



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

REPORT TO CONGRESS

**Fiscal Year 2016 Annual Progress Report on the
C.W. Bill Young Cell Transplantation Program and
National Cord Blood Inventory Program**

Executive Summary

The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109-129, as amended by P.L. 111-264 (section 379(a)(6) of the Public Health Service Act) and P.L. 114-104, includes a requirement in section 3 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.”

This is the fiscal year (FY) 2016 annual report to Congress, which provides background information about the programs authorized by the law, describes the structure and operation of each program, and provides statistical information about the programs from October 1, 2015, through September 30, 2016. This is an update to the 2015 report, which included information through September 30, 2015.

Since the previous report, the Advisory Council on Blood Stem Cell Transplantation held one meeting and made two recommendations to the Secretary of Health and Human Services. The recommendations were regarding studying the economic viability of the cord blood banking system and adopting a new funding framework.

Highlights of this report include activities related to the C.W. Bill Young Cell Transplantation Program (CWBYCTP), such as an expanded pool of 15.9 million volunteer adult marrow registrants, improved survival rates for unrelated-donor transplantation, and increased access to transplantation for underrepresented racial and ethnic populations.

The National Cord Blood Inventory (NCBI) Program contracts with cord blood banks and provides financial support to meet the statutory goal of building a public inventory of at least 150,000 new, high-quality, genetically diverse cord blood units (CBUs). NCBI funds support the collection of NCBI CBUs, which increase access to transplantation. The NCBI continues to grow in size and diversity with over 99,000 CBUs added since 2007 and made available through CWBYCTP. Almost 62 percent of the NCBI units banked were from donors who identified as a race other than Caucasian. Increasing the diversity of NCBI offers an increased chance for transplantation for individuals who lack a suitably tissue-matched relative and cannot find an adequately matched unrelated donor through CWBYCTP donor registry. In 2016, 531 (or 46 percent) of the 1,153 total CBUs shipped for transplantation through the CWBYCTP were NCBI units.



Fiscal Year 2016 Annual Progress Report on the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory Program

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Acronym List

ACBSCT	Advisory Council on Blood Stem Cell Transplantation
ASBMT	American Society of Blood and Marrow Transplantation
BMCC	Bone Marrow Coordinating Center
CBB	Cord Blood Bank
CBCC	Cord Blood Coordinating Center
CBU	Cord Blood Unit
CED	Coverage with Evidence Development
CIBMTR	Center for International Blood and Marrow Transplant Research
CMS	Centers for Medicare & Medicaid Services
CWBYCTP	C.W. Bill Young Cell Transplantation Program
FY	Fiscal Year
HRSA	Health Resources and Services Administration
HSCT	Hematopoietic Stem Cell Transplantation
MDS	Myelodysplastic Syndrome
NCBI	National Cord Blood Inventory
NMDP	National Marrow Donor Program
OASH	Office of the Assistant Secretary for Health
OPA	Office of Patient Advocacy
P.L.	Public Law
SCTOD	Stem Cell Therapeutic Outcomes Database
SPA	Single Point of Access
TNC	Total Nucleated Cell

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 (section 379(a)(6) of the Public Health Service Act) and P.L. 114-104, includes a requirement in section 3 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 Stem Cell Therapeutic and Research Reauthorization Act of 2015 authorizes 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) Healthcare Systems Bureau, Division of Transplantation, is responsible for providing oversight of CWBYCTP and NCBI Programs (see Figure 1).

By statute, the purpose of CWBYCTP is to increase the number of bone marrow and cord blood transplants for recipients suitably matched to biologically unrelated donors. CWBYCTP collaborates with those in the blood stem cell transplantation field to address the need of unrelated blood stem cell transplants for individuals in the United States who have leukemia, lymphoma, sickle cell anemia, or other inherited metabolic or immune system disorders. For some individuals, using marrow or cord blood from an unrelated donor may be their best chance to live longer, healthier lives.

CWBYCTP supports the infrastructure for identifying, matching, and facilitating the distribution of bone marrow and cord blood suitably matched to candidates in need of a blood stem cell transplant. CWBYCTP provides patient and donor advocacy services, case management services, data collection on transplant outcomes, and public and professional educational activities, among many required activities, (see Figure 1).

The NCBI Program contracts with cord blood banks (CBBs) to meet the statutory goal of building a public inventory of at least 150,000 new, high quality, and genetically diverse cord blood units (CBUs). These units are to be made available for transplantation through the CWBYCTP (see Figure 1).

ACBSCT was established to advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services and the Administrator of HRSA on matters carried out by both CWBYCTP and the NCBI Program (see Figure 1). This report provides information

about CWBYCTP, NCBI, and ACBSCT, including the organizational structures, important activities performed, and accomplishments during the past fiscal year (FY).

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

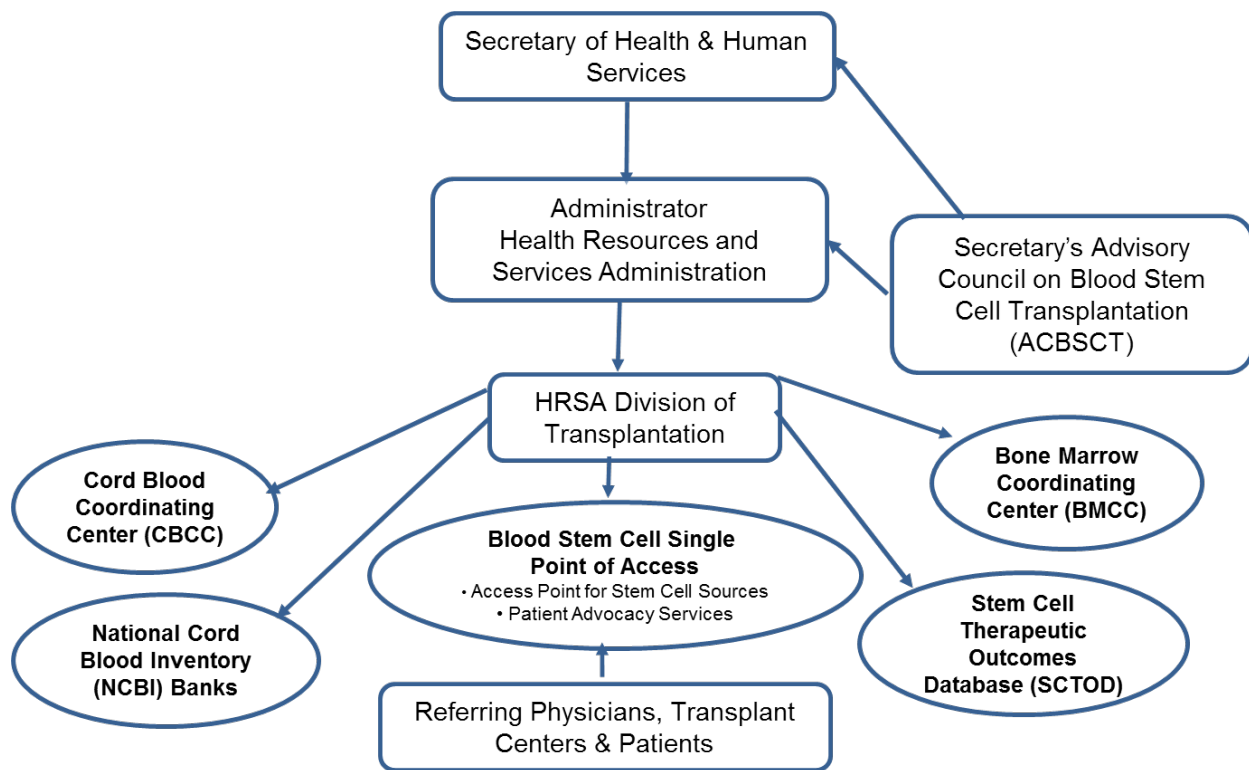
CWBYCTP provides a structure to facilitate blood stem cell transplantation with blood forming cells from unrelated donors for individuals with leukemia and other life-threatening blood disorders. The program also enables data collection on the clinical outcomes of those transplants. CWBYCTP operates through four major contracts awarded through a competitive process during September 2012 (see Figure 1). Each contract has a 1-year base period and four possible 1-year options. During FY 2016, CWBYCTP exercised the fourth option year for each of the four infrastructure contracts. The funding history for the CWBYCTP contracts is in Table 1. The following is a description of the four major contracts:

- The Bone Marrow Coordinating Center (BMCC) coordinates a network of organizations to recruit potential donors with an emphasis on the recruitment of individuals from diverse populations. This network collectively provides safe marrow transplants, provides tissue typing used to match recipients and donors, engages in public and professional educational activities related to blood stem cell donation, and works closely with other parts of CWBYCTP.
- The Cord Blood Coordinating Center (CBCC) coordinates a network of public CBBs, engages in public and professional education activities related to umbilical cord blood donation and transplantation, and works closely with other parts of the CWBYCTP. CBBs support the network by building the NCBI through collecting and providing access to high-quality cord blood units.
- The combined Single Point of Access (SPA) and Office of Patient Advocacy (OPA) maintain the single electronic system through which physicians can identify and access a suitable blood stem cell product from an adult donor or CBU, engages in public and professional educational activities related to treatment options, and provides supportive services to individuals in need of blood stem cell transplants from time of diagnosis through all stages during and after transplant.
- The Stem Cell Therapeutic Outcomes Database (SCTOD) provides an electronic outcomes blood stem cell transplantation database for use by researchers and health care professionals. The SCTOD also provides a repository that stores donor and patient samples for research and the collection and analysis of data on the clinical outcomes of blood stem cell transplants.

Since 2006, HRSA's contractor, the National Marrow Donor Program (NMDP) has held the competitively awarded contracts for the BMCC, CBCC, and SPA/OPA functions. NMDP is a

not-for-profit organization based in Minneapolis, Minnesota, that manages the largest and most diverse bone marrow registry in the world and helps transplant patients without a matched relative to identify adequately matched volunteer adult marrow registrants or umbilical CBUs. Since 2006, the Center for International Blood and Marrow Transplant Research (CIBMTR) (formerly known as the International Bone Marrow Transplant Registry from 1972-2004) at the Medical College of Wisconsin has held the competitively awarded contract for the SCTOD function. CIBMTR is the principal organization in the United States with the responsibility for collecting and analyzing data on the clinical outcomes of blood stem cell transplants. Funding for CIBMTR originates from financial partnerships with HRSA and the National Institutes of Health in the form of grants and contracts, and other financial support from non-federal entities.

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



Data Source: Figure created by HRSA.

Table 1: Allocations for the C.W. Bill Young Cell Transplantation Program Contracts, Fiscal Years 2006–2016

FY	Appropriation +	Bone Marrow Coordinating Center*	Cord Blood Coordinating Center*	Single Point of Access/ Office of Patient Advocacy*	Stem Cell Therapeutic Outcomes Database	Total Obligation to Program Contracts
2006	\$25,145,000	\$16,125,221	\$1,850,985	\$1,226,354	\$4,000,000	\$23,202,560
2007	\$25,168,000	\$21,125,660	\$0	\$0	\$2,240,629	\$23,366,289
2008	\$23,517,000	\$17,161,837	\$10,371	\$713,487	\$3,684,928	\$21,570,623
2009	\$23,517,000	\$16,691,921	\$717,570	\$659,928	\$3,663,174	\$21,732,593
2010	\$23,517,000	\$15,671,402	\$1,196,701	\$679,991	\$3,883,247	\$21,431,341
2011	\$23,374,000	\$15,640,305	\$749,834	\$700,855	\$4,189,900	\$21,280,894
2012	\$23,330,000	\$16,048,000	\$654,990	\$705,505	\$3,847,741	\$21,256,236
2013	\$21,877,000	\$13,948,000	\$1,474,639	\$723,623	\$3,872,054	\$20,018,316
2014	\$22,054,000	\$13,600,370	\$1,495,000	\$742,285	\$3,959,158	\$19,796,813
2015	\$22,109,000	\$13,205,600	\$1,686,225	\$761,505	\$4,055,904	\$19,709,234
2016	\$22,109,000	\$12,415,360	\$1,937,198	\$781,302	\$4,156,111	\$19,289,971
Total	\$255,717,000	\$171,633,676	\$11,773,513	\$7,694,835	\$41,552,846	\$232,654,870

Data Source: Internal HRSA financial information.

+Administrative costs account for the difference between the level of appropriations and the total funds awarded.

*These are cost-sharing contracts. The amount provided reflects the government’s share.

A. Professional and Public Education Activities

In FY 2016, CWBYCTP delivered educational resources and services to physicians, other health care providers, and the public. These resources included online and in-person courses related to myelodysplastic syndromes (MDS), improving sickle cell disease outcomes, post-transplant care and screening recommendations, quality of life after transplant, related donor transplant, and use of cord blood in the past, present, and future.

To address the lack of access to hematopoietic stem cell transplantation (HSCT) for individuals diagnosed with MDS, the American Society for Blood and Marrow Transplantation (ASBMT), CIBMTR, NMDP, and other organizations requested a national coverage determination from the Centers for Medicare & Medicaid Services (CMS). This request resulted in a decision by CMS during 2010, to provide Coverage with Evidence Development (CED). Subsequently, CIBMTR developed two studies approved by CMS as fulfilling CED criteria. The largest study entitled “Assessment of Allogeneic Hematopoietic Stem Cell Transplantation in Medicare Beneficiaries with Myelodysplastic Syndrome and Related Disorders” uses the SCTOD platform. Since approval in 2010, more than 1,800 individuals over age 65 received HSCT for MDS. Most of

these individuals were Medicare beneficiaries (see Table 2 below for the number of individuals registered with CIBMTR by FY).

Table 2: Number of Individuals 65 Years of Age or Older Registered with the Center for International Blood and Marrow Transplantation Research that Received an Allogeneic Transplant at a U.S. Transplant Center for Myelodysplastic Syndrome in Fiscal Years 2010-2016⁺

Fiscal Year	Related Donor	Unrelated Donor	Total
2010	43	61	104
2011	43	91	134
2012	69	146	215
2013	89	209	298
2014	116	214	330
2015	122	276	398
2016	133	267	400
Total	615	1,264	1,879

Data Source: Center for International Blood and Marrow Transplant Research.

+In previous reports to Congress, this table reported only first allogeneic transplants, which underrepresented the number of overall transplants performed. HRSA modified the table in this report to include all allogeneic transplants performed at U.S. transplant centers for MDS.

On January 27, 2016, CMS announced its decision to provide limited national coverage for allogeneic HSCT for individuals with sickle cell disease, multiple myeloma (allogeneic), and myelofibrosis within the context of CED. Previously, CMS excluded allogeneic transplant for multiple myeloma from coverage and was silent about coverage for sickle cell disease and myelofibrosis. The revised coverage mechanism is similar to the process currently in place for MDS. CMS approved the protocols for sickle cell disease and myelofibrosis under the CED mechanism. CIBMTR is preparing additional protocols for individuals with sickle cell disease and multiple myeloma to address CED criteria.

1. Public and professional engagement regarding quality and value in stem cell transplantation

In FY 2016, CWBYCTP engaged in activities through external working committees initially established by the CIBMTR in FY 2015, during the forum “Aligning Quality and Value in HSCT.” A variety of stakeholders representing the blood stem cell transplantation community (including patient advocacy organizations; medical and program directors from transplant centers; payers; and ASBMT leadership, the Foundation for the Accreditation of Cellular Therapy, and CIBMTR) continue to engage through external working groups to demonstrate quality and value in stem cell transplantation.

2. Professional education and outreach through medical education

- Bone Marrow Transplantation Curriculum Modules (English, Spanish)

CWBYCTP offered 16 education modules developed by NMDP to encourage more physicians to choose the field of HSCT. NMDP and ASBMT worked with medical schools to promote the availability of the modules on the NMDP's website at <https://bethematchclinical.org/Resources-and-Education/Education-Courses-and-Events/Curriculum/> to educate medical students, residents, and fellows.

- Education Program for Health Professionals

CWBYCTP offered multiple continuing education activities to inform health professionals of the latest developments in HSCT treatments, decision-making, and patient supportive care. CWBYCTP offered accredited continuing education activities for nurses, nurse practitioners, physicians, physician assistants, social workers, and other allied health professionals. The courses utilized multiple modes and formats to meet a range of educational needs, including 12 webinars, 2 symposia/meetings, 16 presentations as well as 5 sessions and 8 exhibits at professional conferences and meetings. In addition, CWBYCTP provided information on a large number of papers presenting programs and research findings in peer-reviewed journals (access select list of publications at <https://bethematchclinical.org/research-and-news/browse-research/>).

3. Updated mobile application for post-transplant guidelines

CWBYCTP updated the mobile application version of the post-transplant guidelines and care plans that referring physicians consult when their patients return to their care after undergoing transplantation. The Android link to the transplant guidelines is [https://play.google.com/store/apps/details?id=com.nmdp.webView&hl=en#\\$market://search](https://play.google.com/store/apps/details?id=com.nmdp.webView&hl=en#$market://search), and the iPhone link is <https://itunes.apple.com/us/app/transplant-hct-guidelines/id405310144?mt=8>.

B. CWBYCTP Accomplishments and Statistical Highlights

CWBYCTP serves a growing number of individuals in need of unrelated blood stem cell transplantation. Adding volunteer adult marrow registrants and high-quality diverse CBUs to CWBYCTP helps individuals without a matched family member explore viable options and potentially identify a matched blood stem cell source.

- By the end of FY 2016, CWBYCTP included approximately 15.9 million volunteer adult marrow registrants willing to donate to any matched patient.
- In FY 2016, more than 3.5 million of the registrants (approximately 22 percent) self-identified as belonging to an underrepresented racial or ethnic population.
- In FY 2016, the registry added 324,932 potential volunteer adult marrow registrants of bone marrow or peripheral blood stem cells between the ages of 18-44.

Nearly half, 156,542 (48 percent), of these newly added registrants self-identified as belonging to an underrepresented racial or ethnic population.

Increasing the number of blood stem cell sources of umbilical cord blood and volunteer adult marrow registrants, particularly those from medically underrepresented racially and ethnically diverse populations, is important in order to increase access to blood stem cell transplantation. Increasing the number of blood stem cell sources also addresses the statutory aim of ensuring that members of such populations, to the extent practical, have the same probability of finding a suitable unrelated donor as an individual who is not a member of an underrepresented population.

- The total number of transplants (domestic + international) facilitated decreased 3.2 percent from 6,373 in FY 2015 to 6,166 in FY 2016.
- The number of transplants facilitated for domestic individuals decreased 4.3 percent from 5,078 in FY 2015 to 4,862 in FY 2016.
- The number of transplants (domestic and international) performed overall for members of underrepresented racial and ethnic populations decreased 6.7 percent from 1,069 in FY 2015 to 997 in FY 2016.
- The number of transplants (domestic and international) for Asian individuals, from FY 2015 to FY 2016, decreased approximately 6 percent; however, the number of preliminary searches and formal searches for this group grew in FY 2016. The increase in searches is likely the result of a rise in physician referrals for transplantation.
- Transplants for members of underrepresented racial and ethnic populations represent 16.2 percent of the overall 6,166 transplants that CWBYCTP facilitated in FY 2016.

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

Race/Ethnicity	FY 2015	FY 2016	Percent Change
African American	353	312	-11.6%
Asian	237	223	-5.9%
Caucasian	5,304	5,169	-2.5%
Hispanic/Latino	437	418	-4.3%
Hawaiian/Other Pacific Islander	9	9	0.0%
Multiple Races	7	6	-14.3%
American Indian / Alaska Native	26	29	11.5%
Total	6,373	6,166	-3.2%

Data Source: National Marrow Donor Program.

While the number of unrelated blood stem cell transplants facilitated by CWBYCTP, including those for members of underrepresented racial and ethnic populations decreased by 3.2 percent over the past fiscal year, preliminary information suggests that overall patient access to potentially life-saving transplants did not decrease because many individuals received a haplo-identical transplant from a family member. HRSA is collecting information regarding haplo-identical transplants and will share this information in future congressional reports.

In FY 2016, NMDP had 2,627 related donor-recipient research specimens submitted to its repository. NMDP also maintains an unrelated donor-recipient sample repository that received 9,601 specimens in FY 2016.

In FY 2016, the CIBMTR portfolio included 215 studies in progress. Ninety-four peer-reviewed publications involving blood stem cell transplantation resulted from the completion of studies in progress. Several journals published the studies in progress, including the *Journal of the American Medical Association*, *Journal of Clinical Oncology*, *Leukemia*, *Blood*, *Cancer*, *American Journal of Hematology*, *Journal of Antimicrobial Chemotherapy*, *Biology of Blood Marrow Transplantation*, *Journal of Pediatrics*, *Bone Marrow Transplant*. A list of CIBMTR's 2016 publications is available at <https://www.cibmtr.org/ReferenceCenter/PubList/Pages/index.aspx?year=2016>.

C. Transplant Survival Rates

Because CWBYCTP strives to support individuals from diagnosis through transplant and throughout life after transplant, the program establishes goals not only for the number of transplants facilitated, but also for the outcomes of these transplants. CWBYCTP activities include providing a report on transplant center-specific survival rates.

The report on transplant center-specific survival rates provides potential HSCT recipients, their families and the public, with a comparison of survival rates among the centers in the CWBYCTP network. Transplant centers may also use the report as a basis for developing quality improvement initiatives. Extensive transplant and patient outcome data is available online at https://bloodcell.transplant.hrsa.gov/research/transplant_data/us_tx_data/index.html.

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 diverse CBUs, which are made available to individuals through CWBYCTP. Donated CBUs that are not suitable for clinical transplantation are available for research that has been reviewed and approved by experts in the field of transplantation. The costs to recruit, collect, test, cryopreserve, and make CBUs available for listing through CWBYCTP varies by CBB. In FY 2016, the average cost for banks collecting for the NCBI Program was \$3,915 per unit, up from \$3,787 per unit in FY 2015.

HRSA awards contracts to public CBBs through a competitive process and reimburses CBBs on a per unit basis for each unit that meets all of the criteria specified in their contracts. The contracts specify the total number of reimbursed units per year as well as the targeted racial/ethnic mix of donors (see more details in Table 5). Setting racial/ethnic collection goals helps to ensure that cord blood units are collected from genetically diverse populations.

HRSA conducts annual reviews of each contractor's progress. The results of the reviews provide the basis for funding decisions. HRSA exercises options to support the banking of additional CBUs, subject to the availability of funds, for contractors who demonstrate the ability to meet CWBYCTP's goals as identified by the authorizing statute (including the ability to collect and store diverse, high-quality CBUs for unrelated donor transplantation). Funding decisions aim to ensure progress toward achieving the goal of banking at least 150,000 new units of cord blood while ensuring continued growth in the diversity of the available inventory. Table 4 shows the appropriation and funding history and the number of CBUs purchased for the NCBI Program.

Table 4: Appropriations and Contract Allocation History for the National Cord Blood Inventory Program

Fiscal Year	Appropriation⁺	Total Contract Award Amount	Number of NCBI CBUs Purchased[#]
2004 – 2007*	\$27,719,522	\$27,691,700	23,049
2008	\$8,842,770	\$8,287,707	8,938
2009	\$11,983,000	\$11,240,309	10,207
2010	\$11,983,000	\$11,500,295	9,900
2011	\$11,910,037	\$11,384,224	10,571
2012	\$11,887,490	\$10,976,299	9,162
2013	\$11,265,712	\$10,220,997	7,900
2014	\$11,238,000	\$10,398,185	7,469
2015	\$11,266,000	\$10,404,320	6,469
2016	\$11,266,000	\$10,426,197	5,840
Total	\$129,361,531	\$122,530,233	99,505

Data Source: Internal HRSA financial information.

+Administrative costs account for the difference between the level of appropriations and total funds awarded.

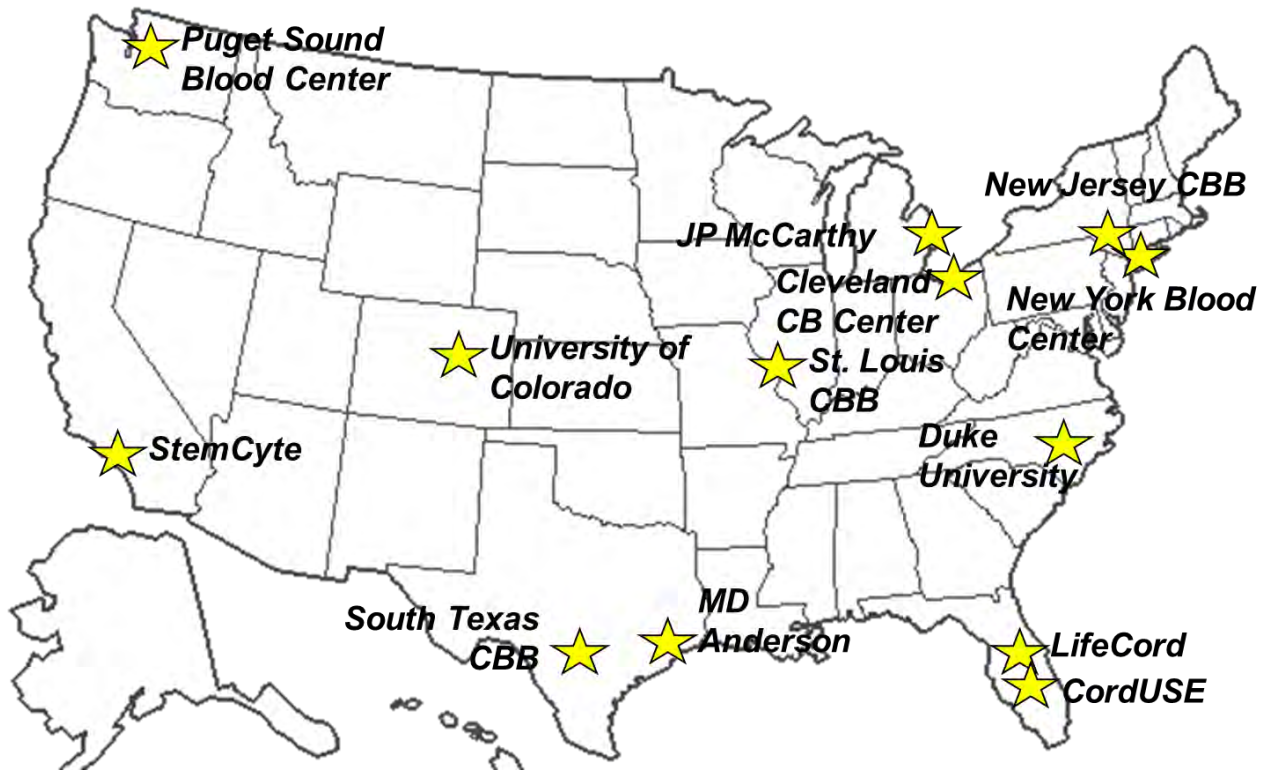
*Contract awards during FY 2007 used funds from no-year appropriations for FYs 2004-2006 and annual appropriations for FY 2007. Per the Appropriation Act for FY 2004, \$988,190 was awarded for a contract with the Institute of Medicine to recommend a structure for the National Cord Blood Stem Cell Bank Program.

#Modification to contracts may result in the number of CBUs that have been funded by the NCBI (also known as NCBI CBUs) varying from prior year reports.

From the inception of the NCBI Program through FY 2016, HRSA has awarded 18 NCBI Program contracts to 13 different contractors (5 contractors hold 2 contracts each) and provided funds to store 89,291¹ NCBI units cumulatively, 62 percent of which were donations from underrepresented racial and ethnic populations. Figure 2 identifies organizations holding an NCBI Program contract as of the end of FY 2016. The figure also shows the geographic distribution of NCBI Program contractors. Geographic dispersion not only ensures continued availability of CBUs should a disaster temporarily impact one region of the country, but it also helps to guarantee that ethnically diverse units will be donated and available to help more individuals in need.

¹ Actual number of units reimbursed by HRSA as of the end of FY 2016.

Figure 2: National Cord Blood Inventory Banks



Data Source: Figure created by HRSA with publicly available information. As of the end of FY 2016, HRSA contracted with 13 umbilical CBBs who collected, tested, stored, and distributed CBUs for the NCBI. Those contractors include Carolinas Cord Blood Bank at Duke University (Duke University), Cleveland Cord Blood Center (Cleveland CB Center), CORD: USE Cord Blood Bank (CORD: USE), JP McCarthy Cord Stem Cell Bank at Wayne State University (JP McCarthy), LifeCord Cord Blood Bank at LifeSouth Community Blood Centers (LifeCord), New Jersey Cord Blood Bank at Bergen Community Regional Blood Center (New Jersey CBB), New York Blood Center, Puget Sound Blood Center, St. Louis Cord Blood Bank at SSM Cardinal Glennon Children’s Medical Center (St. Louis CBB), South Texas Blood and Tissue Center (South Texas CBB), StemCyte, Inc. (StemCyte), University of Colorado, and University of Texas MD Anderson Cancer Center (MD Anderson).

A. NCBI Program Accomplishments and Statistical Highlights

As of September 30, 2016, 99,505 units of cord blood were collected with funds awarded from FY 2007 through FY 2016 (see Table 5). These CBUs represent 66 percent of the minimum statutory goal of at least 150,000 new, high quality, and genetically diverse CBUs. Since 2007, 44 percent (4,898) of the 11,133 cord blood transplants (NCBI and non-NCBI) performed used CBUs selected from the NCBI CBU inventory (see Table 7).

In addition to increasing the NCBI inventory, the support provided to NCBI-contracted banks played an important role in stimulating the collection and banking of additional CBUs (non-NCBI units) and increasing the total number of units available for donation. Additionally, NCBI

banks have provided to researchers more than 62,781 medically unsuitable non-NCBI units for a wide variety of research endeavors.

NCBI continues to grow in size and diversity with over 5,800 new CBUs added annually and made available to individuals through CWBYCTP. Increasing the genetic diversity of NCBI increases the chance for transplantation to those individuals who lack a suitably tissue-matched relative and cannot find an adequately matched unrelated donor through CWBYCTP. At least 50 percent of the newly added CBUs come from racially and ethnically underrepresented donor populations. See Table 5 for a breakdown of CBUs by race and ethnicity funded by the NCBI program.

Table 5: Contract (funded) National Cord Blood Inventory Cord Blood Units by Race and Ethnicity

Fiscal Year	AI/AN⁺	AA[*]	Asian	NH/PI[#]	White, Non-Hispanic	Hispanic – all races	Multi[%]	Totals
2007	35	4,363	1,551	57	7,968	6,996	2,079	23,049
2008	8	1,058	269	4	3,313	3,325	961	8,938
2009	8	876	285	10	4,973	2,683	1,372	10,207
2010	14	661	509	0	3,928	3,487	1,301	9,900
2011	1	2,004	370	12	4,040	2,661	1,483	10,571
2012	16	1,421	480	8	2,879	2,943	1,415	9,162
2013	11	833	333	12	3,003	2,330	1,378	7,900
2014	12	1,302	552	29	3,009	1,504	1,061	7,469
2015 ^Δ	1	1,105	558	9	1,691	1,849	1,256	6,469
2016	2	1,057	460	3	1,815	1,589	914	5,840
Total	108	14,680	5,367	144	36,619	29,367	13,220	99,505
% of Total	0.1%	14.75%	5.39%	0.14%	36.80%	29.51%	13.29%	100%

Data Source: Internal HRSA information.

+American Indian/Alaska Native

*African American

#Native Hawaiian/Pacific Islander

%Multi-racial

^Δ Changes in contract requirements may change numbers from prior years

Table 6: Cord Blood Collections

Fiscal Year	Cumulative Units Made Available²
2007	2,017
2008	11,870
2009	22,920
2010	34,744
2011	43,340
2012	53,609
2013	63,960
2014	74,650
2015	79,276
2016	85,443

Data Source: Internal HRSA information.

Table 7: Cord Blood Units Released for Transplantation

Fiscal Year	National Cord Blood Inventory Units Released for Transplantation	Total Cord Blood Units Released for Transplantation through the C.W. Bill Young Cell Transplantation Program*
2007	4	648
2008	104	898
2009	458	1,056
2010	530	1,153
2011	690	1,180
2012	714	1,191
2013	714	1,102
2014	544	1,359
2015	609	1,393
2016	531	1,153
Total	4,898	11,133

Data Source: Internal HRSA information.

* Includes NCBI and Non-NCBI CBUs.

²Due 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.

B. Demonstration Project to Facilitate the Expansion of Cord Blood Collections at New or Existing Birthing Sites

CWBYCTP continued a demonstration project to develop comprehensive plans to increase the number of cord blood units collected from members of underrepresented racial and ethnic groups with a special emphasis on examining cord blood units with a total nucleated cell (TNC) count $>150 \times 10^7$, at new or existing birthing sites.

FY 2016 funding was awarded to eight CBBs across ten collection sites. Data were collected and analyzed from the selected CBBs quarterly (LifeCord CBB, MD Anderson CBB, Cleveland Cord Blood Center, New Jersey CBB, Bloodworks, Gencure, Lifeforce Cryobanks, and Carolinas CBB).

The participating CBBs experienced multiple challenges obtaining the higher TNC count units (e.g., delays getting into new collection sites, increased use of a delayed clamping technique and labor and delivery staffing changes). As of September 30, 2016, 711 CBUs collected from underrepresented racial and ethnic populations were added from the 10 collection sites with 242 CBUs (34 percent) having a TNC $>150 \times 10^7$.

C. FY 2017 Demonstration Program: Explore Cord Blood Options for Transplant Centers with Difficult Donor Searches

In an effort to minimize transplant treatment delays for individuals, CWBYCTP performed a demonstration project to identify individuals with difficult searches (i.e., unlikely to have a fully matched adult donor). CWBYCTP designed the demonstration project to determine the feasibility of providing transplant centers with cord blood selection information and advice. CWBYCTP provides interested transplant centers with a search strategy if they do not have a fully matched adult donor option and have limited experience with selecting possible cord blood units. The demonstration project involves established CBB experts offering possible cord blood options for individuals who lack an appropriately matched adult donor. In coming years HRSA will continue to provide this service to any transplant center interested in receiving additional advice and consultation regarding appropriate donor graft selection (adult donors or cord blood units).

During FY 2017, HRSA will engage with the blood stem cell community to focus on an enhanced understanding of the biology of cord blood stem cells and engrafting capabilities. The plan is for these collaborative efforts to result in published studies to advance the field of cord blood transplantation. HRSA will provide information regarding the FY 2017 demonstration projects in the FY 2018 congressional report.

D. FY 2016 Study on Financial Feasibility of the Public Cord Blood Banking Industry

Industry experts recently described challenges public CBBs have experienced in affording the cost of the production of a sufficient number of high quality blood units. Subject matter experts within the cord blood banking industry attribute the worsening economic situation of CBBs in recent years to several factors, including the expense of recruiting and adding genetically diverse cord blood units to the inventory, the higher cost of cord blood transplantation compared to marrow or peripheral blood stem cell transplantation, and the expense of facility upgrades to meet Food and Drug Administration licensure requirements.

In March 2016, the ACBSCT recommended that experts conduct a study of the economics of the U.S. public cord blood banking system. In response to the ACBSCT recommendation, HRSA collaborated with the Office of the Assistant Secretary for Health (OASH) to conduct a financial feasibility study of the public cord blood banking industry. OASH has experience conducting and overseeing similar studies within the blood banking industry, and HRSA sought to leverage such experience.

OASH and HRSA are committed to evaluating how public CBBs efficiently use available financial resources and variations in costs among CBBs (e.g., cost of cord blood collection, manufacturing, approaches to achieve financial self-sufficiency). The study, due for completion in autumn 2017, will result in identifying best practices that may improve the financial sustainability of the U.S. public cord blood industry. HRSA will provide any major findings resulting from the study in a future congressional report.

V. Advisory Council on Blood Stem Cell Transplantation

In accordance with the Stem Cell Therapeutic and Research Act of 2005, P.L. 109-129, as amended by P.L. 111-264 (section 379(a)(1)), the Secretary of Health and Human Services established ACBSCT. ACBSCT advises the Secretary and the HRSA Administrator on matters related to CWBYCTP and the NCBI Program. ACBSCT held its first meeting in January 2008, and as of the end of FY 2016, ACBSCT has held 17 additional meetings.

Since its inception, ACBSCT has formed working groups to explore matters related to the following topics:

- Umbilical CBB accreditation;
- Public funding for required outcomes data;
- Cord blood donor confidentiality;
- Access to CBUs for research;
- Informed consent for cord blood donation;
- Scientific factors defining a high-quality CBU;
- Gaps in insurance coverage for transplants;
- Maximizing cord blood collections;

- Procedures for preparing CBUs for infusion; and
- Maximizing the potential uses of cord blood.

By the end of FY 2016, ACBSCT submitted 29 recommendations to the Secretary of Health and Human Services. All ACBSCT meetings are open to the public and announced in the *Federal Register*. Each meeting provides attendees with the opportunity to make public comments. The charter for ACBSCT, its membership roster, agendas for upcoming meetings, and meeting summaries are available on the CWBYCTP website at <http://bloodcell.transplant.hrsa.gov>.

In March 2016, ACBSCT made two recommendations. ACBSCT recommended that HRSA adopt a funding framework that incentivizes the collection of high TNC units for a diverse population and that recognizes higher associated costs of collecting such units. In recognition of the serious challenges confronting the cord blood bank sector and to assure sustainable cord blood bank collection and supply for the future, ACBSCT also recommended that HRSA engage experts to conduct a study of the economics of the U.S. cord blood banking system with the intent to identify current business practices and make recommendations for ways to strengthen the financial operation of this sector to assure long term function. As of September 30, 2016, this work is ongoing. More information regarding recommendations by the Advisory Council are available at http://bloodcell.transplant.hrsa.gov/about/advisory_council/recommendations/index.html.

Summary

By increasing the size and diversity of its blood stem cell registry, CWBYCTP and NCBI have enabled thousands of individuals who lack a suitably tissue-matched relative to explore viable options and identify a matched blood stem source. In less than ten years, over 99,000 new units of cord blood have been added to the NCBI. With almost 16 million volunteer adult marrow registrants, CWBYCTP is increasing access to blood stem cell transplantation. These programs continue to enhance the lives of thousands of men, women, and children who need potentially life-saving bone marrow and cord blood transplants.