U.S. Department of Health and Human Services
Health Resources and Services Administration

REPORT TO CONGRESS

Fiscal Year 2024 Annual Progress Report on the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory Program

Executive Summary

This is the fiscal year (FY) 2024 annual report to Congress that addresses the C.W. Bill Young Cell Transplantation Program (CWBYCTP), the National Cord Blood Inventory (NCBI), and the Advisory Council on Blood Stem Cell Transplantation and their activities from October 1, 2023, through September 30, 2024.

The report provides background information about each program, describes each structure and operation, and provides statistics on the number of bone marrow donor registrants, blood stem cell transplants (using bone marrow or cord blood), and collected umbilical cord blood units (CBU), along with other data. Unless otherwise noted, the information presented is from FY 2024. This is an update to the FY 2023 report, which included information through September 30, 2023.

The purpose of CWBYCTP is to increase the number of bone marrow and cord blood transplants for recipients matched to biologically unrelated donors.[1] Every year, approximately 18,500 patients in the United States are diagnosed with life-threatening blood cancers or other diseases for which a blood stem cell transplant may be their best or only hope for a cure. Often, the ideal donor is a suitably matched family member, but only 25 percent of people have a fully matched relative.[2] The other 75 percent, or nearly 14,000 people, will often require a search for a matched unrelated adult donor or umbilical CBU through CWBYCTP. CWBYCTP supports the infrastructure for identifying, matching, and facilitating the distribution of bone marrow, peripheral blood stem cells, and cord blood from unrelated donors for individuals in need of blood stem cell transplants. Both CWBYCTP and NCBI enabled thousands of transplant candidates who lacked suitably matched relatives to explore viable options and identify matched unrelated blood stem sources (e.g., bone marrow, peripheral blood stem cells, and cord blood).

CWBYCTP aims to increase access to blood stem cell transplants for genetically varied populations by recruiting and increasing the number of donors from such populations to improve their probability of finding a suitable donor. One way CWBYCTP accomplishes this is by directing contract resources toward patient advocacy, public and professional education, data collection, donor recruitment, and expansion of the size and diversity of the CWBYCTP donor registry. By the end of FY 2024, there were over 42 million volunteer adult bone marrow donor registrants accessible through CWBYCTP, of which 9.4 million registrants reside within the United States. Of the United States registrants, 3.8 million (40 percent) self-identified as belonging to a genetically varied population.

The Health Resources and Services Administration, through its NCBI program, contracts with cord blood banks to purchase CBUs to help meet the goal of building a public inventory of at least 150,000 new, high-quality CBUs. NCBI funds support the collection of CBUs, which

[1] Blood stem cell transplants include transplants using bone marrow, cord blood, or peripheral blood stem cells.
[2] Besse, Kelsey; Maiers, Martin; Confer, Dennis; Albrecht, Mark. (2016). On Modeling Human Leukocyte Antigen-Identical Sibling Match Probability for Allogeneic Hematopoietic Cell Transplantation: Estimating the Need for an Unrelated Donor Source. Biol Blood Marrow Transplant. doi: 22. 410-7.10.1016/j.bbmt.2015.09.012.

increases access to transplantation. NCBI continues to grow with nearly 125,900 NCBI CBUs made available on the donor registry through CWBYCTP. More than 63 percent of the total NCBI CBUs are from genetically varied populations.

CWBYCTP continued to serve a broad patient population, with volunteer adult donors and CBUs playing a vital role in expanding transplant access to all patients, including genetically varied populations. CWBYCTP facilitated 7,550 transplants overall, with approximately 1,600 (or 22 percent) of those transplants facilitated for genetically varied populations.

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Acronym List

ACBSCT	Advisory Council on Blood Stem Cell Transplantation
AI/AN	American Indian/Alaskan Native
AML	acute myeloid leukemia
CBB	cord blood bank
CBU	cord blood unit
CWBYCTP	C.W. Bill Young Cell Transplantation Program
FDA	U.S. Food and Drug Administration
FY	fiscal year
HCT	hematopoietic cell transplantation
HLA	human leukocyte antigen
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
NCBI	National Cord Blood Inventory
NH/PI	Native Hawaiian or other Pacific Islander
NMDP	National Marrow Donor Program
OPA	Office of Patient Advocacy
P.L.	Public Law
SCD	sickle cell disease
SCTOD	Stem Cell Therapeutic Outcomes Database
Secretary	Secretary of Health and Human Services
SPA-CC	Single Point of Access - Coordinating Center

I. Legislative Language

The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109-129, as amended by P.L. 111-264 (Stem Cell Therapeutic and Research Reauthorization Act of 2010), and by P.L. 114-104 (Stem Cell Therapeutic and Research Reauthorization Act of 2015), and P.L. 117-15 (Timely Reauthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2021 (TRANSPLANT Act of 2021)), includes a requirement which states, in part:

> *"The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to the Congress . . . an annual report on the activities carried out under this section."*

II. Introduction

The TRANSPLANT Act of 2021 (P.L. 117-15) reauthorizes the C.W. Bill Young Cell Transplantation Program (CWBYCTP), the National Cord Blood Inventory (NCBI), and the Advisory Council on Blood Stem Cell Transplantation (ACBSCT). The Health Resources and Services Administration (HRSA), Health Systems Bureau, Division of Transplantation provides oversight of both CWBYCTP and NCBI program (see Figure 1).

The purpose of CWBYCTP is to increase the number of bone marrow and cord blood transplants for recipients matched to biologically unrelated donors. The program plays a vital role in improving health outcomes by expanding access to blood stem cell transplants to those from genetically varied populations. CWBYCTP collaborates with those in the blood stem cell transplantation field to address the needs of individuals in the United States who have life-threatening diseases such as leukemia, lymphoma, sickle cell anemia, or other metabolic or immune system disorders. For some of these individuals, a transplant using bone marrow or cord blood from unrelated donors may be their best opportunity to live longer, healthier lives.

CWBYCTP supports the infrastructure for identifying, matching, and facilitating the distribution of bone marrow and cord blood from unrelated donors for individuals in need of a blood stem cell transplant. CWBYCTP also offers patient and donor advocacy services, case management services, data collection on transplant outcomes, and educational activities.

The NCBI program contracts with cord blood banks (CBB) to meet the statutory goal of building a public inventory of at least 150,000 new, high-quality, and genetically varied cord blood units (CBU). These CBUs are available for transplantation through CWBYCTP.

The role of ACBSCT is to advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary), acting through the HRSA Administrator, on matters conducted by both CWBYCTP and the NCBI program.

III. C.W. Bill Young Cell Transplantation Program Overview

CWBYCTP provides a structure to facilitate blood stem cell transplantation with blood stem cells from unrelated donors (marrow and cord blood) for individuals with leukemia and other life-threatening blood, metabolic, or immune system disorders. CWBYCTP has five functional areas of focus: bone marrow, cord blood, a single point of access to search for and facilitate access to bone marrow and cord blood, patient advocacy, and stem cell transplant outcomes data. Three separate contracts carry out five functions: the Single Point of Access - Coordinating Center (SPA-CC), the Office of Patient Advocacy (OPA), and the Stem Cell Therapeutic Outcomes Database (SCTOD). In fiscal year (FY) 2024, the Medical College of Wisconsin, the parent organization of the Center for International Blood and Marrow Transplant Research, was the contractor for the SCTOD contract, and National Marrow Donor Program (NMDP) was the contractor for the OPA and SPA-CC contracts. Table 1 below shows the award amounts of appropriated funds under those contracts from 2020 to 2024. The following is a description of the three current contracts:

- The SPA-CC contract is a combination of the Single Point of Access, Bone Marrow Coordinating Center, and Cord Blood Coordinating Center focal areas. SPA-CC coordinates a network of organizations to recruit potential donors with an emphasis on the recruitment of individuals from genetically varied populations to donate blood stem cells. This network collectively provides access to blood stem cell transplants, provides tissue typing to match patients and bone marrow and cord blood donors, and engages in public and professional educational activities related to blood stem cell donation and transplantation. SPA-CC also contains a network of CBBs that lists its CBUs and makes them available for transplantation. SPA-CC maintains a matching and facilitation system for health care professionals and physicians searching on behalf of patients for cells derived from adult bone marrow donors and CBUs through a single point of electronic access.
- The OPA contract supports patient advocacy and case management specific to blood stem cell transplantation, histocompatibility/search expertise, and guidance for patients and physicians. OPA provides public and professional education, information, resources, and support for blood stem cell transplant patients and families from diagnosis through survivorship.
- The SCTOD contract supports an electronic database of blood stem cell transplantation outcomes for use by researchers and health care professionals. The SCTOD contractor maintains a secure repository for storing donor and recipient samples for research and provides analysis of the clinical outcomes of transplant recipients.

Figure 1: C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory Program

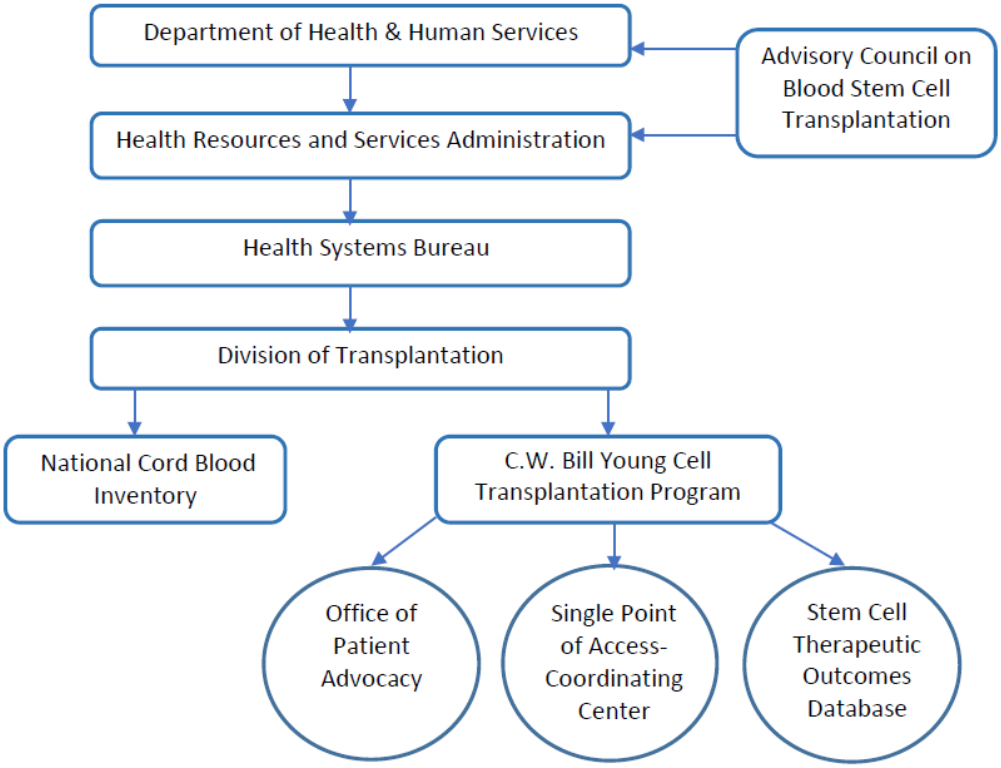

Table 1: Funding for the C.W. Bill Young Cell Transplantation Program Contracts for 2020 to 2024*

FY	Appropriation+	Single Point of Access - Coordinating Center	Office of Patient Advocacy	Stem Cell Therapeutic Outcomes Database	Total Program Contracts
2020	$30,009,000	$21,804,584	$877,293	$4,601,550	$27,283,427
2021**	$31,009,000	$29,888,122	$903,612	$4,730,240	$35,521,974
2022	$32,009,000	$21,343,315	$1,518,782	$5,909,653	$28,771,750
2023	$33,009,000	$23,364,246	$1,564,345	$5,727,767	$30,656,358
2024	$33,009,000	$23,062,097	$1,611,277	$5,913,595	$30,586,969
Total	**$159,045,000**	**$119,462,364**	**$6,475,309**	**$26,882,805**	**$152,820,478**

*Data Source: HRSA accessed on December 17, 2024.
**FY 2021 Appropriations does not include a $7 million reallocation from the NCBI program to CWBYCTP to support cord blood functions within the legislative authority of the TRANSPLANT Act of 2021.
+ Administrative costs account for differences between appropriations and total program contracts awarded.

C.W. Bill Young Cell Transplantation Program Statistical Updates

Every year, approximately 18,500 patients in the United States are diagnosed with life-threatening blood cancers or other diseases for which a blood stem cell transplant may be their best or only hope for a cure. Often, the ideal donor is a suitably matched family member, but only 25 percent of people have a fully matched relative. The other 75 percent, or nearly 14,000 people, often search for a matched, unrelated adult donor or CBU. CWBYCTP serves individuals in need of unrelated blood stem cell transplantation and works to ensure that members of genetically varied populations have the same probability of finding a suitable unrelated donor as an individual who is not a member of a genetically varied population. The chance of finding a suitably matched unrelated donor through CWBYCTP varies by race and ethnicity. Recent advancements in transplantation procedures are expanding the definition of suitable donors to include both fully matched and partially mismatched donors. Overall, these advances have increased the likelihood of finding a suitably matched donor for all patients in need of a transplant. Due to the advances in transplantation that enable favorable outcomes using partially mismatched donors, the probability of Black or African Americans finding a suitable unrelated donor is now 84 percent, compared to 92 percent for Asian/Pacific Islanders, 90 percent for Hispanics/Latinos, 93 percent for American Indians/Alaska Natives (AI/AN), and 98 percent for White-non-Hispanic populations.[3]

As of this report, there are approximately 42 million volunteer adult bone marrow donor registrants accessible through CWBYCTP, of which 9.4 million registrants are within the United States. Of the United States registrants, 3.8 million (40 percent) self-identified as belonging to a genetically varied population. In FY 2024, CWBYCTP added more than 285,400 new registrants (Table 2), and 37 percent of those registrants self-identified as belonging to a genetically varied population, which is more than the 36 percent who self-identified in FY 2023. In FY 2024, there were fewer adult donors added to the donor registry than the nearly 339,500 added in FY 2023 (Table 2).

In FY 2024, the total number of unrelated blood stem cell transplants facilitated by CWBYCTP increased by 8 percentage points from nearly 6,970 in FY 2023 to 7,550 in FY 2024, a total increase of approximately 580. This increase also mirrored the 8 percent increase realized from FY 2022 to FY 2023. During the same FY 2024 period, CWBYCTP facilitated 12 percent more transplants across combined genetically varied categories, from more than 1,450 in FY 2023 to approximately 1,625 in FY 2024. The number of transplants for each group is shown in Table 3.

The SPA-CC contractor continued efforts to increase both the number of genetically varied potential donors on the registry and the number of transplants performed for genetically varied patients due to an increased focus on genetically varied communities, optimizing media and marketing activities to reach these communities more effectively, and educational efforts to build trust within these communities.

[3] Chowdhury, A.S., Maiers, M., Spellman, S.R., Deshpande, T., Bolon Y.T., Devine, S.M. Existence of HLA-Mismatched Unrelated Donors Closes the Gap in Donor Availability Regardless of Recipient Ancestry. *Transplantation and Cellular Therapy*. 2024 Nov; 29(11): 686.e1-686.e8. doi: 10.1016/j.jtct.2024.08.014. Epub 2024 Aug 14. PMID: 37586457.

Table 2: Number of Registrants Added to the C.W. Bill Young Cell Transplantation Program by Race/Ethnicity*

Race/Ethnicity	FY 2023	Percentage of Total Number of Registrants Added	FY 2024	Percentage of Total Number of Registrants Added
American Indian or Alaska Native	650	<1%	**527**	**<1%**
Asian	29,883	9%	**28,552**	**10%**
Black or African American	22,471	7%	**20,253**	**7%**
Multi-racial	26,937	8%	**22,521**	**8%**
Native Hawaiian or Other Pacific Islander	463	<1%	**493**	**<1%**
Unknown**	45,481	13%	**41,221**	**14%**
White-non-Hispanic	173,481	51%	**138,741**	**49%**
Hispanic or Latino+	40,123	12%	**33,111**	**12%**
Total	339,489		**285,419**	

* Data Source: NMDP data as of September 30, 2024. Data is rounded and subject to change.
** Unknown reflects people who did not provide race and ethnicity data.
+ Hispanic or Latino represents a broad ethnicity, and donors may be of any race; a separate category is included to prevent individuals from being counted multiple times.

Table 3: Number of Transplants Facilitated by the C.W. Bill Young Cell Transplantation Program by Race/Ethnicity*

Race/Ethnicity	FY 2023	Percent of Total Number of Transplants Facilitated	FY 2024	Percent of Total Number of Transplants Facilitated
American Indian or Alaska Native	28	<1%	37	<1%
Asian	269	4%	300	4%
Black or African American	345	5%	424	6%
Multi-racial	117	2%	112	1%
Native Hawaiian or Other Pacific Islander	9	<1%	11	<1%
Unknown+	675	10%	648	9%
White-non-Hispanic	4,832	69%	5,276	70%
Hispanic or Latino^	689	10%	742	10%
Total	**6,964**		**7,550**	

*Data Source: NMDP data for domestic and international donors as of September 30, 2024. Data in this report may change due to delayed data responses and result in a varying number of transplants reported from prior-year reports.
+ Unknown reflects people who did not provide race and ethnicity data. This is common when working with international registries where capturing data by race and ethnicity does not occur.
^ Hispanic or Latino represents a broad ethnicity, and donors may be of any race; a separate category is included to prevent individuals from being counted multiple times.

Transplant Survival Rates

CWBYCTP establishes goals for the number of transplants facilitated and for the outcomes of these transplants. To calculate survival rates along with the corresponding probability of survival rates, the CWBYCTP contractor uses analytics and reporting tools that provide center-specific survival performance outcome measures for each transplant center.[4] For this FY 2024 report, transplant outcomes for FY 2022 were the latest full dataset available and are reported and compared to FY 2021 data in Table 4. Additionally, to report the probability of survival rate at 1-year following transplant, transplant centers must follow all transplant recipients for at least 1-year after the procedure to allow the centers the opportunity for adequate follow-up and reporting. HRSA will report on FY 2024 transplant outcomes data, including the probability of 1-year survival, in the FY 2025 annual report.

As Table 4 reflects, the program performance goal of 69 percent patient survival at 1-year post-transplant was surpassed in all tracked categories. Overall, survival rates remained relatively stable between FY 2021 and FY 2022 across the broad categories for stem cell transplant.

Table 4: 1-year Post-Transplant Survival Rate (U.S. Transplant Centers) 2021 and 2022*

Donor Type	FY 2021	FY 2022
Unrelated Transplants		
Adult Donor	74%	75%
Single Cord	80%	82%
Double Cord	76%	77%
Related Transplants		
Matched Related	80%	83%
Mismatched Related	75%	74%

*Data Source: Center for International Blood and Marrow Transplant Research data as of November 1, 2024.

C.W. Bill Young Cell Transplantation Program Professional Education and Outreach Highlights

Throughout FY 2024, the OPA contractor provided educational opportunities to health care providers in hematology and blood stem cell transplantation. Advances in transplantation have contributed to increased donor options for patients and improved outcomes; therefore, the contractor organized educational efforts around these advances to encourage timely referral along with the use of evidence-based guidelines to use when considering referral for a transplant consult.

[4] Information about the Center-Specific Survival Analysis is available at https://bethematch.org/tcdirectory/search/ (not supported in Internet Explorer/Edge).

Improving Access and Outcomes

The OPA contractor educates those within the blood stem cell community on the latest research and advances affecting outcomes and access to transplants, as well as the importance of timely transplant referral and early human leukocyte antigen (HLA) typing for patients.

In FY 2024, OPA developed six episodes in the *Explore Cell Therapy Podcast* series. This education series was designed to deliver practice-changing research on hematopoietic stem cell transplantation (HCT) and other cellular therapies to advance knowledge about donor selection, transplant timing, health parity, and overcoming barriers. OPA engaged physicians who specialize in HCT and physicians at community hematology/oncology practices to deliver this series of podcasts:

- A New Era in Graft-versus-Host Disease Prevention (November 27, 2023; 286 downloads)
  Part 1: Post Transplant Cyclophosphamide and Improved Outcomes
  Part 2: Progressive Research and the Future of Care
- Trend in HCT Equity, Access and Outcomes (February 6, 2024; 144 downloads)
  Part 1: Improvements and Challenges
  Part 2: Personalization and Future Care
- Streamlining HCT Referral (August 12, 2024; 241 downloads)
  Part 1: Overcoming Barriers through Coordinated Care
  Part 2: Assessing the Impact and Future State

Health Professional Education Activities and Engagement

In FY 2024, SPA-CC and OPA contractors offered a variety of programs to educate and engage health care professionals about the need for blood stem cell transplants and services offered through CWBYCTP. This included programs with continuing education credits for medical professionals; holding workshops for key stakeholders in the blood stem cell community on transplant issues; disseminating findings from studies on the importance of early HLA typing and referral for optimal patient outcomes; and hosting webinars and virtual roundtables for transplant centers to learn about how physicians address challenging patient cases and to share resources that support clinical decision-making.

Education focused on expanding access to transplants, optimizing donor selection, and improving outcomes. The OPA contractor, in partnership with the American Society for Transplantation and Cellular Therapy, developed a five-part online education program, "The Evolution of HCT Self-Paced Learning Course."[5] The series covered transplant basics and outcomes, patient eligibility for transplant, donor availability, addressing barriers, shared care practices, and preparing patients for successful HCT. The OPA contractor delivered educational content on these topics through online education modules, webinars, e-newsletters, podcasts, and published research summaries. The five parts of this program had a combined nearly 2,900 page

[5] NMDP. The Evolution of HCT Self-Paced Learning Course. Available at https://network.nmdp.org/training-education/catalog/the-evolution-of-hct-self-paced-learning-course.

views and offered 4.25 continuing education credits to physicians and nurses who completed the program.

CWBYCTP continues to focus on professional education programs to highlight blood stem cell transplant as a curative option for many diseases, including acute myeloid leukemia (AML), high-risk myelodysplastic syndrome, and aplastic anemia. This focus includes emphasizing advances in precision medicine and measurable residual disease testing to predict and prevent AML relapse, and advances in risk stratification criteria that expand the use of transplants for myelodysplastic syndrome. Disease-specific education programs included:

- First-Line Bone Marrow Transplant for Severe Aplastic Anemia, NMDP Explore Cell Therapy: OPA developed a two-part podcast episode on the use of bone marrow transplant as first-line treatment for severe aplastic anemia (released June 11, 2024; 167 downloads).
- Urgency vs. Optimization in the Treatment of AML Pharmacological Advances and the Role of HCT: OPA hosted a webinar on pharmacological advances in the treatment of AML and the optimal timing for transplant, as well as ways to improve access to care (May 7, 2024; 328 participants registered for the on-demand recording and 170 attended live).
- Physician Exchange on Myelodysplastic Syndrome: In partnership with the American Society for Transplantation and Cellular Therapy, OPA co-hosted a panel-style physician exchange between hematology/oncology and transplant physicians on research, tools, clinical trials considered, best practices, and shared challenges when considering transplant for patients with myelodysplastic syndrome (American Society of Clinical Oncology 2024 conference, Chicago, Illinois, May 31, 2024; 11 live conference attendees in addition to five expert panelists).

C.W. Bill Young Cell Transplantation Program Patient Services and Public Educational Resources

Patient Navigation Services and Educational Resources

The SPA-CC and OPA contractors provide patient navigation services and develop resources to guide patients through all phases of transplantation. The SPA-CC and OPA contractors collaborate to provide transplant search data to providers and patients. The OPA contractor's outreach program works with patients to identify concerns and help remove barriers to transplant through referral to services offered by the OPA contractor, the SPA-CC contractor, and other organizations. In FY 2024, OPA's patient navigators made nearly 4,500 outbound calls to patients who have had a search of the registry.

During the period of this report, the OPA contractor continued its focus on outreach and educational resources for people with sickle cell disease (SCD). Patient navigators continue to focus their work on supporting the unique needs of this patient population. The contractors disseminated 1,350 SCD outreach packages, which contain educational handouts regarding SCD therapies and resources available through OPA.

Post-transplant survival is of primary interest to patients and HRSA. The OPA contractor leads the program website and provides survival data in two formats: (1) transplant center-specific survival data through the transplant center directory online, and (2) disease-specific survival data through the survival data query tool on the Program website.[6,7] The survival data query tool on the program website was revised to provide easier access to the data, and the data were updated.

Using information from SCTOD, the OPA contractor annually prepares and distributes charts summarizing current uses and outcomes of cellular therapies, which encompasses blood stem cell transplantations, in a set of U.S. Summary Slides that describe information related to practices and general survival outcomes after cellular therapies.[8]

Summary of Published and Unpublished Studies for Stem Cell Therapeutic Outcomes Database

In FY 2024, the SCTOD contractor developed, conducted, and published research studies in the following areas:

- Evaluating the optimal selection, harvesting, and processing of an unrelated donor graft;
- Evaluating the optimal choice and handling of a CBU for transplantation;
- Comparing alternative donor and graft sources for patients without HLA identical sibling donor(s);
- Evaluating optimal patient selection and treatment strategies for unrelated donor blood stem cell transplants;
- Evaluating optimal patient selection and treatment strategies for cord blood stem cell transplant;
- Evaluating access to care; and
- Evaluating quality of life and late effects of allogeneic blood stem cell transplant.

The SCTOD contractor completed studies on blood stem cell transplantation, resulting in 39 peer-reviewed publications in FY 2024.[9] In addition, there are approximately 133 studies in progress.[10] A number of these studies are in plain language to make them reader-friendly for the public. During FY 2024, the SCTOD contractor also published 18 plain language or non-scientific summaries, surpassing the SCTOD contractor's annual goal of eight summaries designed specifically for patient use.[11]

[6] HRSA. Transplant Survival Rates Survival Data Query Tool. Available at https://bloodstemcell.hrsa.gov/data/transplant-survival-report.
[7] NMPD. Transplant Center Search. Available at https://www.nmdp.org/what-we-do/partnerships/global-transplant-network.
[8] CIBMTR. (n.d). Summary Slides and Reports. Available at: https://cibmtr.org/CIBMTR/Resources/Summary-Slides-Reports.
[9] CIBMTR. Publications. Available at https://cibmtr.org/CIBMTR/Resources/Publications.
[10] CIBMTR. All Studies. Available at https://cibmtr.org/CIBMTR/Studies/All-Studies.
[11] CIBMTR. Study Summaries. Available at https://cibmtr.org/CIBMTR/Utility-Nav/Patients/Study-Summaries.

Single Point of Access - Coordinating Center Support Demonstration Projects for FY 2024

The Stem Cell Therapeutic and Research Act of 2005, P.L. 109-129, and as amended, includes a requirement that states, in part:

> *"…support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks [sic] receiving a contract under the National Cord Blood Inventory program…"*

FY 2024 Project Summary (Cord Blood Immersion Program - Year 1)

In FY 2024, HRSA supported the creation of a Cord Blood Immersion Program to facilitate junior clinicians gaining hands-on experience with expert mentors in cord blood transplantation. The Cord Blood Immersion Program paired two junior physicians interested in learning about cord blood transplantation with two expert physician mentors (one focused on pediatric transplant and one on transplanting adults) for an immersive 2-week, in-person training. The Immersion Program was conceptualized through conversations between the SPA-CC contractor, the Cord Blood Advisory Group, and the broader cord blood community to define priorities of high impact affecting the field. This program intends to help ensure access to cord blood transplant training for the next generation of transplant clinicians, improving the quality of practice and, ultimately, patient outcomes of cord blood transplantation.

All parties involved gave positive feedback during the 2-week training period, which took place between May and June 2024. In addition to learning on-site with expert mentors, the two mentees spent time in CBBs, accessed education materials created by NMDP, shared their experiences with the Cord Blood Advisory Group, and attended the 2024 Annual Cord Blood Connect conference in Miami, Florida.

FY 2025 Demonstration Project Summary (Cord Blood Immersion Program - Year 2)

In FY 2025, CWBYCTP will support a second iteration of the Cord Blood Immersion Program by expanding access to the 2-week training to potentially four junior physicians interested in learning about cord blood transplants. The program will again pair four mentees with two expert mentors to learn about either pediatric or adult cord blood transplantation. In addition to the educational portion of the program, in FY 2025, the SPA-CC contractor will conduct a robust evaluation of the Cord Blood Immersion Program and its potential impact on cord blood transplant.

IV. National Cord Blood Inventory Program Overview

The NCBI program contracts with CBBs to meet the statutory goal of building a public inventory of at least 150,000 new, high-quality, genetically varied CBUs, available to individuals through the CWBYCTP donor registry. CBBs may also make donated CBUs available for research if

they are not suitable for clinical transplantation. The costs to recruit, collect, test, cryopreserve, store, and make CBUs available for listing through CWBYCTP vary by CBB.

HRSA awards contracts to public CBBs through a competitive process and reimburses CBBs on a per-CBU basis for each unit that meets all the criteria specified in the contracts. The contracts specify the total number of CBUs HRSA will reimburse per year and the agreed-upon genetic variability of donors (Table 6). Setting genetic variability collection goals helps to ensure that collected CBUs emanate from genetically varied populations.

HRSA conducts annual reviews of each contractor's progress, and the results provide the basis for future funding decisions. When funding is available, HRSA exercises contract options to support the banking of additional CBUs. Table 5 shows the previous 5 years of the NCBI program's appropriations and funding history. Contracted banks faced challenges meeting collection requirements stemming from the impacts of the COVID-19 pandemic, which led to lower FY 2021 funds expended on contract awards than projected. HRSA reprogrammed $7 million in funding to CWBYCTP to support the activities of the CBBs other than direct CBU purchases.

Table 5: Appropriations and Contract Funding History for the National Cord Blood Inventory Program for 2020 to 2024*

FY	Appropriation[+]	Total Contract Award
2020	$17,266,000	$16,221,529
2021	$18,266,000	$8,518,294^
2022	$18,266,000	$17,391,017
2023	$19,266,000	$18,391,615
2024	$19,266,000	$16,504,647**
Total	$92,330,000	$77,027,102

*Data Source: HRSA information as of December 17, 2024.
[+]Administrative costs account for differences between appropriations and total contract awards.
^In 2021, HRSA reallocated $7.0 million from the NCBI program to CWBYCTP to support cord blood functions through Demonstration Projects. The Demonstration Projects aimed to increase cord blood utilization and improve transplant outcomes.
**$2.0 million of the original contract award was used toward a separate contract to review and provide recommendations for enhancements to the NCBI program.

From the inception of the NCBI program in FY 2004 through FY 2024, HRSA awarded 28 NCBI program contracts to 13 different contractors. Figure 2 identifies organizations with contracts as of the end of FY 2024 and their geographic distribution. Geographic dispersion not only ensures the continued availability of CBUs should a disaster temporarily impact one region of the country but also helps to guarantee that genetically varied CBUs will be collected and available to help more individuals in need.

Figure 2: National Cord Blood Inventory Banks*

*Data Source: Figure created by HRSA with publicly available information. As of the end of FY 2024, HRSA contracted with 10 CBBs for NCBI CBUs. Those contractors include five CBBs still operating active collections: Carolinas Cord Blood Bank at Duke University, Cleveland Cord Blood Center, LifeCord Cord Blood Bank at LifeSouth Community Blood Centers, Bloodworks, and the University of Texas MD Anderson Cancer Center; and five CBBs with maintenance contracts for units previously collected: JP McCarthy Cord Stem Cell Bank at Wayne State University, New Jersey Cord Blood Bank at Bergen Community Regional Blood Center, New York Blood Center, St. Louis Cord Blood Bank at SSM Cardinal Glennon Children's Medical Center, and South Texas Blood and Tissue Center (Gencure).

National Cord Blood Inventory Program Accomplishments and Statistical Highlights

CBBs collected and made available for patient searches approximately 18,600 CBUs from FY 2020 through FY 2024 (Table 7), and CWBYCTP selected 55 percent of the CBUs released for transplantation from NCBI (Table 8). CBU collection and banking remain key in serving a varied population. As NCBI's inventory of CBUs grows and becomes more variable, it will continue to provide increased access to a wider group of patients. Table 6 provides a breakdown of CBUs contracted by the NCBI program by race and ethnicity over the past 5 years. To align with the contract structure for NCBI, in 2019 the program started reporting on CBUs for Multi-race, AI/AN, and Native Hawaiian or Other Pacific Islander (NH/PI) (as denoted in Table 6). CBUs from genetically varied populations (Black or African American, Hispanic or Latino, Multi-race, AI/AN, and NH/PI) account for 67 percent of units collected through the program.

Adding CBUs from genetically varied populations help increase access to blood stem cell transplantation for those who lack a suitably matched adult donor. Lower collection totals in FYs 2021 through 2024 reflect the residual impact of the COVID-19 pandemic, as well as the staffing shortages that occurred in many collection facilities, along with the increased cost to collect, test, and maintain or store CBUs long-term. Lower collections were also due to the unavailability of a U.S. Food and Drug Administration (FDA)-approved test to check for the Zika virus in donors; however, this impact has since been mitigated. In May 2024, FDA changed its policy regarding Zika, noting that it is no longer a relevant communicable disease agent or disease. [12] The cord blood banking community views this change favorably, and it should positively impact cord blood collections for NCBI. As shown in Table 8, the number of total CBU shipments has decreased since FY 2020. This downward trend is primarily due to the increased use of alternative therapies, including haploidentical transplants. Haploidentical transplants use blood stem cells from donors who are biologically related to the recipient and are not facilitated through CWBYCTP (Table 8).

Table 6: Contracted National Cord Blood Inventory Cord Blood Units by Race/Ethnicity for 2020 to 2024*

FY	Asian	Black or African American	Hispanic or Latino**	White	Multi-race, AI/AN & NH/PI	Totals
2020	256	780	1,330	1,335	866	4,567
2021	185	482	1,072	1,621	757	4,117
2022	256	591	1,331	1,364	893	4,435
2023	420	347	1,217	1,366	825	4,175
2024	239	619	1,084	1,292	727	3,961
Total	**1356**	**2819**	**6034**	**6978**	**4068**	**21,255**
% of Total	**6%**	**13%**	**28%**	**33%**	**19%**	**100%**

*Data Source: Internal HRSA information as of September 30, 2024.
**Hispanic or Latino represents a broad ethnicity, and donors may be of any race; a separate category is included to prevent individuals from being counted multiple times.

[12] FDA. (n.d.). Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding FDA's Determination that Zika Virus is No Longer a Relevant Communicable Disease Agent or Disease. Available at: https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/information-human-cell-tissue-and-cellular-and-tissue-based-product-hctp-establishments-regarding.

Table 7: NCBI Cord Blood Collections*

FY	Number of Units Contracted for	Total CBU Collected and Made Available** for Patient Searches +	Cumulative CBU Made Available
2020	4,567	4,100	111,398
2021	4,117	4,100	115,641
2022	4,435	3,200	118,793
2023	4,175	3,400	122,512
2024	3,961	3,700	125,873

*Data Source: NMDP data as of September 30, 2024.
**Due to the lag between when CBUs are collected and when they have been fully tested and qualified for listing on the public registry, not all of the units collected with funds from a given FY will be available on the registry during that same FY.
+ This data is subject to potential adjustments based on updates to CBB-driven CBU clinical records or NCBI removal and replacement activities. As such, the yearly collected volumes will be rounded.

Table 8: Cord Blood Units Released for Transplantation from 2020 to 2024*

FY	NCBI-funded CBU Shipments	Total CBU Shipments**
2020	344	702
2021	313	589
2022	342	576
2023	281	506
2024	289	489
Total	**1,569**	**2,862**

*Data Source: NMDP data as of September 30, 2024.
**Includes both NCBI and non-NCBI CBUs.

NCBI Statutory and Programmatic Assessment Project

In FY 2024, HRSA awarded a $2.0 million contract to the federally funded development and research center MITRE for a Statutory and Programmatic Assessment of the National Cord Blood Inventory Program. The goal of this contract is to receive actionable and evidence-based recommendations for HRSA to meet the NCBI program statutory requirements, improve program implementation, increase the supply of genetically varied CBUs, and increase the number of cord blood transplants for recipients matched to biologically unrelated donors. This is in alignment with HRSA's strategic objective 2.1: *Improve the availability, affordability, and capacity of health care services, systems, and infrastructure,* and U.S. Department of Health and Human Services (HHS) Strategic Plan Objective 1.3*: Expand equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health*. The final program recommendations are expected in September 2025.

V. Advisory Council on Blood Stem Cell Transplantation

Per the Stem Cell Therapeutic and Research Act of 2005 (P.L. 109-129), as amended, the Secretary established ACBSCT to advise the Secretary and HRSA Administrator on matters related to CWBYCTP and the NCBI program. ACBSCT met two times in calendar year 2024

(i.e., August 22, 2024, and October 24, 2024), to review issues related to CWBYCTP and the NCBI program. During the meeting in August 2024, the Advisory Council made three recommendations to the Secretary, as noted below. For NCBI, HHS should define a high-quality CBU as one meeting the specifications outlined in the FDA Guidance for Industry for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood.

HHS should strongly encourage the National Institutes of Health or other relevant HHS agencies to support research specifically focused on cord blood transplantation and cord blood-derived cellular therapy, including the necessary associated infrastructure. This research funding aims to leverage the utilization of NCBI-funded high-quality CBUs to meet the need for treatment of patients with life-threatening cancers and non-malignant diseases.

HHS should support, fund, and continue additional demonstration projects that have the potential to increase cord blood utilization and thereby extend access to allogeneic hematopoietic transplantation, especially for minority patient groups.

Conclusion

CWBYCTP and NCBI worked to expand access to blood stem cell transplants for all patients, including those from genetically varied populations, and carried out initiatives to promote fair access to health in its operations.

CWBYCTP added more than 285,400 adult donor registrants and facilitated approximately 580 more transplants than in FY 2023, with mismatched, unrelated transplants contributing to the increase. CWBYCTP facilitated 7,550 transplants overall, with approximately 1,625 of those transplants (or 22 percent) performed on individuals from genetically varied populations. Close to 490 CBUs were released for transplantation from CWBYCTP, with approximately 290 of those CBUs being from NCBI.

In addition, OPA, SCTOD, and SPA-CC contractors continued to work together to provide public and professional educational opportunities and engage with stakeholders in the blood stem cell community to advance research and improve transplant outcomes.

The NCBI program continued to play a vital role in providing transplant candidates with an additional blood stem cell source by adding thousands of CBUs to its inventory.

ACBSCT continued to meet and provide advice, guidance, and recommendations to the Secretary on matters regarding CWBYCTP and NCBI.

With the sustained support of Congress, these programs will continue to save and enhance the lives of thousands of adults and children who need a potentially life-saving blood stem cell transplant.