collection were selected, and samples were sent in the form of DNA swabs to a laboratory for long range or full gene NGS HLA typing. The following goals were outlined for this effort:

- Evaluation of sample suitability for NGS (next-generation sequencing) typing methods.
- Cross-comparison of NGS typing platform results.
- Collection of sequence-based HLA allele results for the QC sample typing database.

Results from the first 200 samples clearly showed that the age of the swab (date of QC swab production) inversely correlated with the ability to achieve long range PCR amplification of the DNA obtained from the cotton tipped swab used by NMDP for donor recruitment. For samples greater than two years old, amplicons of greater than 5 kb in length were not reliably reproducible. For samples between six months and two years old, select samples did not produce high quality results.

Therefore, a new cohort of 200 samples was tested at a second laboratory using a different NGS platform, but still reliant on long range PCR amplification. This second set consisted of QC swabs that had been produced in the last eight months and the two cohorts had 103 master QC lots in common. Results were obtained from all of the 200 samples in this cohort as of October of 2015 which concluded the typing project.

The project established that QC swab samples greater than six months of age begin to decline in their suitability to be used for NGS methods that rely on long range PCR amplification and are

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essentially not testable at two years of age by these methods. There was little difference in the results obtained from the 103 samples that were tested on both platforms.

NMDP now has 103 QC master lots that have been well characterized at HLA-A, B, C, DRB1, DQB1, and DPB1 by multiple long range NGS methods for use as future laboratory blind QC samples. Additionally, there are 194 QC master lots that have been typed at least one time by a long range NGS method.

Cord Blood Unit QC sample collection

NMDP has actively engaged network cord blood banks to acquire units that are not deemed suitable for banking in an effort to increase the diversity of cord blood material for the cord QC program. In the grant period, the units available for use in the cord QC program has nearly doubled in total number and expanded allelic diversity. NMDP will continue this approach with the goal of increasing allelic diversity and number of unique units available.

Additional Projects to Ensure Quality of HLA Data

Following the success of the review of rare allele typing and the identification of alleles which were incorrectly typed, this project has moved to the evaluation of less common alleles reported in the Be The Match Registry. Review of HLA results of less common alleles reported to the NMDP on adult volunteer samples revealed typings that were suspicious and may have been incorrectly reported due to various reasons including:

- Typing methodologies used to report the allele were problematic
- Allele reporting of the allele in question were more prevalent prior to 2002
- Presence of two less common alleles in a donor typing
- Primary data interpretation does not support the uncommon allele
- Allele reported in a race/ethnic group different from the reference cell in the IMGT/HLA database

Samples were identified using the above rules and retyped by SSOP technology. A subset of the SSOP results was confirmed by SBT to ensure accuracy. A total of 330 samples were typed through the project.

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Table 2 shows the results of the retyping of 201 HLA-B non-CWD reported allele calls that initially had supporting primary data. The low confirmation rate (24%) demonstrated that the primary data reporting had inaccurate results as the actual rare/uncommon allele calls.

Table 2. Results of the re-typing of 201 HLA-B non-CWD allelic results reported to the Registry.

Outcome	N (% total)
Confirmed	49 (24%)
Corrected to common	122 (61%)
Corrected to uncommon	22 (11%)
Unclear	6 (3%)
New	2 (1%)

These projects also identify problematic alleles that become candidates for inclusion within the NMDP QC program. A manuscript on earlier retyping work was published in Tissue Antigens.

- Unrelated donor HLA re-typing effort to verify prevalence of newer alleles:
 - o HLA-A*24:23, A*30:10, DRB1*08:11, DRB1*15:03, and DRB1*15:06.
Kempenich J1, Dehn J, Flickinger G, Setterholm M. Tissue Antigens. 2014 Nov;84(5):489-91. doi: 10.1111/tan.12442. Epub 2014 Sep 21.

Work-Up Ready Pre-screened Donor

The goal of this project is to provide transplant centers with a pool of prescreened, workup ready donors in order to decrease time to transplant. During the grant period, the NMDP identified a pool of donors with the five most common unphased genotypes observed in patients searching for an unrelated donor. New patients with these genotypes are submitted to the NMDP for a

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preliminary search at least two times per month, on average. Across these different genotypes, many of the donors lack desired non-HLA information, such as CMV status, which can only be confirmed with a new donor blood sample.

To maximize the amount of information gathered and to streamline the process, the NMDP is focusing on male donors under the age of 26, and strategically upgrading information, including availability, ABO type, CMV status, DPB1 typing, and Killer Immunoglobulin-like Receptor (KIR) typing, using the following process flow:

1. The NMDP identifies donors of interest
2. NMDP donor contact team reaches out to the donor and upon contact:
 - a. Administers a preliminary health history questionnaire, which populates a last contact date for the donor visible to transplant centers
 - b. Schedules a blood draw for the donor at a contract laboratory
 - c. Simultaneously schedules an information session for the donor to occur after the blood draw
3. When a donor is confirmed as available and is scheduled for a blood draw, the NMDP ships a blood sample kit to the draw site and requests that the donor's existing biorepository sample be sent for DPB1 and KIR typing.
4. The contract laboratory performs ABO/CMV serologic testing and DPB1/KIR testing
5. While the sample is being testing, the NMDP adult donor management services team conducts an information session with the donor, further educating the donor on the donation process and confirming continued availability and interest.
6. The NMDP continues to monitor new preliminary search requests, and when a patient with one of the five genotypes of interest is identified, cross-references the patient information with the characterized donor pool identified by the above process. The ideal donor for these patients is not only a 10/10 HLA match to the patient, but is also ABO/CMV matched, DPB1 matched or permissively-mismatched, and carries the appropriate KIR genes to promote relapse-free survival if the patient is diagnosed with AML. These donors are then recommended to the Transplant Center via the NMDP Case Manager as a prescreened donor who can be taken immediately to workup, if desired.

This project started donor contact in June 2015 and results will be reported in the next grant period.

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Primary DNA typing data can be used within the Registry to improve the quality and resolution of volunteer donor HLA assignments.

- A system for storing genotype lists (GL service) was implemented. This allows storage and transmission of HLA allele ambiguities without using human-curated letter ambiguity codes. This GL service was deployed and tested at gl.nmdp.org for all available IMGT/HLA database versions (Table 3). Strict enforcement of version-specific nomenclature constraints are in place. A landing page has been developed that links from gl.nmdp.org to the current IMGT/HLA version (3.18.0), an ‘explorer’ application that provides a GUI interface to work with the service and a set of developer resources with links to the source code and documentation.

Table 3 – IMGT/HLA database versions where GL-service is active at gl.nmdp.org

1.5.0	1.14.0	2.6.0	2.15.0	2.24.0	3.2.0	3.11.0
1.6.0	1.15.0	2.7.0	2.16.0	2.25.0	3.3.0	3.12.0
1.7.0	1.16.0	2.8.0	2.17.0	2.25.1	3.4.0	3.13.1
1.8.0	2.0.0	2.9.0	2.18.0	2.25.2	3.5.0	3.14.0
1.9.0	2.1.0	2.10.0	2.19.0	2.26.0	3.6.0	3.15.0
1.10.0	2.2.0	2.11.0	2.20.0	2.27.0	3.7.0	3.16.0
1.11.0	2.3.0	2.12.0	2.21.0	2.28.0	3.8.0	3.17.0
1.12.0	2.4.0	2.13.0	2.22.0	3.0.0	3.9.0	3.18.0
1.13.0	2.5.0	2.14.0	2.23.0	3.1.0	3.10.0	

- A GL Lift Over service was deployed and tested at gl.nmdp.org. (<https://gl.nmdp.org/liftover>). This is a RESTful microservice for ‘lifting over’ a GL resource from a source GL service (version) to a target GL service (version). This facilitates unifying datasets generated under different nomenclature versions and addresses allele renaming, creation and deletion.
- A Data Standards Hackathon (DaSH) meeting was held in Bethesda, Maryland on September 26-27, 2014 with the goal of having implementers work to integrate a toolset with the various NGS systems and analysis software packages currently in use. There were 40 attendees including representatives from all NGS hardware and software vendors, NIH, academia and the donor registry community. The main outcomes from the meeting were the development of the MIRING (Minimal Information for Reporting Immunogenomic NGS Genotyping) categories and the HML (Histoimmunogenetics Markup Language) message format.

Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor or cord blood unit.

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The following was accomplished during the grant period:

- Bayes Classifier for Multi-Race: NMDP implemented a web service to perform multi-race imputation using a Bayes' Classifier, which is a statistical methodology to minimize the probability of misclassification. This tool was used for analysis in a number of studies including the Ancestry Questionnaire Phase 1 and the search prognosis tool (see below). Work is ongoing to incorporate the Bayes' Classifier into the Expectation Maximization (EM) kernel and the HapLogic matching kernel to address the unmet need of multi-race donors and patients.
- Six abstracts were presented at the 2015 EFI annual meeting
 - Using SNPs to improve phasing of HLA haplotypes. Paunic V, Freeman J, Maiers M.
 - Impudigree: an imputation-based automated pedigree tool. Freeman J, Madbouly A, Maiers M
 - Improved HLA-Based Race/Ethnic Classification Using Donor Geography and Census Demographic Data. Gragert L, Albrecht M, Besse K, Bashyal P, Maiers M
 - HLA Diversity in the Ezer Mizion Registry. Halagan M, Stein J, Manor S, Madbouly A, Gragert L, Shriki N, Yaniv I, Maiers M, Zisser B
 - HLA Class II Six-locus DRB3/4/5~DRB1~DQA1~DQB1~DPA1~DPB1 High Resolution Haplotype Frequencies of the Major US Populations. Halagan M, Gragert L, Hurley C, Masaberg C, Maiers M
 - HLA allele and haplotype frequencies for Christian and Muslim Arab donors in Hadassah registry. Bishara A, Brautbar C, Israel S, Halagan M, Madbouly A, Fernandez-Viña M, Maiers M

Search Prognosis - Genotype Frequency Study

The goal of this project was to develop a simple scoring system that uses a patient's genotype frequency to determine whether the patient is likely to have a 10/10 donor (good search), a 9/10 donor (fair search), or neither (poor search). The data collection and analysis for this project was completed and a manuscript is under development. The genotype frequency boundaries for the three prognosis categories were defined in each of the four broad race groups - African American (AFA), Hispanic (HIS), White (WH), and Asian/Pacific Islander (API) - and an unknown race group (UNK) using a proportional odds model on a training data set of over 2400 patients.

A validation analysis was conducted in a second cohort (n=2411) to assess the precision of using genotype frequency to predict search prognosis revealing strong correlation with the results of the initial discovery cohort. Additionally, a second validation was performed against an

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independent cohort previously resolved as having a 10/10, 9/10, or no such matched donor, which demonstrated the genotype frequency categories defined here provide differential likelihood of donor matching. A prototype online tool that can output a search prognosis (good, fair, or poor) by simply entering a patient's HLA has also been developed.

Unique and less common patient haplotypes

HapLogic III offers accurate matching predictions for patients and donors with good haplotype representation in the registry. Patient entry into Traxis allows TCs to report patients' race and ethnicity; however instances still occur where the patient HLA entered into Traxis cannot be characterized by HapLogic. This may happen when a patient's reported race falls into a sub race group where the haplotype frequency tables were derived from a small sample size and may be incomplete. This situation also happens in multi-race patients, as Traxis does not allow entry of multi race information, or in the case of previously uncharacterized or uncommon patient HLA. Close examination of these types of patient searches will help to gain a better understanding of the frequency of this event and identify how often patients' HLA can be described by another race table or when it cannot be described in any race table, and determine which haplotypes lacking from the haplotype frequency reference data have representation among the low-resolution typed donor pool.

To examine these searches, from March 2014 through March 2015, we identified NMDP domestic preliminary search patients with HLA typing for which there were no haplotype pairs in any race group. The incidence of patient searches which lacked haplotype frequency data overall in *any* race group was 1.2% (144 of 12172 preliminary searches). We also evaluated whether haplotypes could be described using multiple race tables. Of the 144 patients in the cohort, 27 had two haplotypes projected using race tables from multiple race groups, but 117 (81%) had at least 1 uncommon haplotype that had not been previously characterized in the NMDP haplotype frequency reference data. Non-Caucasian patients had the highest incidence of uncommon patient haplotypes. Up to 20 potential 8/8 or 10/10 donors were typed for each patient, but no 10/10 donors were identified for patients with uncommon haplotypes. Five patients had 8/8 donors identified, and all had uncommon DRB1-DQB1 associations. In some cases the best potential mismatched donors were typed to aid in identification of a suitable donor for these difficult searches. For these cases, 38% (55 of the 144 patients) had a suitable donor (7/8 matched or better) identified either before or after additional donor HLA typing was performed.

The incidence of patient searches which lack haplotype frequency data in the patient's self-reported race and/or ethnicity was 3.1% (383 of 12172 preliminary searches). Of these 383 patient searches, 55 (14%) had suboptimal HapLogic predictions due to the lack of haplotype

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frequency data in their self-identified race group. Communication with the transplant centers resulted in race and/or ethnicity changes for many of these patients, which resulted in improved and accurate HapLogic predictions for potentially matched donors and CBUs.

This project has provided valuable information and insight into these difficult patient searches. Characterizing the occurrence of these events can help target intervention in future patient searches and understand how search strategy can assist these patients in the identification of an URD. This project was completed in March 2015 and an abstract presented at the American Society of Histocompatibility and Immunogenetics (ASHI) Annual Meeting 2015.¹

Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

Donor Match Rate Studies

DPB1 Donor Selection Study

Recent research suggests that beyond 8/8 allele level matching at HLA-A, B, C, DRB1, matching at HLA-DPB1 should be considered to improve patient survival rates in allogeneic stem cell transplantation. Non-permissive T-cell epitope (TCE) mismatches at DPB1 are associated with a higher incidence of transplant related mortality in patients that have a 10/10 matched donor. The aim of the project is to identify the DPB1 TCE match rates of patients with 10/10 URD in the Be The Match Registry as well as understand how much prospective donor testing is required to optimize DPB1 matching.

A total of 535 patients were enrolled into the study from 33 domestic transplant centers. 156 donors have been typed at DPB1 on behalf of these patient searches. Patient T cell epitope group (TCE) was determined based on the DPB1 alleles present, and classified according to highest immunogenic reactivity (*i.e.* TCE group 1 > group 2 > group 3).

DPB1 matching rates greatly improved for patients regardless of TCE group. The strategy to identify well matched donors that are either DPB1 allele matched or permissively mismatched

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does not hinder search progression and is likely for a majority of patients enrolled in the study. The results are summarized in Table 4. As more donors are added to the registry with DPB1 typing, this should improve pre-typing match rates. An abstract of the initial patient search analysis was submitted and presented as a poster at the BMT Tandem Meetings in February 2015.²

	Pre Donor Typing TCE Match(% of Total)	Post Donor Typing TCE Match (% of Total)	Total
Group 1	9 (24%)	17 (45%)	38
Group 2	37 (27%)	78 (57%)	137
Group 3	204 (57%)	288 (80%)	360
Total	250 (47%)	383 (72%)	535

Table 4. Results of the DPB1 donor selection study

Using Genotype Frequency Prognosis to Improve Patient Path to Transplant

This project used a previously developed prognostic scoring system based on patient genotype frequency to identify the most difficult patient preliminary searches and prompt intervention for search strategy advice and donor selection. During the project period:

- A SQL database query and internet-based tool have been developed to identify new, domestic preliminary patients with poor search prognosis across all broad race groups using the patient's HLA typing. These cases have been previously determined to have limited donor options, where identifying a 9/10 or better matched donor may not be possible.
- A total of 68 domestic, preliminary searches with poor search prognosis were enrolled in the intervention group for this project. These searches received proactive aid via donor contact and/or donor typing if potential 9/10 or better matched donors (predictions >1%) are identified on the search. Search Strategy Advice (SSA) is requested from an NMDP

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Immunogenetic Specialist if no suitable matches are identified. The likely best matched donors and/or cord blood units are highlighted on the search strategy reviews to bring them to the transplant centers attention..

- A total of 64 domestic, preliminary searches were enrolled in the non-intervention group. This group received no proactive aid from the NMDP and will be used as a control to the intervention group to determine if proactive case intervention makes a difference in case outcome.
- Donors were sent for proactive NMDP contact for 14 intervention cases and for proactive typing for 30 cases. An HLA review has been requested for 33 cases. Some cases have received more than 1 intervention (donor contact/donor typing/HLA review).
- Transplant centers have been contacted regarding 24 intervention cases.

NIH Search Support

The National Institutes of Health (NIH) has been accepted as an NMDP transplant center since 2007. Prior to that time, the NIH, representing our Nation's premier medical research endeavor, was not applying their considerable problem-solving skills to issues surrounding unrelated donor transplantation. The NMDP, with ONR support, set out to remedy that deficiency by entering into collaboration with NIH. This collaboration has been extremely successful.

The NMDP is collaborating with intramural NIH transplant programs from the National Cancer Institute, the National Heart Lung and Blood Institute and the National Institute of Allergy and Infectious Diseases. These programs are investigating alternative approaches in unrelated donor transplantation to improve patient outcomes. The actual transplants and the investigational portions of each transplant (i.e., the research protocols) are supported entirely with NIH funds. Navy funding supplies support for donor identification, selection and collection. NMDP donors are not research subjects on these protocols because the donors are making standard donations for accepted transplant indications. The research component of these transplants is conducted entirely by NIH intramural program staff and funded entirely with NIH dollars. The NMDP provided support for the collection of 20 products (12 PBSC, 4 marrow, 2 cord blood units and 2 therapeutic T cell products) under this grant.

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Immunogenetic Studies in Transplantation

HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations, it will not be possible to delay transplant until a perfectly matched donor can be found.

Donor/Recipient Pair Project

A retrospective Donor/Recipient Pair HLA typing project to characterize class I (HLA-A, B and C) and class II (HLA-DRB, DQB1, DQA1, DPA1 and DPB1) alleles of stored donor/recipient paired samples was initiated in 1994. To date, over 19,000 unrelated paired samples and more than 900 related paired samples from the Repository have been fully characterized and the resultant data are available for research use. The data are stored in an NMDP developed database and is available to any researcher with a CIBMTR approved study wishing to analyze the impact of matching as either the focus of, or as a variable in a research study. To date, over 135 published research studies (not including abstracts) have used these data, including the seminal publication from Lee et al, describing the importance of high resolution HLA matching in unrelated donor transplantation that formed the basis for NMDP's updated guidelines for unrelated adult donor HCT HLA matching. The allele level data are also used to assess genetic diversity within the NMDP transplant population. Genetic diversity analyses have focused on the evaluation of HLA haplotypes within the donor and recipient data set made possible by the completeness of the major histocompatibility complex (MHC) loci characterized (11 loci), the level of resolution achieved and the high level of quality control. These studies have generated multiple manuscripts and abstracts to date with work still in progress. The statistical models developed for the project data were also applied to HapLogic, HapLogic II and HapLogic III.

In 2013, the typing strategy for the donor/cord and recipient samples being tested was significantly changed to take advantage of high quality results and the reduced cost of full panel high resolution typing including; HLA-A, B, C, DRB, DQB1 and DPB1. High resolution panel typing allows for sample identity conformation thus resulting in the discontinuation of intermediate resolution typing. The project has continued to not type the DQA1 locus due to the greater than 98% linkage seen with DQB1 and continues high resolution DPB1 typing. Recent studies have demonstrated significant impact of permissive and non-permissive DPB1 matching on mortality. Exchange of DQA1 typing and addition of DPB1 typing did not impact the total cost.

During the period of performance, HLA typing labs were contracted to type 2,536 unrelated and 1,128 related transplant pairs for the project. Of the unrelated pairs, 92 and 171 were of single and double cord blood transplant cases, respectively. All samples were typed using NGS methodologies at a minimum of ARS group resolution. After successful completion of the typing, each pair was audited for use in analyses. All samples were selected in collaboration with

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the CIBMTR Statistical Center to ensure the additional cases would benefit ongoing and future analyses. Transplantation practices are constantly evolving and the project will continue to enroll the most recent transplant pairs to ensure that changes in practice can be evaluated with fully quality controlled high resolution HLA data. With the implementation of the IPR database, we continue to audit sample groups that contain both KIR and high resolution HLA to allow for inclusion in studies.

HLA-DPB1 crossover frequency analysis of HLA matched sibling Donor/Recipient pairs

Previous studies have demonstrated a significant impact of DPB1 matching on aGVHD, relapse and transplant related mortality. The large genetic distance between the HLA-DPB1 locus and the remainder of the HLA loci may result in high rates of genetic crossover. Previously, the NMDP has not had access to samples to evaluate this phenomenon. The collection of a large cohort of presumed HLA identical sibling donor transplant pairs through the CIBMTR Related Donor Repository provided the opportunity to explore the role of HLA-DPB1 crossover and resultant mismatch in allogeneic HCT. The preliminary analysis of the frequency of HLA crossover events in a population of 993 pairs of related sibling transplants was recently completed. DPB1 crossover events resulting in a mismatch were observed in approximately 2.5% of the population. A quarter of the mismatches were non-permissive according to the TCE algorithm. The impact of the mismatches on clinical outcome will be evaluated in the next grant period. However, the low frequency of the events limits the statistical power to detect a difference in outcome.

KIR Copy Number Variation Analysis

Our collective knowledge of the structural diversity at the KIR gene level is still coarse, especially for unrelated and non-European populations. Dozens of structural haplotypes have been described for the KIR region. Most studies and typing's have been conducted at gene presence/absence (PA) resolution, and transplantation guidelines are at the PA genotype level. We hypothesized that copy number typing could allow more accurate haplotype predictions and therefore provide more refined haplotype frequencies. The improvements in haplotype predictions could potentially increase the resolution in association studies from the genotype level to the haplotype level.

Genotyping was performed at presence/absence (100%) and for gene copy number (CNV) (10%) resolution for 10,000 individuals in 5 populations: AFA, API, CAU, HIS, NAM. CNV testing

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was performed in collaboration with the Traherne laboratory at Cambridge Institute for Medical Research, University of Cambridge. Typing was completed during the performance period and data under analysis will be completed in the next grant period.

Antigen Recognition Site Mismatching study

Amino acid mismatches outside the antigen recognition site (ARS) (i.e., exons 2 and 3 for HLA class I and exon 2 for class II) are ignored under current HLA matching guidelines with the assumption that these differences are irrelevant. There is little data to confirm or refute this assumption; furthermore, the amount of data needed to form a conclusion is unattainable. In order to provide more information, the ARS allo-reactivity assessment project will provide insight into the allowable percent tolerance of matching needed outside of the ARS. It is collaboration between the NMDP and Europdonor under the direction of Machteld Oudshoorn and Franz Claas from Leiden, Netherlands.

Initial investigation of the Class II ARS mismatch of DRB1*14:01 and DRB1*14:54 and DRB3*02:01 and 02:02 respectively have produced preliminary results demonstrating two weakly positive and one positive alloreactive result. Interestingly, all positive results occurred in one direction only, which is DRB1*14:01 / DRB3*02:01 against DRB1*14:54 / DRB3*02:02. This data from the Class II analysis was presented in an oral abstract at the 2013 EFI conference in Maastricht, Netherlands. To confirm these results, we identified 135 additional donors via registry queries. Fresh blood draws were collected from 22 donors and peripheral blood mononuclear cells cryopreserved for evaluation. The samples were shipped to the project laboratory for testing with results expected to be reported in the next grant period.

Even when patient and donor are HLA matched, GVHD occurs, therefore, other loci may play a role.

- Research Web Services - We implemented two web-services for research: one for HLA validation and one for matching. These services are being used by EMMES in their Advantage EDC™ software to compute HLA “research” match grades to determine eligibility for BMT-CTN trials. The use of these web services insures that HLA assessment is consistent between EMMES and CIBMTR.
- We have continued the development and support of the Immunobiology Project Results database including preparing the application to be migrated to a new database platform (Oracle).
- The genotyping for the Clinical Ancestry Study was completed, bioinformatics genetic ancestry admixture and donor/recipient distance assigned and the statistical analysis is underway. The aim of this study is to investigate, for donor-recipient pairs that are

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matched at the five primary HLA loci (HLA-A, -C, -B, -DRB1 and -DQB1), how genetic ancestry similarity could affect transplant outcome. The specific objectives of the study are:

- Study the effect of differences in genetic ancestry, as detected by ancestry informative Single Nucleotide Polymorphisms (SNPs) for HLA matched unrelated donors and recipients, on HSCT transplantation outcomes.
- Study the effect of recipient non-HLA genetic ancestry on HSCT transplant outcomes.
- Evaluate the correlation of self-identified race with information derived from genetic ancestry studies.

Table 5 lists currently active and completed CIBMTR/NMDP-supported studies that are conducted on NMDP samples. The CIBMTR/NMDP encourages such collaborative projects and closely monitor them. Such studies are instrumental to understanding the role of non-HLA loci in HCT. The data is obtained and generated via NMDP donor and recipient research samples, along with their outcomes and demographics. The researchers are required to submit the interpreted results of all assays performed on the samples. The data submission requirement ensures that all sample testing yields information that is readily available to the HCT research community for subsequent analysis and eliminates or reduces duplicative testing to preserve resources and sample inventory. These results are stored in the IPR and IIDB databases, and associated with their samples in the CIBMTR Research Repository database.

Non-HLA data is available for use in research studies in a fashion analogous to the Donor/Recipient Pair Project generated HLA data and is made available, when possible, via the NMDP Bioinformatics web site. Data origin will be noted for all information stored, along with relevant citations. Access to the detailed data will be subject to the existing NMDP/CIBMTR data request procedures.

Table 5. Immunobiology typing projects utilizing NMDP samples and contributing data to the IPR database

Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
NK Cells, Their Receptors and Unrelated Donor Transplant ^{3,4}	J. Miller	2300 pairs	KIR	RT-PCR, FACS, SSO, MALDI-TOF	Yes
Survey of Diversity of Immune Response Genes in Unrelated Hematopoietic Stem Cell Transplantation	C. Hurley	40 Pairs	cytokine and KIR	SBT	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Candidate Gene Study to Examine the Impact of Chemokine and Chemokine Receptor Gene Polymorphisms on the Incidence and Severity of Acute and Chronic GVHD ⁵	R. Abdi	1300 pairs	CCL1, CCL2, CCR5, CCR2, CX3CR1	Taqman PCR	Yes
Functional Significance of Killer Ig-like Receptor (KIR) Genes in HLA Matched and Mismatched Unrelated HCT ⁶	B. Dupont, K. Hsu	2000 pairs	KIR	SSP	Yes
Functional Significance of Cytokine Gene Polymorphism in Modulation Risk of Post-Transplant Complications ⁷	E. Petersdorf	2500 pairs	>30 Immune response genes	Taqman PCR	Yes
Identification of Functional SNPs in Unrelated HCT ^{8,9}	E. Petersdorf	3500 pairs	Entire MHC region	Taqman PCR	In Process
Use of Female Donors with Pre-existing Antibody to H-Y Antigen will Result in Robust Serologic Response to H-Y Antigens in Male HSC transplantation Recipients ¹⁰	D. Miklos	288 pairs	H-Y Antigen	ELISA, protein array	Yes
Multiplexed Genotyping of Human Minor Histocompatibility Antigens (mHAg): Clinical Relevance of mHAg Disparity in Stem Cell Transplantation ¹¹	T. Ellis	730 pairs	mHAg	Allele-specific Primer Extension	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Genetic Polymorphisms in the Genes Encoding Human Interleukin-7 Receptor- α : Prognostic significance in Allogeneic Stem Cell Transplantation ¹²	K. Muller	851 pairs	IL-7	Taqman PCR	Yes
The Effect of Non-Inherited Maternal Antigens in Cord Blood Transplantation ¹³	L. Baxter-Lowe	102 pairs	HLA	SBT	Yes
Detection of HLA Antibody in Single Antigen HLA-Mismatched Unrelated Donor Transplants	S. Arai, D. Miklos	200 pairs	Anti-body	ELISA, Protein array	Yes
Detection of Donor-Directed, HLA-Specific Alloantibodies in Recipients of Unrelated Stem Cell Transplantation and Their Relationship to Graft/Patient Outcome ¹⁴	R. Bray	111 pairs	Anti-bodies	Flow cytometry	Yes
Genome-wide Association in Unrelated Donor Transplant Recipients and Donors: A Pilot Study	R. Goyal	858 pairs	> 600,000 Genome wide SNPs	Human 610 - Quad V1 arrays	Yes
SNPs in the p53 Pathway and Outcomes in URD HCT	B. DuPont	1500 pairs	p53, ATM, MDM2 and p21/Waf1	Taqman	In process
Association of Donor and Recipient Gene Polymorphisms of Drug and Innate Immune Response with Outcomes after URD HCT	V. Rocha	725 pairs	GSTP, GSTT, GSTM, UGT CD14, TIRAP, and NALPs	Taqman	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
To Develop and Test a Prognostic Index for Survival in CML URD HCT ⁷	A. Dickinson	1100 pairs	TNF, IL-1RA and IL-10	Taqman	Yes
Evaluation of TGF-β1 Promoter and Signal Peptide Polymorphisms as Risk Factors for Renal Dysfunction in HCT Patients Treated with Cyclosporine A ¹⁵	R. Shah	400 samples	TGF-β1	Taqman	Yes
Donor and Recipient Telomere Length as Predictors of Outcomes after Hematopoietic Stem Cell Transplant in Patients with Acquired Severe Aplastic Anemia ¹⁶	S. Gadalla	650 samples	Telomere length and Telomerase Polymorphisms	Taqman	Yes
Development of a GVHD Prevention Biodiagnostic Test	R. Somogyi	450 samples	Gene Expression Array	Array	Yes
Genetic polymorphisms and HCT related mortality Re: Pre-HCT conditioning in matched unrelated donor HCT ¹⁷	T. Hahn	>4,000 pairs	GWAS	Array	In process
Impact of CTLA4 SNPs on outcome after URD transplant ¹⁸	M. Jagasia	1,200 pairs	CTLA-4 SNPs	Taqman	Yes
KIR genotyping and immune function in MDS patients prior to unrelated donor transplantation ¹⁹	E. E. Warlick and J. Miller	970 samples	KIR genotype, expression and cellular function	SSP, flow cytometry and cellular assays	In process
Plasma YKL-40 and CHI3LI genotype to predict mortality after unrelated donor HCT	B. Kornblit	800 pairs	YKL-40 plasma levels and CHI3LI SNPs	ELISA and Taqman	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Natural killer cell genomics and outcomes after allogeneic transplantation for lymphoma	V. Bachanova, J. Miller, D. Weisdorf and L. Burns	800 pairs	KIR genotype, expression and cellular function	SSP, flow cytometry and cellular assays	Yes
Effect of genetic ancestry matching on HCT outcomes	A. Madbouly, M. Maiers and N. Majhail	2300 pairs	Ancestry Informative Markers	Taqman GWAS	Yes
Impact of MHC Class I chain related polymorphisms on HCT outcomes	M. Askar and R. Sobecks	700 pairs	MICA genotypes	Taqman	Yes
Impact of donor signal-regulatory protein alpha polymorphism on HCT outcome	A. Gassas, J. Danska and S. Rajakumar	400 pairs	SIRP- α SNPs	Taqman	In process
Discrepancy analysis of microsatellite loci as a proxy measure for ancestral differentiation	J. Harvey, C. Steward and V. Rocha	800 pairs	Microsatellites and STR	Taqman	In process
Prognostic impact of somatic mutation and the levels of CXC chemokine ligands in MDS	W. Saber, R.C. Lindsley and B. Ebert	1300 pairs	Chemokine levels Somatic mutations	ELISA Sequence capture	Yes
Mitochondrial DNA haplotypes and outcome	M. Verneris and J. Ross	4000 pairs	SNPs	Taqman	In process
Assessing T cell repertoire similarity in HLA mismatched HCT	E. Meyer	50 samples	TCR repertoire sequence	NGS	In process
Impact of SNPs in the Gamma Block of the MHC	M. Askar and R. Sobecks	700 pairs	SNPs	Taqman	In process
Clinical outcomes among HCT recipients as a function of socioeconomic status and transcriptome differences	J. Knight, J.D. Rizzo and S. Cole	252 samples	Gene expression array	Array	In process

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Natural killer cell genomics and outcomes after HCT for CLL	V. Bachanova, J. Miller, D. Weisdorf and S. Cooley	600 samples	KIR genotype	SSP	In process
Donor telomere length and outcomes after HCT for acute leukemia	S. Gadalla, S. Savage, D. Loftus and E. Hytopoulos	1145 samples	Leukocyte telomere length	qPCR	In process
KIR gene content and pediatric acute leukemia HCT outcome	M. Verneris, J. Miller and S. Cooley	500 samples	KIR genotype	SSP	In process
Functional genetic variants of the ST2 gene in pairs of recipient and donors for risk stratification of GVHD and TRM outcomes.	S. Paczesny and S. Spellman	1000 pairs	sST2	Taqman	In process
The role of HLA-E compatibility in the prognosis of acute leukemia patients undergoing 10/10 HLA matched HCT	C. Tsamadou, D. Furst and J. Mytilineos	3300 pairs	HLA-E	NGS	In process

Clinical Research in Transplantation

Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

Observational Research

Through the CIBMTR Working Committee structure, which includes many highly successful researchers in clinical transplantation, the NMDP expanded its research activities to increase scientific knowledge of blood and marrow transplantation. This was accomplished by performing retrospective studies to identify the most promising transplant approaches, and by identifying the patients most likely to benefit from this therapy. In addition, research in immunobiology was conducted to better understand how transplantation works including how to harness the power of the immune system to control cancer.

The CIBMTR collects data for approximately 19,000 new transplant recipients annually as well as a continually increasing volume of follow-up data on previously reported recipients and donors. Figure 9 shows cumulative accession of transplants since 1970 when the International

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Bone Marrow Transplant Registry began collecting these data. These data are the basis for the CIBMTR Observational Research program and are accessed by the Working Committees to conduct studies.

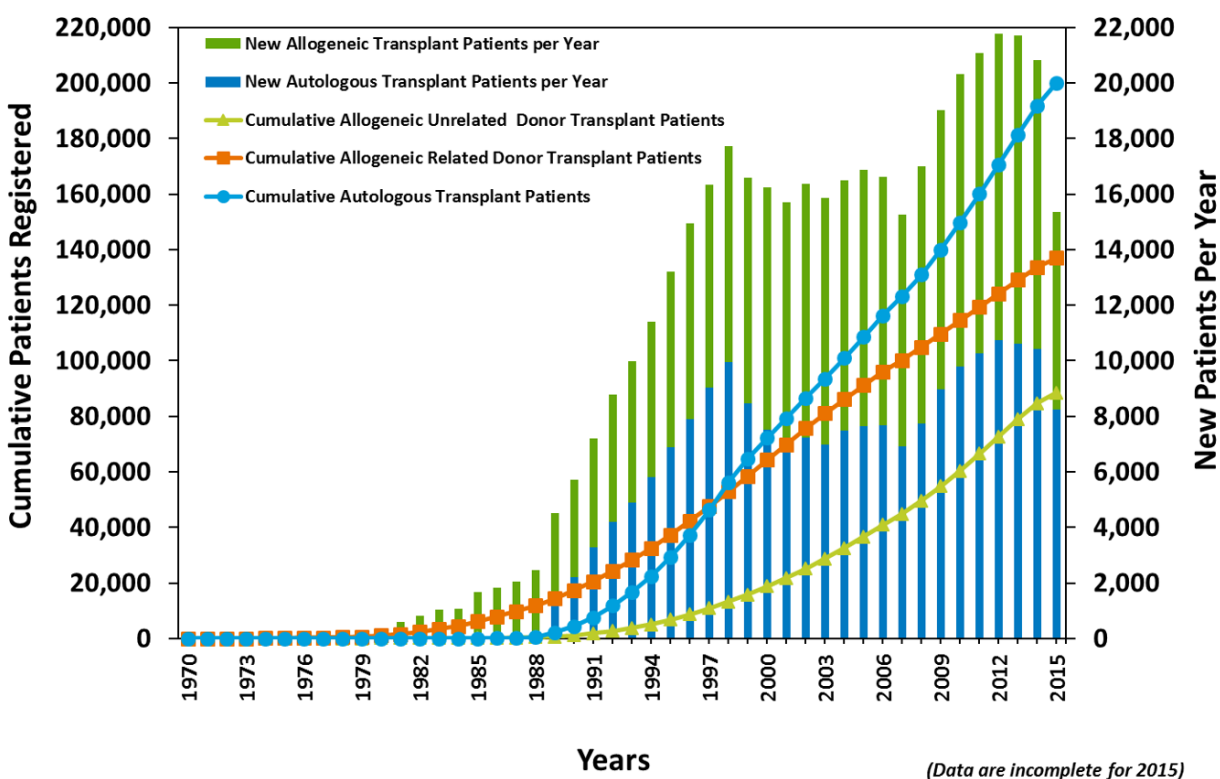


Figure 9. Accession of Transplant Recipients Registered with the CIBMTR

Currently, there are 15 Working Committees within the CIBMTR with 228 active studies in progress (42 in manuscript preparation and 186 in various states of completion). In 2014, the CIBMTR published a total of 76 peer-reviewed publications (59 working committee studies, 2 Health Services Research, 10 BMT CTN, 4 Statistical Methods and 3 other) (Figure 11). Sources of funding for these studies vary by investigator, but the majority use NMDP resources and CIBMTR statistical support.

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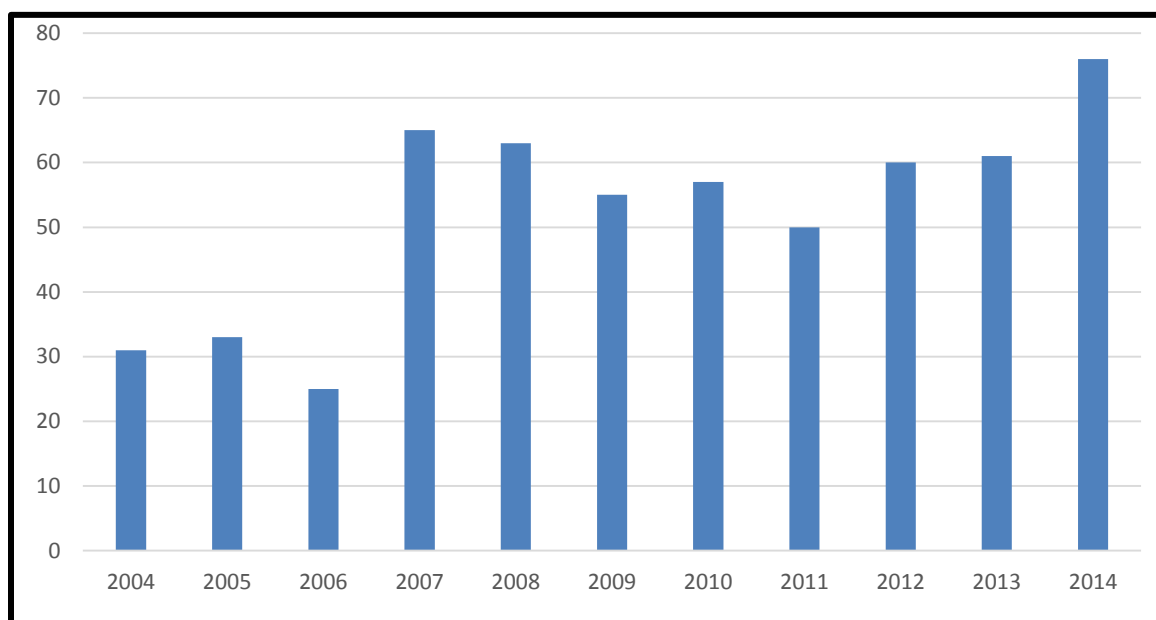


Figure 21. CIBMTR peer-reviewed publications by year.

Clinical Trials

In October 2010, RCI BMT activated a study referred to as the Long Term Donor Follow up study. The primary goal of this study is to evaluate the hypothesis that the incidence of targeted malignant, thrombotic and autoimmune disorders after unrelated hematopoietic stem cell donation are similar between unstimulated BM and filgrastim-mobilized PBSC donors. Once the donor has consented to participate, the donor is contacted and asked study specific questions every other year. This will continue until study completion which is estimated to be 2020. If the donor reports an incidence of interest, a request for their medical records is made. Cases of targeted disorders are reviewed by the medical monitors to confirm the veracity of the report.

As of this report, a total of 9,639 donors are enrolled in the retrospective cohort, donors who had donated prior to October 2010. The donor centers have prospectively enrolled donors during the work up process and to date a total of 10,552 donors have enrolled. The table below summarizes the accrual by cohort and product. The SRG team is responsible for the follow up assessments of just over 63% of the enrolled donors. To date the SRG has completed a total of 17,164 assessments of which 2501 were during this past year.

	Marrow	PBSC	Both	Total
Prospective Cohort	2657	7787	108	10552
Retrospective Cohort	3824	5442	373	9639
Totals	6481	13229	481	20191

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In 2011, accrual was completed to the Phase II, open-label, multi-center, prospective study of double unit umbilical cord blood transplant (UCBT) in adult patients with hematologic malignancies. Follow up data was completed late 2012 with monitoring and dataset prep completing in 2013. The results were published in 2014:

- Barker JN, Fei M, Karanes C, Horwitz M, Devine S, Kindwall-Keller TL, Holter J, Adams A, Logan B, Navarro WH, Riches M; RCI BMT 05-DCB Protocol Team. Results of a prospective multicentre myeloablative double-unit cord blood transplantation trial in adult patients with acute leukaemia and myelodysplasia. Br J Haematol. 2015 Feb;168(3):405-12. doi: 10.1111/bjh.13136. Epub 2014 Oct 1. PubMed PMID:25272241.

Other Clinical Research activities

Work continued on exploring options for a) comprehensive system for management of activities and studies within the Survey Research Group (SRG) and b) electronic data capture system (EDC) and clinical trial management system (CTMS) to coordinate operational and administrative activities within RCI BMT. Full design review processes were completed for both projects. CIBMTR leadership made the decision was made to develop the SRG solution in the Salesforce platform and contract with Medidata for the EDC and CTMS solution.

SRG solution:

The (SRG) Call tracking enhancement project continued development through the end of the grant period. SRG staff in collaboration with CIT worked with external developers to build the new call tracking system. This new system will increase the stability and efficiency of study, time point, subject and contact attempt management and processes. It will allow SRG to view and manage all activities for multiple studies in one place and automate several workflow, analysis and study management activities that were previously very manual, difficult and inconsistent across studies.

EDC and CTMS:

Discussions are in process with Medidata related to RAVE and CTMS. There will be a knowledge transfer process at which time our internal staff will be fully trained in managing the systems. Once completed we anticipate efficiencies in study initiation processes.

During this grant period work continued in the investigator sponsored research area when an NMDP unrelated donor was involved. Staff provide support to a project which involves data collection from NMDP donors addressing the question if product transplanted from a donor on statin drugs reduces GVHD. Staff also are supporting a project with a pharmaceutical company whose trial involved a research sample from the unrelated donor.

Cord Blood research initiatives

During the grant period, the Cord Blood Research Sub-advisory Group met semi-monthly to discuss study priorities and plan analyses for the following:

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The NMDP facilitates a proficiency testing (PT) program for network cord blood banks (CBB). The purpose of this program is to monitor and evaluate the accuracy of a CBB's assay performance and analysis through inter-CBB comparisons. The program was initiated in 2004 and distributes one testing panel annually. Initially, the program reflected the local testing of individual CBBs who performed the assays according to their internal protocols. Due to the highly subjective nature of the colony forming unit (CFU) assay, this resulted in very little inter-CBB consensus of results. To address the poor consensus for the CFU assay, the program was modified to require that the participants use a standardized protocol and reagents distributed by Stem Cell Technologies (SCT), thereby controlling the introduction of variability in testing results from the use of different CFU protocols. In the current form of the program, participants are instructed to perform, analyze, and report results for the following assays: total nucleated cell count (TNCC), %CD34+ cells gated on viable cells, %CD34+/CD45+ gated on viable cells, and colony forming unit enumeration and identification. Throughout the years of the program, the inter-CBB coefficient of variation (CV) has remained high for the enumeration of CFUs, despite efforts to control for this, as evidenced by the PT data analysis from 2014.

	N	Mean	SD	CV	Median	Range
BFU-E	30	17.77	6.88	38.69	16.88	10.90-24.65
CFU-GM	31	18.31	5.74	31.37	17.75	12.57-24.05
CFU-GEMM	29	2.26	1.72	76.18	2.50	0.54-3.98
Total Colonies	33	35.33	14.23	40.28	37.50	21.10-49.56

The NMDP Cord Blood Advisory Group (CBAG) raised concerns about the current program because the SCT CFU protocol used by participants does not reflect the CBB's standard methodologies. The results of the SCT CFU protocol testing only assesses the participants proficiency in performing an assay on an annual basis in a manner that is not consistent with the methodologies used to report product characteristics through Emtrax for use in CBU selection algorithms by TCs. The Cord Blood Research Sub-advisory group started work on a re-design of the SCT administered PT program to compare testing results generated using CBB in-house methodologies, reagents, and instruments compared to the use of the standardized SCT protocol and reagents on a standardized sample. The revised program was launched in 2015 with support provided through a subsequent grant.

Immunobiology Research

During a previous grant period, the NMDP developed the Immunobiology Research grant request and award procedures for use by the IBWC and developed the IBWC Web site (http://www.cibmtr.org/COMMITTEES/Working_Committees/Immunobiology/index.html).

The content was further refined and migrated to the CIBMTR.org Web site in 2010 and is refreshed annually.

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During grant period funds supported significant outreach efforts by the IBWC leadership to increase exposure for the IBWC to basic scientists. The IBWC leadership attended several scientific meetings including: American Society of Hematology, BMT Tandem, European Group for Blood and Marrow Transplant and International Cord Blood Symposium meetings. Support permitted the committee to maintain a strong performance record with 10 publications (submitted or accepted) supported by the grant and collaboration on 3 grants. In addition, 7 new proposals were accepted by the IBWC during the 2014 BMT Tandem Meeting.

IBWC manuscripts (submitted/accepted):

1. Eapen M, Klein JP, Ruggeri A, Spellman S, Lee SJ, Anasetti C, Arcese W, Barker JN, Baxter-Lowe LA, Brown M, Fernandez-Vina MA, Freeman J, He W, Paola Iori A, Horowitz MM, Locatelli F, Marino S, Maiers M, Michel G, Sanz GF, Gluckman E, and Rocha V. Impact of allele-level HLA matching on outcomes after myeloablative single unit umbilical cord blood transplantation for hematologic malignancy. **Published. Blood. 2 Jan 2014; 123(1):133-140.**
2. Fernandez-Vina M, Wang T, Lee SJ, Haagenson M, Aljurf M, Askar M, Battiwalla M, Baxter-Lowe LA, Gajewski J, Jakubowski A, Marino S, Oudshoorn M, Marsh S, Petersdorf E, Schultz K, Turner EV, Waller E, Woolfrey A, Umejiego JB, Spellman S, and Setterholm MI. Identification of a permissible HLA Mismatch in Hematopoietic Stem Cell Transplantation. **Published. Blood. 20 Feb 2014; 123(8):1270-1278.**
3. Gleason MK, Ross JA, Warlick ED, Lund TC, Verneris MR, Wiernik A, Spellman S, Haagenson MD, Lenvik AJ, Litzow MR, Epling-Burnette PK, Weiner LM, Weisdorf DJ, Vallera DA, Miller JS. CD16xCD33 bispecific killer cell engager (BiKE) activates NK cells from MDS patients against primary MDS and MDSC CD33⁺ targets. **Published. Blood. 8 May 2014; 123(19):3016-3026.**
4. Cooley S, Weisdorf DJ, Guethlein LA, Klein JP, Wang T, Marsh SGE, Spellman S, Haagenson MD, Saetern K, Ladner M, Trachtenberg E, Parham P, Miller JS. Recipient HLA-C1 enhances the clinical advantage of killer-cell immunoglobulin-like receptor B haplotype donors in unrelated transplantation for acute myelogenous leukemia. **Published. J Immunol. 15 May 2014; 192(10):4592-4600.**
5. Sengsayadeth S, Wang T, Lee SJ, Haagenson MD, Spellman S, Fernandez-Viña MA, Muller CR, Verneris MR, Savani BN, Jagasia M. Cytotoxic T-Lymphocyte Antigen-4 (CTLA-4) Single Nucleotide Polymorphisms Do Not Impact Outcomes after Unrelated Donor Transplant: A Center for International Blood and Marrow Transplant Research Analysis. **Published. Biol Blood Marrow Transplant. 1 Jun 2014; 20(6):900-903.**

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6. Fleischhauer K, Fernandez-Viña MA, Wang T, Haagenson M, Battiwalla M, Baxter-Lowe LA, Ciceri F, Dehn J, Gajewski J, Hale GA, Heemskerk MBA, Marino SR, McCarthy PL, Miklos D, Oudshoorn M, Pollack MS, Reddy V, Senitzer D, Shaw BE, Waller EK, Lee SJ, and Spellman SR. Risk-associations between HLA-DPB1 T cell epitope matching and outcome of unrelated hematopoietic cell transplantation are independent from HLA-DPA1. **Published. Bone Marrow Transplant. 1 Sep 2014; 49(9):1176-1183.**
7. Pidala J, Lee SJ, Ahn KW, Spellman S, Wang H-L, Aljurf M, Askar M, Dehn J, Fernandez Viña M, Gratwohl A, Gupta V, Hanna R, Horowitz MM, Hurley CK, Inamoto Y, Kassin AA, Nishihori T, Mueller C, Oudshoorn M, Prasad V, Prasad V, Robinson J, Saber W, Schultz KR, Shaw B, Storek J, Wood WA, Woolfrey AE, Anasetti C. Non-permissive -DPB1 mismatch among otherwise HLA-matched donor-recipient pairs results in increased overall mortality after myeloablative unrelated allogeneic hematopoietic cell transplantation for hematologic malignancies. **Published. Blood. 16 Oct 2014; 124(16):2596-2606.**
8. Petersdorf EW, Gooley TA, Malkki M, Bacigalupo AP, Cesbron A, Du Toit E, Ehninger G, Egeland T, Fischer GF, Gervais T, Haagenson MD, Horowitz MM, Hsu K, Jindra P, Madrigal A, Oudshoorn M, Ringdén O, Schroeder ML, Spellman SR, Tiercy JM, Velardi A, Witt CS, O'Huigin C, Apps R, Carrington M. HLA-C expression levels define permissible mismatches in hematopoietic cell transplantation. **Published. Blood. Epub 16 Oct 2014, DOI: 10.1182/blood-2014-09-599969.**
9. Kornblit B, Enevold C, Wang T, Spellman S, Haagenson M, Lee SJ, Muller K. Toll-like receptor polymorphisms in allogeneic hematopoietic cell transplantation. Published, Biol Blood Marrow Transplant, Epub 19 Nov 2014, DOI:10.1016/j.bbmt.2014.09.016, Feb 2015; 21(2):259-265.
10. Gadalla SM, Wang T, Haagenson M, Spellman SR, Lee SJ, Williams KM, Wong JY, De Vivo I, Savage SA. Donor and Recipient Telomere Length as Predictors of Outcomes after Hematopoietic Stem Cell Transplant in Patients with Acquired Severe Aplastic Anemia. JAMA 2015. JAMA. 2015 Feb 10;313(6):594-602. doi: 10.1001/jama.2015.7. PubMed PMID: 25668263; PubMed Central PMCID: PMC4388056.

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IBWC 2014 proposals:

1. The prognostic impact of somatic mutations and levels of CXC chemokine ligands on post hematopoietic cell transplantation (HCT) outcomes in patients with myelodysplastic syndromes (MDS). PIs: Wael Saber, Coleman Lindsley, Benjamin Ebert
2. Donor-Specific anti HLA antibodies, Allele and Antigen level HLA mismatches in the outcomes of Transplantation of Non-Malignant Diseases with Unrelated Donors. PIs: Marcelo Fernandez-Vina and Ann Woolfrey
3. Structural/Functional Models of HLA for Data Mining of Permissive Mismatching in Allogeneic Hematopoietic Stem Cell Transplantation. PI: Loren Gragert
4. Indirectly recognizable HLA epitopes (PIRCHES): a retrospective validation study on the role of indirect recognition of mismatched HLA in hematopoietic stem-cell transplantation outcome. PI: Eric Spierings
5. A Retrospective Assessment of Outcomes of Follicular Lymphoma Patients who have Undergone Allogeneic Stem Cell Transplant Based on Human Leukocyte Antigen (HLA) Type. PIs: Basem William, Marcos de Lima, Marcelo Fernandez-Vina and Brian Hill
6. Assessing the similarity of the T cell receptor repertoire in allogeneic hematopoietic stem cell recipients with the same single human leukocyte mismatches. PI: Everett Meyer
7. mtDNA haplotypes and unrelated donor transplant outcomes. PIs: Michael Verneris and Julie Ross

CIT Minneapolis Initiatives

The scope of the work performed by the CIBMTR IT department in Minneapolis includes collecting and reporting outcomes data on all allogeneic transplantations performed in the U.S. (for the SCTOD, as required by U.S. law). U.S. transplant centers also voluntarily submit autologous transplantation data, and transplant centers worldwide voluntarily submit both autologous and allogeneic transplantation data. As a result, the CIBMTR clinical database now contains information on more than 450,000 transplant recipients. CIT strives to provide applications that will reduce center burden for government mandated forms and provide high quality data on demand.

CIT Application Suite:

- FormsNet: Recipient – Donor - Clinical Trials

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- AGNIS
- Management Reporting
- Sample Tracking
- Auditing

FormsNet

Since its original release in Dec 2007, the Recipient Module of the FormsNet application has been used at more than 410 centers to register 153,805 patients and collect over 998,700 forms with more than 10 million data elements. This program was developed for both local data entry from paper forms and web-based entry by clinical centers. Currently over 94.5% of the data are being entered by clinical centers via the web. In the last six months, NMDP derived 99% by calculating forms submitted electronically divided by those forms eligible for electronic submission. Two forms (2801 – log of appended documents and 2802 – transfer forms) can only be submitted on paper to ensure audit standards.

FormsNet (FN) is a secure, Web-based application for submission of outcomes data to CIBMTR(Recipient module), support for Donor clearance, follow-up and safety (Donor module), and support of electronic data capture for RCI-BMT Clinical Trials (Clinical Trials module). The original features of real-time error validation and override capabilities, and the option to generate a Forms Due Report to track all forms due for every patient have been improved and enhanced. The original deployment in December 2007 was built in 126,000 lines of code supporting 90 Recipient forms and no user tools. Today there are over 1 million lines of code supporting 242 forms, tools, web services, email, and three user-based modules. The application is fully integrated with the CIT applications suite supporting CIBMTR. The application was converted from its original website to a web application with an enhanced object oriented code structure. Service Oriented Architecture integration services were created to provide flexibility and extensibility for future enhancements. In 2012, the planned upgrade to FormsNet replaced the technical foundation of the current FN2 application, with more agile, efficient & effective systems. It improved the user experience by providing enhanced functionality (defined by the network users). In 2014, the Donor module was upgraded to the FormsNet 3 platform, providing the same benefits for Donor module users as realized by Recipient module users.

RITN

As part of the RITN preparedness efforts, Institutional Review Board-approved protocols are in place at multiple RITN centers for the collection of demographic, situational and clinical data from radiation casualties who are sent to RITN hospitals and provide informed consent. The CIBMTR is uniquely positioned to collect this data, based on the existing data collection system and the program's long track-record of collecting similar data on more than 22,000 blood and marrow transplant recipients annually. Importantly, the data collection approach for radiation

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casualties will differ from that which is collected daily in CIBMTR centers since only those who receive a transplant are tracked in the current system. This data collection process will not only capture those who undergo blood and marrow transplantation but also all radiation casualties treated at RITN centers and provide informed consent. The data obtained from the RITN Data Collection Interface will be an invaluable resource for subsequent efforts to improve triage, treatment and monitoring approaches for individuals exposed to radiation.

During the grant period, CIBMTR performed analysis and design to support the RITN data collection needs. This included confirming the overall scope, interviewing key stakeholders, identifying business needs/requirements, defining required forms and other key design elements essential to begin development early in 2015 under a subsequent grant.

AGNIS

AGNIS is a system for electronic messaging of standard Common Data Elements (CDEs) between participating nodes. Messaging can occur between transplant centers, registries, investigators or any combination of entities willing to map relevant data elements and install the software/messaging system. The system relies on two key components, data standards in the form of common data elements (CDEs), and software for transferring the data, providing audit trails, conveying error messages, etc.

- CDE Development:
CIBMTR has invested substantial effort defining CDEs for CIBMTR forms. All CDEs are defined in the Cancer Data Standards Repository (caDSR) of the NCI. This leverages a strong national system of standards regarding the definitions and related metadata. Additionally, a substantial portion of the CDEs have also been defined in the Biomedical Research Integrated Domain Group (BRIDG) model, which is compatible with HL7, the most prevalent ‘language’ used in biomedical informatics.

- caDSR:
 - o Definitions have been created for nearly 3,000 CDEs associated with more than 10,000 data points on more than 90 forms.

The following 16 recipient outcome forms have been released in the caDSR and are available for electronic data exchange via AGNIS: seven mandated forms (pre- and post-TED, HLA, IDM, Infusion, Chimerism, and Selected Post-TED), five Comprehensive Forms (Baseline, 100 day Follow-Up, 6 mo. to 2 yr. Follow-up, Annual Follow-Up, and Death), Unique ID Assignment, Indication for CRID Assignment, and two disease specific inserts (Pre- and Post-HSCT Hodgkin and Non-Hodgkins Lymphoma).

- System Users:

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- Independent Transplant Centers:
 - 4 centers actively submitting and retrieving data through AGNIS: H. Lee Moffitt, MD Anderson, Cleveland Clinic, and Stanford
 - 1 center actively retrieving through AGNIS: Seidman Cancer Center
 - 4-6 centers actively developing solutions, including Mayo and MSKCC
 - 2-3 centers considering RED cap database solutions: Cornell, Chicago, and University of Montreal
- Transplant centers using Vendor solutions:
 - 43 centers working with StemSoft to submit and receive all AGNIS supported forms from CIBMTR
 - 8 centers actively utilizing AGNIS
 - Other centers authorized, but not active at this time
 - 2 centers authorized to submit and retrieve all AGNIS supported forms via OTTR software and actively submitting 4 at this time: Barnes Jewish and St. Louis Children's
 - 3 center authorized to submit and retrieve all AGNIS supported forms via Mediware software and center testing is in progress: Hackensack, Georgetown and Kentucky
 - 4 centers authorized Liaison Technologies to develop capability to submit and retrieve all AGNIS supported forms (formerly Remedy Informatics. Remedy had 18 centers authorized)
 - 7 centers in the Sarah Cannon consortium working with Velos to develop capability to submit and retrieve all AGNIS supported forms
 - 2 additional vendors developing software: StemTrek and Title21
- System Enhancements:

During the grant period, the AGNIS team accomplished the following:

- The AGNIS platform was used for over 13,000 submissions to FormsNet
- Provided ongoing support for EBMT-CIBMTR and CIBMTR-Eurocord AGNIS connections
- EBMT has submitted > 8000 initial forms and is beginning to send follow-up forms for those transplants (for 50 centers)
- Released new ticketing system for request and issue management, held user forum at the ASBMT Tandem Meetings, now support 7 new form revisions, initiated design for the core AGNIS processing engine improvements, provided enhanced tools, improved mapping support for centers, and additional support for submission of comprehensive report forms.

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- Registry connections:

- o EBMT has been working with the CIBMTR to develop a pathway to share TED-level data from EBMT centers that also participate in the CIBMTR. Mapping has occurred for the Pre-TED, Post-TED at 100 days, Unique ID, and Infusion forms. Data submission, initially manually and now with automation, has occurred for participating centers who have not submitted forms to CIBMTR since 2008 for new transplants.
 - This approach has provided over 24,000 new form records.
 - With automation, expect to receive about 40,000 Pre-TED, Post-TED, Unique ID and Infusion forms
- o The U.S. Immunodeficiencies Network (USIDNet) is an outcomes registry for Immune deficiencies sponsored by the NIAID that has a database system that has been re-constructed in the last few years. CIBMTR collaborates for a prospective study and in that context USIDNet obtained small amount of funding to collect outcomes data for patients with Immune Deficiencies from CIBMTR through AGNIS. CIBMTR provides requested data to USIDNET on an annual basis.

- EMR connections:

CIBMTR worked with EPIC to integrate 51 standard CDEs into the BMT registration form in EPIC (BMT smartform).

Information Management

The CIBMTR Information Management Strategy (IMS) project's main objective is to establish a comprehensive program for the management of data across the enterprise, turning the large volumes of data into a strategic asset supporting high value, sophisticated analyses. The Data Warehouse is the primary deliverable for this project. At delivery, the Data Warehouse will contain high quality, validated data readily available to researchers for immunobiology, outcomes, and other types of analyses. CIBMTR operational teams will be able to dramatically reduce the amount of time they spend on data consolidation, preparation, and validation of datasets and instead focus on the analysis. As a result, analyses will be completed in a timely manner facilitating decision-making based on these data assets.

This effort is aligned with NMDP enterprise architectural standards. The first deliverable implemented an Integrated Data Store (IDS) which serves as the foundation for the long-term data warehouse. Using the IDS as the unified data source, the first phase of the Data Warehouse was completed by integrating data used for immunobiology analyses into the Data Warehouse. Table 6 below shows the types of data stored in the Data Warehouse and their data sources, including data sources added since the original release of the IDS.

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Table 6. Types of sources of data in CIBMTR Data Warehouse

Focus area	Description	Source
IDM	• Donor IDMs information for NMDP facilitated HCTs	Legacy (Formsnet1) & current FormsNet3
Infusion data	• 50 most Requested Variables for ad-hoc and center volumes reporting requests from FN3 • Clinical outcome data tied to each infusion event (future)	FormsNet3, SIP
Research Specimen Data	• Research Repository Specimen Inventory data on related and unrelated cords, donors, and recipient samples • Data on Research Repository Specimen submission and compliance	BIO Res (IPR/RR) Lab Vantage vendor application
NMDP Source Data	• Cord Blood Unit Data • Double Cord (Multi)	StarLink CordLink (SyBase) Emtrax through Reg ODS
HLA/KIR Match Data	• Transformed CIBMTR Legacy HLA data • HLA data for donor/recipient for NMDP facilitated HCTs, legacy and current (STAR/SIP) (form 2005) • HLA data transformation on new form 2005/non-NMDP Tx SCTOD data • Donor-Recipient Match Grade results (HLA Save) • KIR data • Re-Evaluate current data sources	• CIBMTR OBS DB • STAR • FormsNet3 • IPR • HLA Save
Donor & Recipient data	• Transformed Donor and Recipient data • Provides self-service environment for analysis through pre-defined joins (business view of the metadata), calculations and generating adhoc data sets • Capability for near real time(~ 5 minutes) data sharing and analytics across forms through combined and unified virtualization layer (views) • Faster turnaround on visibility to data quality fixes.	• FormsNet3

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Focus area	Description	Source
Metadata	• Provides data lineage, impact analysis and FormsNet metadata analysis	• FormsNet Metadata, BODI metadata, OBIEE metadata
Center volumes	• Provides metrics around the number of infusions by center/donor type/product type/disease/age group/race variables • Replaces existing manual process	• FormsNet, NMDP

In addition to the referenced source data consolidated in the Data Warehouse, CIT has also implemented operational improvements to the warehouse, and developed, in 2014, the following functionality that is dependent on the data from the Data Warehouse.

- Expanded automated processes to capture center transplant activity and volumes reporting Dashboards for Recipient research and adhoc reporting capability, and for expansion to Donor reporting capabilities.
- HLA and match grade variables for use in studies
- Metadata and impact analysis capabilities across multiple data sources
- Support for resolution of HLA errors on Form 2005
- Support of Research Repository Sample data transfer from LabVantage to CIBMTR Data warehouse. This includes operational reports capturing HRSA requirements and enrollment data.

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IX. Acronyms

AABB	American Association of Blood Banks
AAFA	African American (NMDP race code)
AAR/IP	After Action Review/Improvement Plan
ABA	American Burn Association
ABD	Antigen Binding Domain
ABMTR	Autologous Blood and Marrow Transplant Registry
AC	Apheresis Center
AFA	African American
AFB	African
AFRRI	Armed Forces Radiobiology Research Institute
AGNIS®	A Growable Network Information System
AHA	American Hospital Association
AHLS	Advanced HAZMAT Life Support
AIM	Ancestry Informative Markers
AINDI	South Asian
AISC	American Indian South or Central
ALANAM	Alaska Native or Aleut

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ALD	Asymmetric Linkage Disequilibrium
ALDH	Aldehyde Dehydrogenase
ALDHbr	Aldehyde Dehydrogenase bright
ALT-LOCI	Alternate Loci
AMIND	North American Indian
AML	Acute Myelogenous Leukemia
AMR	American Indian
ANSI	American National Standards Institute
API	Application Programming Interface
AQP	Ancestry Questionnaire Project
ARC GIS	ArcGIS is a brand name: GIS = Geographical Information System
ARD	Antigen Recognition Domain
ARRA	The American Recovery and Reinvestment Act of 2009
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)
ARS	Antigen Recognition Site
ASBMT	American Society for Blood and Marrow Transplantation
ASEATTA	Australian and South East Asian Tissue Typing Association
ASH	American Society for Histocompatibility
ASHG	American Society of Human Genetics
ASHI	American Society for Histocompatibility and Immunogenetics
ASI	Asian American
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
AUC	Area Under Curve
B-LCLs	B-Lymphocytic Cell Lines
B2B	Business to Business
BAA	Broad Agency Announcement
BARDA	Biomedical Advanced Research and Development Authority
BBMT	Biology of Blood and Marrow Transplantation
BCP	Business Continuity Planning
BCPeX	Business Continuity Plan Exercise
BFU-E	Burst Forming Unit-Erythrocytes
BGI	Beijing Genome Institute
BISC	Bioinformatics Integration Support Contract
BM	Bone Marrow
BMCC	Bone Marrow Coordinating Center
BMDW	Bone Marrow Donors Worldwide
BMT	Bone Marrow Transplant/Transplantation
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network

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BODI	Business Objects Data Integrator
BRAGG	Bioinformatics Research Advisory Ginger Group
BRIDG	Biomedical Research Integrated Domain Group
BRT	Basic Radiation Training
BTM	Be The Match
caBIG	NIH/NCI Cancer Biomedical Informatics Grid
caDSR	Cancer Data Standards Repository
C&A	Certification and Accreditation
CAP	College of American Pathologists
CARB	Black Caribbean
CARHIS	Caribbean Hispanic
CARIBI	Caribbean Indian
CATI	Computer Assisted Telephone Interviewing
CAU	Caucasian
C&A	Certification and Accreditation
CB	Cord Blood
CBA	Cord Blood Association
CBAG	Cord Blood Advisory Group
CBITT	Center for Biomedical Informatics and Information Technology
CBMTG	Canadian Blood and Marrow Transplant Group
CBB	Cord Blood Bank
CBC	Congressional Black Caucus
CBS	Canadian Blood Service
CBT	Cord Blood Transplantation
CBU	Cord Blood Unit
CC	Collection Center
CCD	Continuity of Care Document
CD	Cluster of Differentiation
CDA	Clinical Document Architecture
CDC	Centers for Disease Control
CFU	Colony Forming Unit
CDE	Common Data Elements
CDISC	Clinical Data Interchange Standards Consortium
CEM	Certified Emergency Manager
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CEP	Collect Eject Protect
CFU	Colony Forming Unit
CFU-GM	Colony Forming Unit-Granulocyte Macrophage

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CFU-GEMM	Colony Forming Unit-Gran Erythrocyte Macrophage Monocyte
CG-WG	Clinical Genomics Work Group
cGy	CentiGrey
CHORI	Children's Hospital of Oakland Research Institute
CHOP	The Children's Hospital of Philadelphia
CHS	Certified Histocompatibility Specialist
CHTC	Certified Hematopoietic Transplant Coordinator
CIBMTR®	Center for International Blood & Marrow Transplant Research
CIO	Chief Information Officer
CIT	CIBMTR Information Technology
CLIA	Clinical Laboratory Improvement Amendment
CMCR	Centers for Medical Countermeasures Against Radiation
CMDP	China Marrow Donor Program
CME	Continuing Medical Education
CMF	Community Matching Funds
CML	Chronic Myelogenous Leukemia
CMO	Chief Medical Officer
CMS	Center for Medicare and Medicaid Services
CMV	Cytomegalovirus
CNV	Copy Number Variation
COG	Children's Oncology Group
CPA	Center Performance Analytics
CPI	Continuous Process Improvement
CREG	Cross Reactive Groups
CRF	Case Report Forms
CRID	CIBMTR Recipient ID
CRIS	Computerized Repository Inventory System
CRO	Chief Recruitment Officer
CSF	Colony Stimulating Factors
CSO	Chief Strategy Officer
CSS	Center Support Services
CSS	Custom Search Support
CT	Confirmatory Testing
CTA	Clinical Trial Application
CTLp	Cytotoxic T Lymphocyte Precursor
CTMS	Clinical Trial Management System
CUPC	Cisco Unified Personal Communicator
CV	Co-efficient of Variations
CWD	Common Well Documented

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DAIT	Division of Allergy, Immunology, and Transplantation
DaSH	Data Standards Hackathon
DC	Donor Center
DCAA	Defense Contract Audit Agency
DFCI	Dana-Farber Cancer Institute
DHHS	Department of Health and Human Services
DIY	Do It Yourself
DKMS	Deutsche Knochenmarkspenderdatei
DMSO	Dimethylsulphoxide
DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOE	Department of Energy
DP	Domain Prediction
DQ	Data Quality
DR	Disaster Recovery
D/R	Donor/Recipient
DRPP	Donor Related Pair Project
DSA	Donor specific anti-HLA antibody
DSMB	Data Safety Monitoring Board
DSTU	Draft Standard for Trial Use
DVD	Digital Video Disc
EBMT	European Group for Blood and Marrow Transplantation
EC	Ethics Committee
ED	Emergency Department
eDBiC	Enhanced Data Back to Centers
EDC	Electronic Data Capture
EFI	European Federation for Immunogenetics
EHR	Electronic Health Record
ELISA	Enzyme-linked Immunosorbant Assay
ELISpot	Enzyme-linked Immunosorbent Spot
EM	Expectation Maximization
EMDIS	European Marrow Donor Information System
EMR	Electronic Medical Records
EMS	Emergency Medical System
ENS	Emergency Notification System
ERSI	Environment Remote Sensing Institute
ESRI	Environmental Systems Research Institute
EUR	European American
E-utilities	Entrez Programming Utilities

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FACS	Fluorescent Activated Cell Sorting
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FDR	Fund Drive Request
FGM	France Greffe de Moelle
FHCRC	Fred Hutchinson Cancer Research Center
FHIR	Fast Healthcare Interoperability Resources
FILII	Filipino
FLOCK	Flow Cytometry Analysis Component
FN	FormsNet
FN3	FormsNet3
Fst	Fixation Index
FWA	Federal-wide Assurance
FY	Fiscal Year
GEMM	Granulocyte, Erythrocyte, Monocyte/macrophage, Megakaryocyte
GETS	Government Emergency Telecommunications Service
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)
GDRGEN	Group (HLA)-DR Generic
GETS	Government Emergency Telecommunication Service
GIS	Geographic Information System
GL	Genotype List
GM	Granulocyte Macrophage
GM-CSF	Granulocyte Macrophage Colony Stimulating Factor
GS	General Services
GTR	Genetic Testing Registry
GUI	Graphical User Interface
GVHD	Graft vs. Host Disease
GWAS	Genome Wide Association Studies
GWASH	Genome-Wide Association Scan for Histocompatibility Antigens
Gy	Gray-measure of dose of irradiation
HARPs	HLA Ambiguity Resolution Primers
HAWI	Hawaiian or other Pacific Islander Unspecified
HAZMAT	Hazardous Material
HBCU	Historical Black Colleges and University
HC	Hematopoietic Cell
HCS®	Health Care Standard
HCT	Hematopoietic Cell Transplantation
HEPP	Hospital Emergency Preparedness Program
HHQ	Health History Questionnaire

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HHS	Health and Human Services
HIEDFS	HLA Information Exchange Data Format Standards
HIPAA	Health Insurance Portability and Accountability Act
HIS	Hispanic
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
HML	Histoimmunogenetics Mark-up Language
HR	High Resolution
HRSA	Health Resources and Services Administration
HSC	Hematopoietic Stem Cell
HSCT	Hematopoietic Stem Cell Transplant
HSR	Health Services Research
HTML	HyperText Markup Language
HWE	Hardy-Weinberg Equilibrium
IBMDR	Italian Bone Marrow Donor Registry
IBMTR	International Bone Marrow Transplant Registry
IBWC	Immunobiology Working Committee
ICRHER	International Consortium for Research on Health Effects of Radiation
ID	Identification
IDAWG	Immunogenetics Data Analysis Working Group
IDM	Infectious Disease Markers
IDS	Integrated Data Store
IDW	Integrated Data Warehouse
Ig	Immunoglobulin
IHIW	International Histocompatibility and Immunogenetics Workshop
IHIWS	International Histocompatibility Work Shop
IHWG	International Histocompatibility Working Group
IIDB	Immunobiology Integration Database
IIMMS	International Immunomics Society
IMGT	ImMunoGeneTics
IMStrategy	Information Management Strategy
ImmPort	Immunology Database and Analysis Portal
IND	Investigational New Drug
IND	Improvised Nuclear Device
IPD	Immuno Polymorphism Database
IPR	Immunobiology Project Results
IRB	Institutional Review Board
IS	Information Services
ISO	International Organization for Standardization

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IT	Information Technology
JAPI	Japanese
JCHO	Joint Commission of Healthcare Organizations
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KIR	Killer Immunoglobulin-like Receptor
KORI	Korean
KT	Kiloton
LD	Linkage Disequilibrium
LEL	Low Expression Alleles
LOINC	Logical Observation Identifiers Names and Codes
LSSG	Life Sciences Strategy Group
LTA	Lymphotoxin Alpha
M	Million
MALDI-TOF	Matrix-Assisted Laser Desorption/Ionization – Time Of Flight
MBS	Masters of Biological Science
MCW	Medical College of Wisconsin
MD	Medical Doctor
MDACC	MD Anderson Cancer Center
MDHT	Model Driven Health Tools
MDS	Myelodysplastic Syndrome
MENAFc	MidEast/North Coast of Africa
mHAg	Minor Histocompatibility Antigen
MHC	Major Histocompatibility Complex
MICA	MHC Class I-Like Molecule, Chain A
MICB	MHC Class I-Like Molecule, Chain B
MIRING	Minimal Information for Reporting Immunogenomic NGS Genotyping
MKE	Milwaukee
MLC	Mixed Lymphocyte Culture
MLR	Mixed loss Ratio
MOU	Memorandum of Understanding
MRD	Minimal Residual Disease
MSD	Matched Sibling Donor
MSKCC	Memorial Sloan-Kettering Cancer Center
MSP	Minneapolis
MSWHIS	Mexican or Chicano
MUD	Matched Unrelated Donor
NAC	Nuclear Accident Committee
NACCHO	National Association of County and City Health Officials
NAM	Native American

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NAMER	North American
NARR	National Alliance for Radiation Readiness
NCBI	National Center for Biotechnology Information
NCBM	National Conference of Black Mayors
NCHI	Chinese
NCI	National Cancer Institute
NDMS	National Disaster Medical System
NECEP	New England Center for Emergency Preparedness
NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
NGS	Next Generation Sequencing
NHLBI	National Heart Lung and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMA	Non-inherited maternal antigen
NIMS	National Incident Management System
NK	Natural Killer
NL	Netherlands
NLE	National Level Exercise
NLM	National Library of Medicine
NMDP®	National Marrow Donor Program
NNSA	National Nuclear Security Administration
NRP	National Response Plan
NST	Non-myeloablative Allogeneic Stem Cell Transplantation
NYC	New York City
OB	Obstetrician
OB/GYN	Obstetrics & Gynecology
OCP	Operational Continuity Planning
OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
OHRP	Office of Human Research Protections
OIT	Office of Information Technology
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPA	Office of Patient Advocacy
P2P	Peer-to-Peer
PA	Presence/Absence
PBMC	Peripheral Blood Mononuclear Cells
PBSC	Peripheral Blood Stem Cell
PCR	Polymerase Chain Reaction
PED	Pedigree

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PI	Principal Investigator
POI	Procedures of Interaction
PP	Pseudopatient
PSA	Public Service Announcement
PT	Proficiency Testing
QAMS	Quality Assurance Membership Services
QARM	Quality Assurance and Risk Management
QC	Quality control
QR	Quick Response
R	Race Pair
R&D	Research and Development
RCC	Renal Cell Carcinoma
RCI	Resource for Clinical Investigations
RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
RD Safe	Related Donor Safety
REAC/TS	Radiation Emergency Assistance Center/Training Site
RED	Radiological Exposure Devices
REDMO	Spanish Bone Marrow Donor Registry
REMM	Radiation Event Medical Management
REMPAN	Radiation Emergency Medical Preparedness and Assistance
REST	Representational State Transfer
RFA	Request for Application
RFP	Request for Proposal
RFQ	Request for Quotation
RG	Recruitment Group
Rh	Rhesus
RITN	Radiation Injury Treatment Network
ROC	Receiver Operating Characteristics
RSSA	R-Shiny Search Application
RT-PCR	Reverse Transcriptase-Polymerase Chain Reaction
SAA	Severe Aplastic Anemia
SAP	Single Amino-Acid Polymorphisms
SBT	Sequence Based Typing
SCAHIS	South/Central American Hispanic
SCAMB	Black South or Central America
SCD	Sickle Cell Disease
SCSEAI	Southeast Asian
SCT	Stem Cell Transplantation
SCTOD	Stem Cell Therapeutics Outcome Database

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SEARCH	Page 10
SFVT	Sequence Feature Variant Type
SG	Sample Group
SHF	Synthetic Haplotype Frequency
SIRE	Self Identified Race and Ethnicity
SLCBB	St. Louis Cord Blood Bank
SLW	STAR Link® Web
SMRT	Single Molecule, Real-Time
SNP	Single Nucleotide Polymorphism
SNS	Strategic National Stockpile
SOA	Service Oriented Architecture
SOP	Standard Operating Procedure
SQL	Structured Query Language
SRA	Sequence Read Archive
SRB	Survey Research Group
SRG	Survey Research Group
SSA	Search Strategy Advice
SSO	Sequence Specific Oligonucleotides
SSP	Sequence Specific Primers
SSOP	Sequence Specific Oligonucleotide Probes
SSRS	Sample Storage Research Study
STAR®	Search, Tracking and Registry
SVM	Support Vector Machine
SWOG	Southwest Oncology Group
TBI	Total Body Irradiation
TC	Transplant Center
TCE	T-cell Epitope
TCR	T-cell Receptor
TED	Transplant Essential Data
TNC	Total Nucleated Cell
TNCC	Total Nucleated Cell Count
TRM	Transplant Related Mortality
TSA	Transportation Security Agency
TTY	Text Telephone
TU	Temporarily Unavailable
UCB	Umbilical Cord Blood
UCBT	Umbilical Cord Blood Transplant
UCSF	University of California – San Francisco
UI	User Interface

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UML	Unified Modeling Language
UNK	Unkown
URD	Unrelated Registry Donor
US	United States
USAID	United States Agency for International Development
USID	Unique System Identifier
USIDNet	US Immunodeficiencies Network
USB	Universal Serial Bus
UTR	Untranslated Region
VCF	Variant Call Format
VIET	Vietnamese
VP	Vice President
VPN	Virtual Private Network
WBMT	Worldwide Network for Bone Marrow Transplantation
WC	Working Committees
WebEOC®	Web-based Emergency Operations Center
WGA	Whole Genome Amplification
WH	White
WHO	World Health Organization
WMDA	World Marrow Donor Association
WU	Work-up
XML	Extensible Markup Language
ZKRD	Zentrales Knochenmarkspender – Register für die Bundesrepublik Deutschland
7 AAD	7-Aminoactinomycin D