

2.2 Bone Marrow Coordinating Center

The Bone Marrow Coordinating Center (BMCC) is another of the components of the C.W. Bill Young Cell Transplantation Program that is administered by NMDP.

2.2.1 New Mission/Contract Requirements

The BMCC is charged with:

- Recruiting more marrow donors, especially those of racially and ethnically diverse backgrounds. This includes making sure there are sufficient numbers of potential donors of specific races and ethnicities to meet the needs of patients who require a transplant.
- Coordinating a network of national and international centers that work together to provide safe bone marrow transplants. NMDP maintains standards that govern donor recruitment, donor screening, collection, storage, processing, release, transportation, and administration of marrow, peripheral blood, and cord blood hematopoietic stem cells it facilitates. Staff members regularly monitor each center's performance to make sure it complies with these standards. This includes an annual renewal process for all members of the network. The network is made up of:
 - Donor centers and/or recruitment organizations for raising awareness, recruiting potential marrow donors, and managing donors throughout the donation process.
 - Cooperative registries (registries in other countries that have agreements with the BMCC) for identifying marrow donors and cord blood units outside of the United States.
 - Laboratories for identifying tissue types (HLA) and infectious diseases.
 - Tissue repositories for storing samples.
 - Collection centers (or hospitals) for bone marrow donation and apheresis centers for PBSC donations.
 - Transplant centers (hospitals with experienced transplant teams) for taking care of patients who receive a bone marrow, PBSC or cord blood transplant.
- Providing an efficient system for collecting samples and identifying and matching tissue types through one electronic system (SPA). This includes:
 - Collecting and identifying the tissue types of donors and patients.
 - Maintaining a national registry so that a potential marrow donor who matches a patient's tissue type can be found quickly.
 - Providing more extensive tissue typing and medical evaluations of potential marrow donors to protect donor and patient safety.
- Collaborating with the OPA to provide educational information for patients, the public and medical professionals, and to help patients throughout the transplant process. This includes:
 - Allowing patients and physicians to electronically explore the possibility of finding a marrow donor or CBU.
 - Searching worldwide for all tissue sources through one electronic system.
 - Providing search progress updates to patients and health care professionals at transplant centers.
- Ensuring data about transplant outcomes is collected and provided to researchers. This is meant to improve the availability, efficiency and safety of transplants from unrelated donors and to explore ways to reduce transplant associated costs.
- Protecting patient and donor confidentiality throughout the search and transplant process, as well as when providing outcomes and research data.
- Planning for public health emergencies requiring bone marrow transplants.

2.2.2 Demographic Data on the Donor Registry

NMDP's Donor Registry has grown to include more than eight million registered volunteer donors and more than 100,000 cord blood units, which represents the largest and most racially and ethnically diverse registry of its kind in the world.

Because tissue types are inherited, patients are more likely to match someone from their own race or ethnicity. Adding more donors and CBUs from diverse racial and ethnic backgrounds to

the Registry increases the likelihood that all patients will find the match they need. Efforts are also targeted at recruiting younger donors, since they are healthier and have a longer time to be a qualified donor.

The following charts show the distribution of the Registry by donor gender (Figure 3), age (Figure 4), and race or ethnicity (Figure 5) as of December 31, 2009.

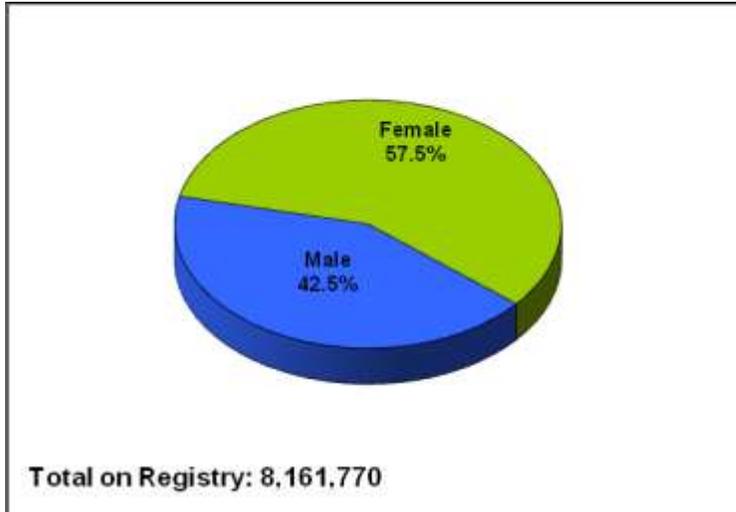


Figure 3. Distribution of NMDP donor registry by donor gender, as of 12/31/2009

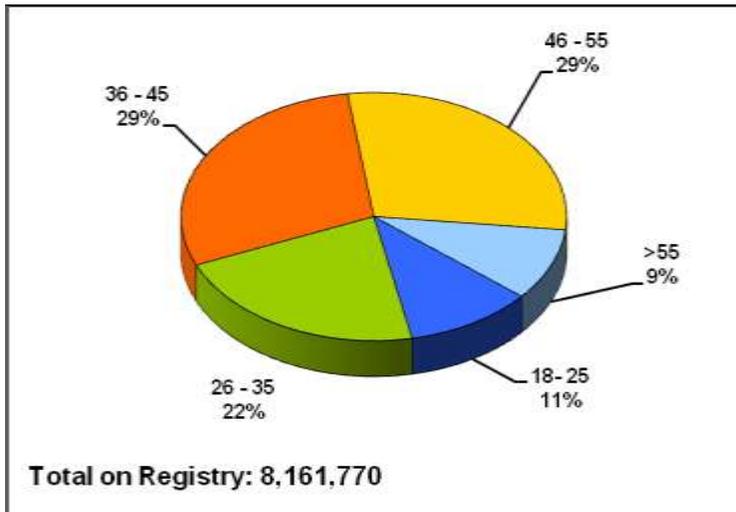


Figure 4. Distribution of NMDP donor registry by donor age, as of 12/31/2009

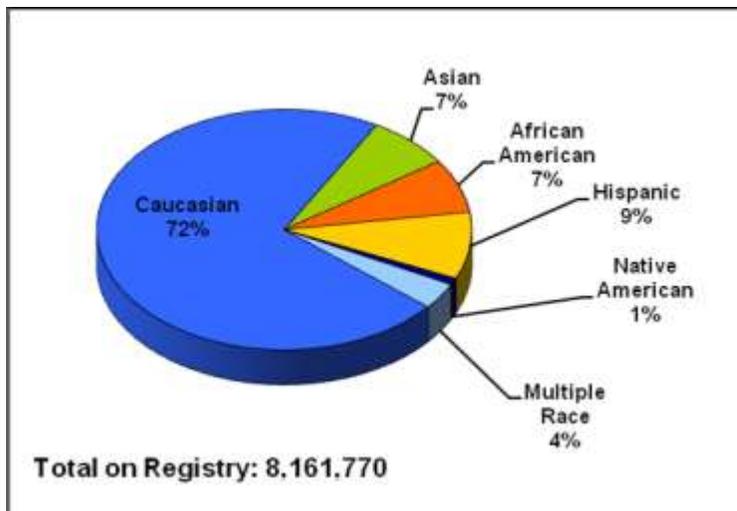


Figure 5. Distribution of NMDP donor registry by donor race/ethnicity, as of 12/31/2009

2.2.3 Selection and Use of Adult Blood Cells

Every year, thousands of men, women and children are diagnosed with life-threatening diseases such as leukemia and lymphoma. Many of them will die unless they get a bone marrow or cord blood transplant from a genetically matched donor. Some people find a match in their family, but 70 percent do not. These patients depend on the NMDP to help them find an unrelated PBSC, marrow or CBU donor.

2.2.3.1 Total Number of Transplants for Calendar Years 2008-09

Since it began operations in 1987, NMDP has facilitated more than 38,000 marrow and cord blood transplants for patients who do not have matching donors in their families. On average, NMDP facilitates more than 400 transplants each month, with more than 4,800 marrow and cord blood transplants taking place in fiscal year 2009.

Figure 6 shows the steady growth of transplants facilitated by NMDP and the distribution by donation type (graft): marrow, peripheral blood stem cell and cord blood.

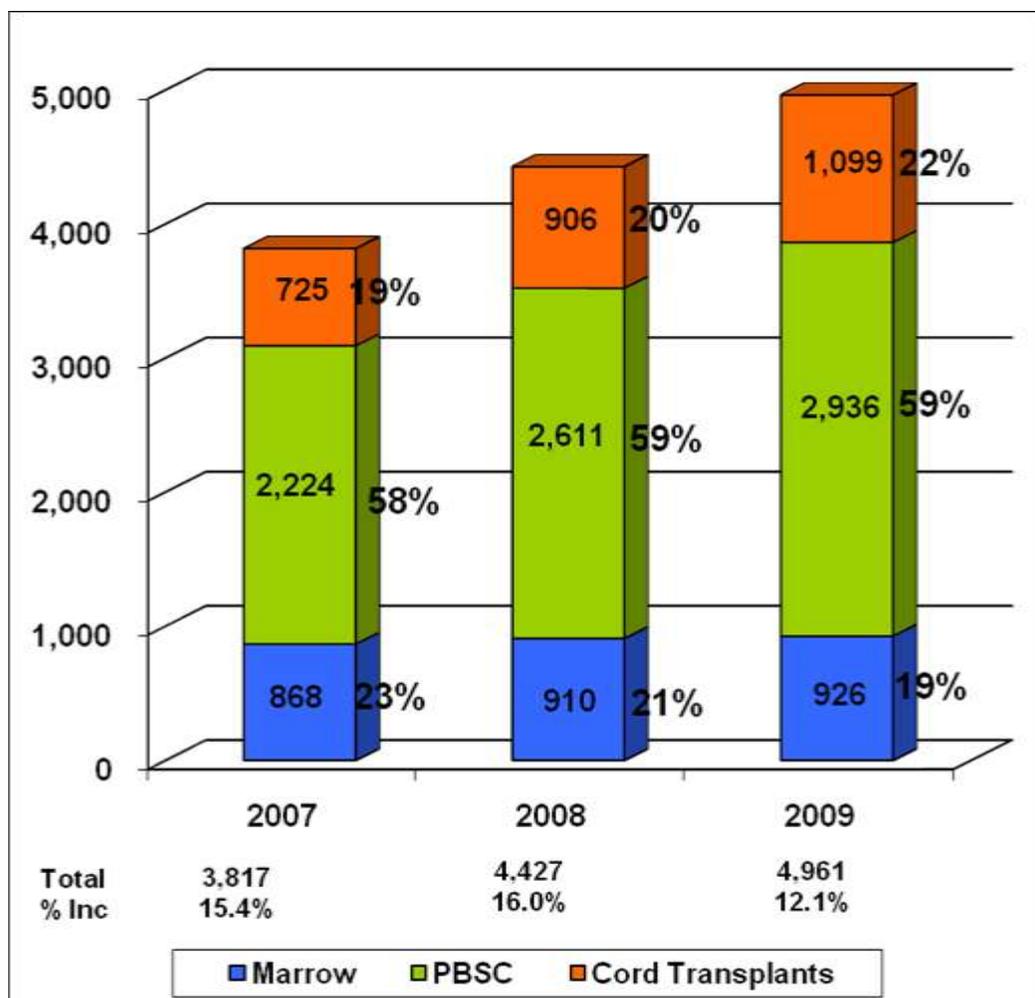


Figure 6. NMDP transplants and distribution by donation type, fiscal years 2007-2009.

Using two cord blood units to increase the cell dose has become an increasingly important option for adult patients. In 2009, the NMDP facilitated more than 300 multicord transplants, more than twice as many as in 2007.

2.2.3.2 Race and Age of Recipients

Advances such as reduced-intensity preparation and conditioning prior to a transplant have made it a treatment option for more patients, particularly older patients. In 2009, 40 percent of NMDP facilitated transplants occurred in patients over the age of 50. The following charts show the distribution of transplants by patient race or ethnicity (Figures 7 and 9) as well as by patient age (Figures 8 and 10) during calendar years 2008 and 2009.

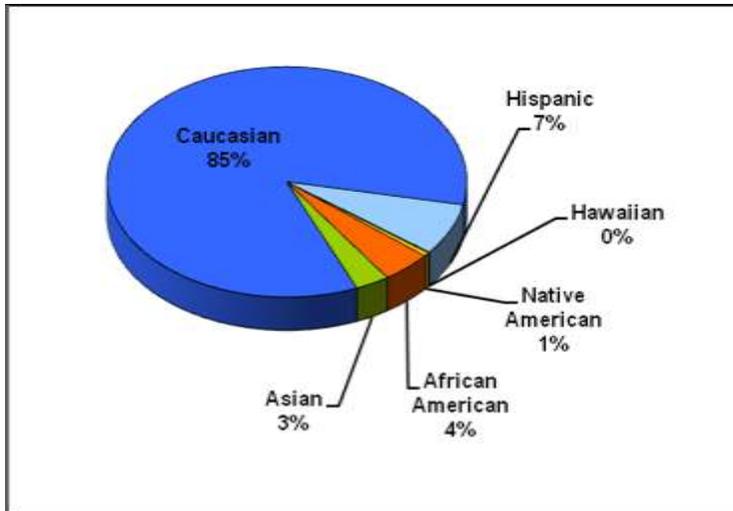


Figure 7. Race/ethnicity of NMDP transplant recipients in fiscal year 2008

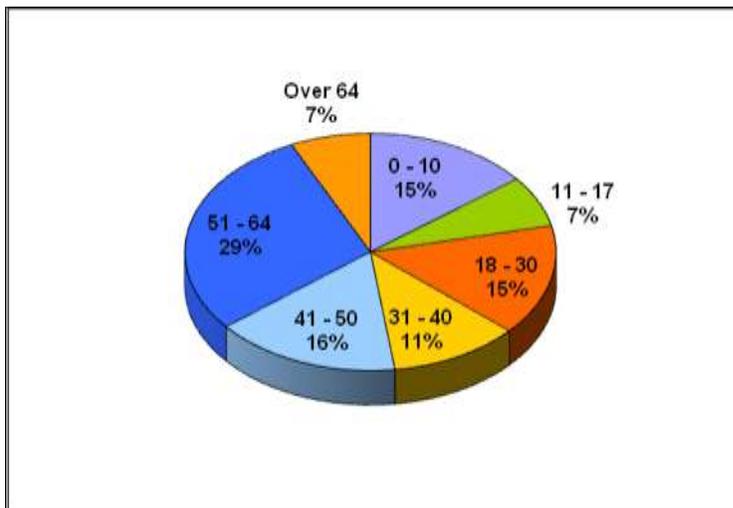


Figure 8. Age of NMDP transplant recipients in fiscal year 2008

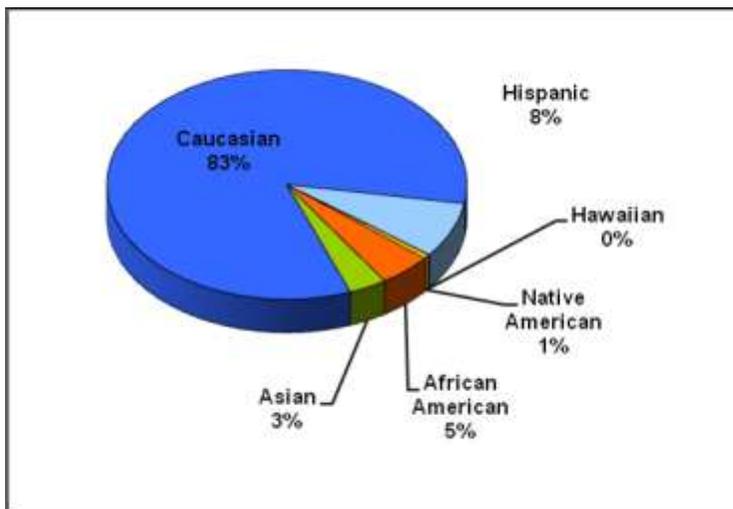


Figure 9. Race/ethnicity of NMDP transplant recipients in fiscal year 2009

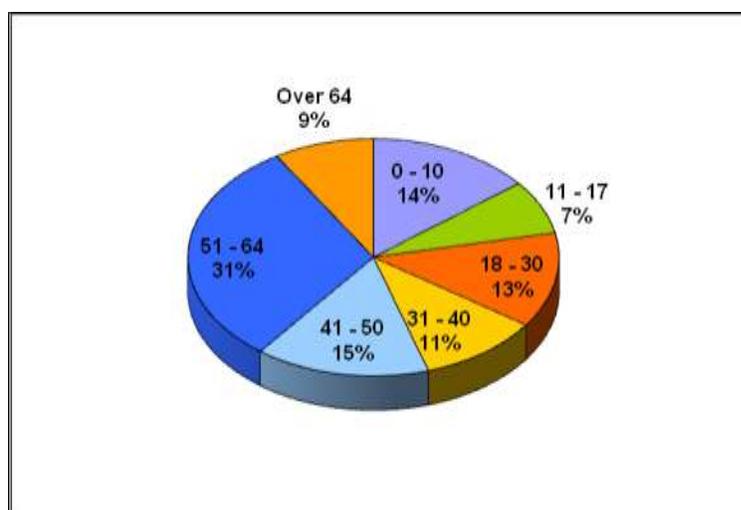


Figure 10. Age of NMDP transplant recipients in fiscal year 2009.

2.2.4 Donor Recruitment

On average, 48,000 new potential donors join NMDP's Be The Match Registry each month. NMDP works with civic, community, corporate and faith-based organizations to recruit volunteer donors from diverse communities. Groups of individuals identified by NMDP for focused recruitment are: American Indian, Alaska Native, Asian/Native Hawaiian and other Pacific Islanders, Black or African-American, and Hispanic or Latinos.

Table 7 shows the race/ethnicity of newly recruited donors.

Ethnicity of Newly Recruited Donors	2008	2009
African-American	43,834	46,111
Hispanic/Latino	55,701	77,150
Asian/Pacific Islander	9,381	54,948
American Indian/Alaska Native	2,774	3,206
Multi Race	36,386	47,165
Caucasian	202,659	252,509
Total Recruitment	400,735	481,089

Table 7. Race/ethnicity of newly recruited donors, calendar years 2008-09.

Forty-two percent—more than 245,000—of the potential donors who joined NMDP's Be The Match Registry in 2009 were from diverse racial and ethnic communities.

2.2.4.1 Donor Recruitment and Registry Diversification

NMDP periodically performs an analysis of the size of the Registry, most recently in 2009, to determine the effect of their recruitment activities on successful donor matching for patients. Specific recommendations from this analysis were provided to HRSA. NMDP's goal is to identify geographic regions where it is most likely to recruit subjects to balance the Registry with the HLA types that are needed. NMDP continues to improve its use of donor HLA data and population research so that patients can make best use of the Registry.

2.2.4.2 Online Donor Registration

Online donor registration, or "Do-It-Yourself" recruitment (<http://www.marlow.org/JOIN/index.html>), continues to evolve via enhancements in technology.

Through this online method, donors can join the registry by confirming they meet basic registry guidelines, completing the form, ordering the registration kit, following the instructions in the kit to collect a swab of cheek cells and returning the kit for HLA typing. Online social media will play a greater role in communicating with potential donors in the future. As communities evolve within the “virtual” environment, do-it-yourself donor registration will enable NMDP to target key audiences efficiently, educate them on its mission, and engage them in its lifesaving work. Much like what patient families, community groups, corporations and national partnerships are doing, NMDP will increasingly use Web-based recruitment services.

2.2.4.3 Recruitment Performance Management System

NMDP continually monitors its own efforts to recruit a diverse and committed group of donors on its Registry. One tool it uses is performance management programs, including the Tiered Recruitment Performance Management System. The intent of a performance management system is to identify areas of strength and opportunities for improvement in donor recruitment processes. The NMDP uses four measurements to evaluate its own performance and that of its recruitment partners:

- Percent of Caucasian recruitment goal achieved
- Percent of total minority goal achieved
- Caucasian availability as measured by the Post Recruitment Survey
- The availability of minority donors as measured by the Post Recruitment Survey

The Post Recruitment Survey asks some recently-recruited NMDP donors to assess their understanding of the donation process, and their likelihood to participate if they were formally activated during a search in the future. It is a tool developed by NMDP in conjunction with vendor, Westat. Approximately 1,000 donors are interviewed by phone monthly 6-8 weeks following their recruitment onto the Registry. This survey seeks to assess donor knowledge, commitment and feedback regarding their experience with the recruitment process. Donor responses to a series of questions from the survey, pertaining to donor commitment to proceed if requested (e.g. availability), are compiled into a donor commitment score. This commitment score is factored at the individual recruiter and recruitment group level and is half the total weighting of the Tiered Recruitment Performance Management system.

2.2.4.4 DNA-based HLA-A, HLA-B and HLA-DR Typing at Time of Recruitment

Donors provide tissue samples at the time they join the Registry, a portion of which is used for immediate DNA-based HLA testing. The remainder is then stored at the NMDP Repository for future testing. Most donors provide four buccal (cheek) swabs, while a small percent provide a blood sample. Samples are shipped to testing laboratories to be evaluated for HLA-A, HLA-B, and HLA-DRB1. Approximately 30 percent of new donors are now also typed for HLA-C.

HLA-C typing was begun because a recent study showed that it might be valuable to collect this information when the donor is recruited. That study showed that this information was likely to be needed, especially for minority marrow and PBSC donors. Transplant centers prefer to have this additional information available when evaluating adult blood stem cell donors for their patients. Given this finding, NMDP is adding HLA-C typing to its processing for approximately 34 percent of new donors, starting in late 2008.

HLA typing results are reported to the NMDP within two weeks of the laboratory receiving the sample. All laboratories are certified for HLA testing, have strict internal quality control programs, and participate in the NMDP Quality Control Sample Testing Program. All samples are given Intermediate Resolution typing, and 38 percent are given higher resolution typing. Contracts to laboratories for HLA typing services are based on the following goals:

- Increasing the resolution of HLA typing

- Receiving high-quality, accurate reports
- Reporting results in 14-days or less
- Decreasing the cost of HLA typing

2.2.4.5 Volunteer Donor Retention

Since the beginning of its operations, NMDP has contracted with scientists to support research on what motivates donors and how best to follow up on patient-directed donation requests. NMDP has used these research findings to:

- Develop training programs for staff and volunteers from donor centers and recruitment organizations
- Produce educational materials that provide donors with the information they want
- Create opportunities for potential donors to make informed, committed decisions about joining the Registry

NMDP also analyzes variables that may have an impact on donor availability. It then sends out monthly data to member centers to allow them to regularly assess their donor registration performance.

NMDP’s ability to recruit donors that are willing to continue on to the stage of confirmatory tissue type testing (HLA typing) has declined across all broad race categories. In order for a donor to be considered “available” for this purpose, the donor must pass a health screening and consent to provide a blood sample for testing. Figure 11 shows donor availability by donor race for the years 2007, 2008 and 2009, where a slight decrease in availability has occurred.

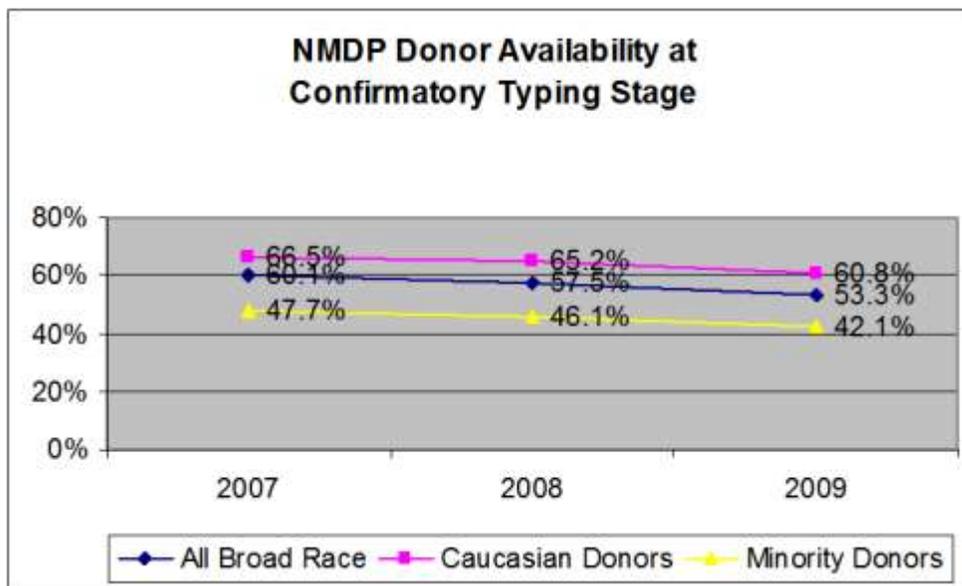


Figure 11. Available donors at the confirmatory typing stage, 2007-09.

To address this slightly declining trend in donor availability, NMDP proactively communicates with existing donors and conducts Registry data cleanup. NMDP communicates with its member organizations in order to: 1) maintain current member contact information for faster searches, and 2) strengthen member awareness, interest and commitment to the donor registry. This strategy also provides opportunities for members to volunteer and stay engaged with the Registry.

2.2.5 Search Process Improvement

2.2.5.1 Donor Management Performance System

NMDP strives to improve its performance at every step of the search and donation process. The NMDP Donor Management Performance system (similar to the recruitment management performance system) was designed to improve the organization's capabilities, by evaluating the donor management process as part of an integrated model of timeliness, availability and excellent customer service. This system defines clear performance expectations, and rewards donor centers when their performance meets and exceeds goals.

The NMDP uses five measures to evaluate how well donor centers are doing:

- Sample collection timelines
- Caucasian donor availability
- Minority donor availability
- Donor clearance timelines
- Donor satisfaction customer service score

Donor clearance timelines are measured from the day the donor is contacted and requested to have typing done as a potential donor, until the day they receive final approval to become a donor. This process includes an information session and medical evaluation of the prospective donor.

The donor satisfaction customer service score comes from a post donation satisfaction survey distributed to donors the month after their donation. Its purpose is to find out how satisfied donors are with their experience and to identify areas where the process can be improved. Service access, service quality and the donor's experience with program staff are all evaluated.

2.2.5.2 Analysis of Search Completion

NMDP routinely analyzes the timelines and outcomes for the donor search process. An evaluation of donor searches done between May 2006 and June 2007 revealed some important information. It showed that certain racial/ethnic groups were more likely to continue in the process from preliminary search to formal search and from formal search to transplant within six months. Caucasian, Hispanic and Asian/Pacific Islander recipients continued to the formal search phase more often than Black/African-American recipients did. Hispanic patients, followed by Caucasian patients, were most likely to proceed from the formal search stage to the transplant.

Older recipients had much better percentages advancing to the formal search stage, but were less likely to receive a transplant than younger patients. Comparison of data between 2005 and 2007 showed an encouraging trend: more patients progressed from the formal search stage to a transplant, although this improvement was not statistically significant. The analysis also showed a trend toward shorter times for the search stage to progress from the preliminary and formal search stages to a transplant.

It also showed that many (42 percent) of the cord blood units that were ordered had previously been confirmatory typed, and were available for immediate shipment. This demonstrates the benefits of having a centralized cord typing laboratory and confirming CBU typing ahead of time. NMDP will continue to evaluate and analyze these important aspects of the search process.

2.2.5.3 Customized HLA Typing

NMDP launched a Customized HLA Typing service in August 2002. This was created in response to requests from transplant centers for more flexibility in the search process. It allows transplant centers to request tailored, or specific HLA typing, from the NMDP laboratories. The Customized HLA Typing service was designed to reduce search times and increase flexibility.

Transplant centers using this service can select particular factors that they would like to hone in on to match a particular patient's HLA (tissue) type. Figure 12 shows the number of customized searches by fiscal year.

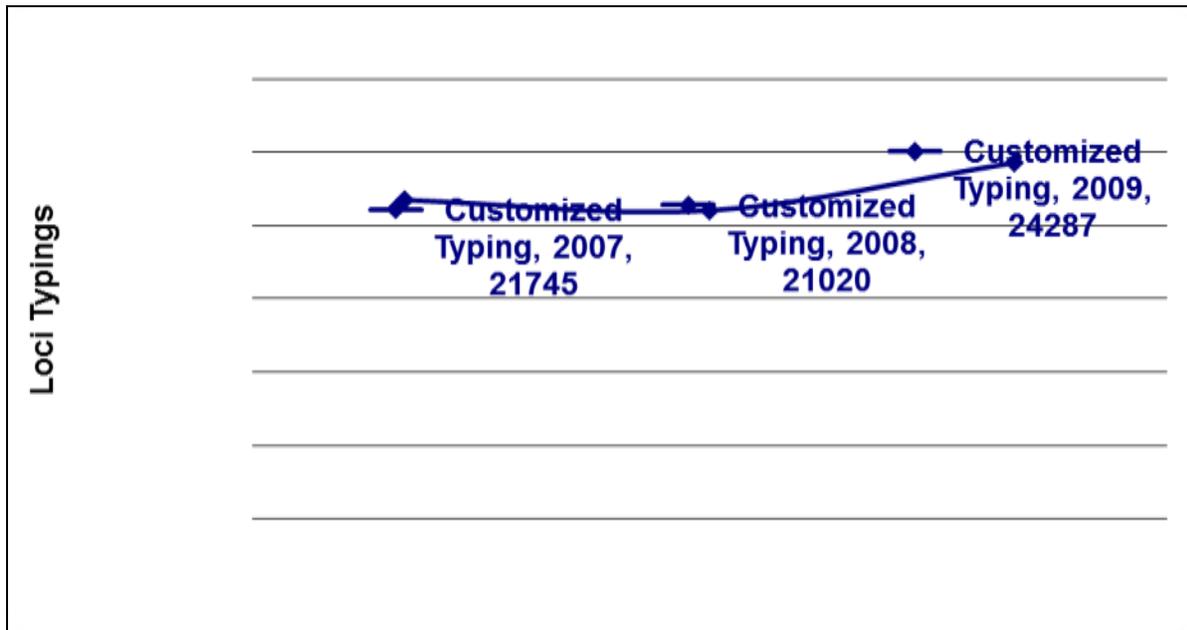


Figure 12. Customized donor data searches, fiscal years 2007-09

2.2.6 Other Projects

2.2.6.1 Quality Assurance Efforts to Safeguard Donors and Patients

Protecting the health, confidentiality and good will of donors and patients is critical to NMDP's mission and purpose. NMDP continually works to improve the recovery monitoring process for any donor that is experiencing post-donation complications. The goal is to ensure that donors receive adequate support, including medical care or disability coverage, until they recover. Serious and unexpected adverse events are reported to HRSA. Since PBSCs and CBUs are collected as part of an Investigational New Drug study with the Food and Drug Administration (FDA), serious and unexpected adverse events related to these donations and transplants are also reported to the FDA.

2.2.6.2 Contingency Planning

The NMDP Emergency Preparedness program is responsible for organizational emergency preparedness, business continuity, Coordinating Center security and organizational emergency communications. This function was formally established in June 2005 to support NMDP's efforts to plan for public health emergencies that might require bone marrow transplants.

NMDP also collaborates with the American Society for Blood and Marrow Transplantation (ASBMT) to coordinate the Radiation Injury Treatment Network® (RITN). It is made up of 56 NMDP centers (transplant centers, donor centers and cord blood banks) that receive ongoing training for a mass casualty marrow-toxic incident (such as exposure to ionizing radiation or mustard gas). RITN, in collaboration with other experts at the U.S. Department of Health and Human Services, provides for comprehensive evaluation and treatment for victims of radiation exposure or other marrow-toxic injuries. They are developing treatment guidelines, educating health care professionals, working to expand the network and coordinating appropriate disaster

specific responses. These materials are available to health care professionals on CD-ROM and a Web site (<http://www.ritn.net/>).