



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

REPORT TO CONGRESS

**Fiscal Year 2015 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), 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 an update to the fiscal year (FY) 2014 annual report to Congress, which included information through September 30, 2014. This report 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 as of September 30, 2015.

Since the development of the previous report, the Advisory Council on Blood Stem Cell Transplantation held one meeting and made one recommendation to the Secretary of Health and Human Services. The new recommendation addresses reimbursement for the acquisition of blood stem cells, bone marrow, or umbilical cord blood products for hematopoietic stem cell transplant.

Highlights of this report include activities related to the C.W. Bill Young Cell Transplantation Program (CWBYCTP), such as an expanded pool of 13.6 million volunteer adult marrow registrants, improved survival rates for unrelated-donor transplantation, and increased access to transplantation for minority patients.

Additionally, the National Cord Blood Inventory (NCBI) continues to grow in size and diversity with over 7,000 new cord blood units (CBUs) being added each year and made available to patients through the CWBYCTP. Increasing the diversity of the NCBI offers an increased chance for transplantation for those patients who lack a suitably tissue-matched relative and cannot find an adequately matched unrelated donor through the CWBYCTP. At least 50 percent of the newly added CBUs come from racially and ethnically underrepresented donor populations on the registry. Between FYs 2007 and 2015, over 93,000 new units of cord blood were added to the NCBI, and 38 percent of those units were from donors who identified as White non-Hispanic or Latino. CBUs that have been funded by the NCBI (also known as NCBI CBUs) are increasing access to transplantation. In 2015, 609 (or 44 percent) of the 1,393 total CBUs shipped for transplantation through the CWBYCTP were NCBI units.



Fiscal Year 2015 Annual Progress Report on the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory Program

Table of Contents

List of Figures	3
List of Tables	3
Acronym List	4
I. Legislative Language	5
II. Introduction	5
III. C.W. Bill Young Cell Transplantation Program Overview	6
A. Professional and Public Education Activities	8
1. Public and professional engagement regarding quality and value in stem cell transplantation.....	9
2. Professional education and outreach through medical education: Bone Marrow Transplantation Curriculum Modules (English, Spanish)	10
3. Public and professional outreach and education.....	10
B. CWBYCTP Accomplishments and Statistical Highlights	10
C. Transplant Survival Rates	11
IV. National Cord Blood Inventory Program Overview	12
A. NCBI Program Accomplishments and Statistical Highlights	14
B. Demonstration Project to Facilitate the Expansion of Cord Blood Collections at New or Existing Birthing Sites	16
C. FY 2016 Demonstration Program: Explore Cord Blood Options for Transplant Centers with Difficult Donor Searches	17
V. Advisory Council on Blood Stem Cell Transplantation.....	17
Summary and Conclusions	18

List of Figures

Figure 1: C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory Program.....	8
Figure 2: National Cord Blood Inventory Banks	14

List of Tables

Table 1: Allocations for the C.W. Bill Young Cell Transplantation Program Contracts, Fiscal Years 2006-2015	9
Table 2: Number of Patients 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 2010-2015.....	10
Table 3: Number of Transplants for Minority Patients Facilitated by the C.W. Bill Young Cell Transplantation Program.....	12
Table 4: Appropriations and Contract Allocation History for the National Cord Blood Inventory Program	13
Table 5: Contract (funded) National Cord Blood Inventory Cord Blood Units by Race and Ethnicity.....	15
Table 6: Cord Blood Collections	16
Table 7: Cord Blood Units Released for Transplantation.....	16

Acronym List

ACBSCT	Advisory Council on Blood Stem Cell Transplantation
ASBMT	American Society of Blood and Marrow Transplantation
BMT	Bone Marrow Transplantation
CBB	Cord Blood Bank
CBU	Cord Blood Unit
CIBMTR	Center for International Blood and Marrow Transplant Research
CWBYCTP	C.W. Bill Young Cell Transplantation Program
FY	Fiscal Year
HRSA	Health Resources and Services Administration
MDS	Myelodysplastic Syndrome
NCBI	National Cord Blood Inventory
NMDP	National Marrow Donor Program
P.L.	Public Law

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), 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 and Reauthorization Act 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’s (HRSA) Healthcare Systems Bureau, Division of Transplantation, is the operating division responsible for providing oversight of the CWBYCTP and NCBI Program (see Figure 1).

According to statutory requirements, the purpose of the CWBYCTP is to increase the number of bone marrow and cord blood transplants for recipients who are suitably matched to biologically unrelated donors. Under the program, an infrastructure is supported to operate a system for identifying, matching, and facilitating the distribution of bone marrow and cord blood that is suitably matched to candidate patients. Among many required activities, the CWBYCTP provides support for data collection on transplant outcomes, public and professional educational activities, patient and donor advocacy services, and patient management services (see Figure 1).

The NCBI Program contracts with cord blood banks (CBB) to meet the statutory goal to build 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).

The ACBSCT is 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 the CWBYCTP and the NCBI Program (see Figure 1). This report provides information about the CWBYCTP, NCBI, and ACBSCT, including the organizational structures, important activities that were carried out, and accomplishments during the past fiscal year (FY).

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

The CWBYCTP provides a structure to facilitate blood stem cell transplantation with blood forming cells from unrelated donors for patients with leukemia and other life-threatening blood disorders. The program also enables data collection on the clinical outcomes of those transplants. The CWBYCTP is operated through four major contracts that were awarded through a competitive process in September 2012 (see Figure 1). Each contract has a 1-year base period and four possible 1-year options. During FY 2015, the CWBYCTP exercised the third option year for each of the four infrastructure contracts that are described below. The funding history for the CWBYCTP contracts through FY 2015 can be found in Table 1. The following is a description of the four major contracts:

- The Bone Marrow Coordinating Center coordinates a network of organizations to recruit potential donors (with an emphasis on the recruitment of individuals from diverse populations), coordinates a network of centers that work together to provide safe marrow transplants, provides tissue-typing to match recipients and donors, engages in public and professional educational activities related to blood stem cells, and works closely with other parts of the CWBYCTP.
- The Cord Blood Coordinating Center 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.
- A combined Single Point of Access and Office of Patient Advocacy maintains 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 activities related to treatment options, and provides supportive services to patients in need of blood stem cell transplants from time of diagnosis through all stages during and after transplant.
- The Stem Cell Therapeutic Outcomes Database (Outcomes Database) provides an electronic outcomes database for use by researchers and health care professionals about blood stem cell transplantation. There are also provisions for a repository that stores donor and patient samples for research and for 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 Bone Marrow Coordinating Center, the Cord Blood Coordinating Center, and the Single Point of Access/Office of Patient Advocacy contracts. 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 match transplant patients without a matched relative to adequately matched volunteer adult marrow registrants or umbilical CBUs. Since 2006, the Center for International Blood and Marrow Transplant Research (CIBMTR) at the Medical College of Wisconsin has held the competitively awarded contract for the Stem Cell

Therapeutics Outcomes Database. Through grants and contracts with HRSA and the National Institutes of Health and other financial support from non-federal entities, the CIBMTR (formerly known as the International Bone Marrow Transplant Registry from 1972-2004) has been the principal organization in the United States with the responsibility for collecting and analyzing data on the clinical outcomes of blood stem cell transplants.

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

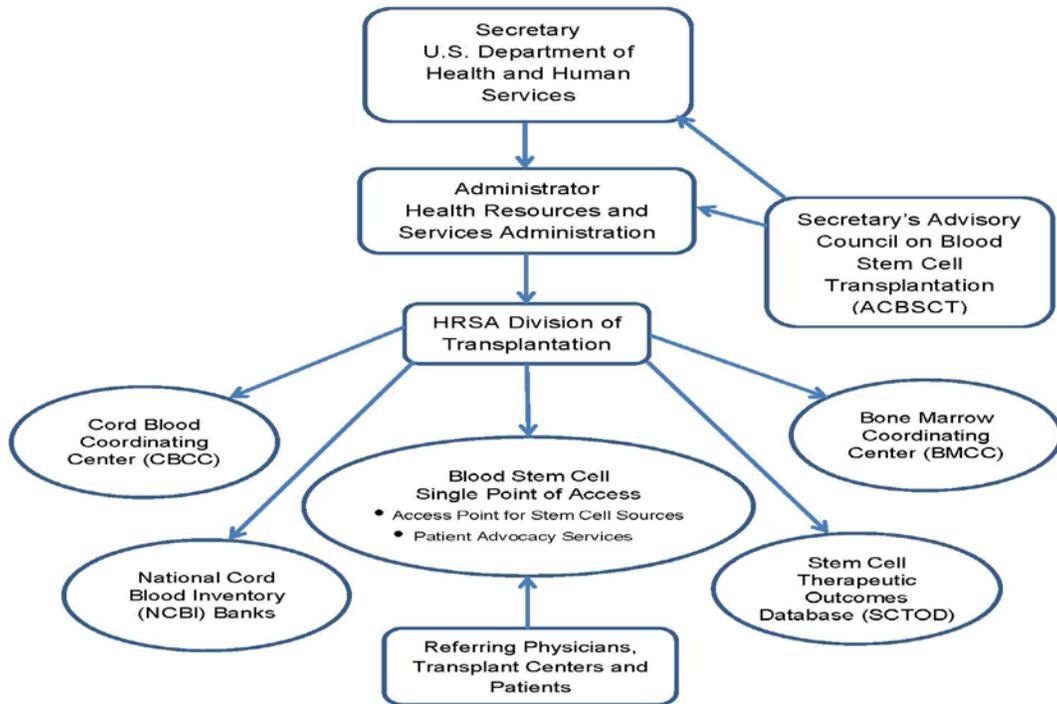


Table 1: Allocations for the C.W. Bill Young Cell Transplantation Program Contracts, Fiscal Years 2006 – 2015

Fiscal Year	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
Total	\$233,608,000	\$ 159,218,316	\$9,836,315	\$6,913,533	\$37,396,735	\$213,364,899

+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

The CWBYCTP delivered educational resources and services to physicians and the general public. These included Continuing Medical Education programs to raise awareness of appropriate transplant indications, including myelodysplastic syndromes (MDS) and sickle cell anemia. Other continuing medical education programs included online and live courses about Pediatric Survivorship after Transplant, the Obstetrician’s Role in Increasing Patients’ Access to Cord Blood, and Timing of Therapeutic Choices for Older Adults.

Other professional education and outreach efforts included tutorials on (1) Coping with Chronic Graft Versus Host Disease; (2) Resilience: What is It and How Can We Promote it in Parents of Children with Cancer; (3) Quality of Life for Bone Marrow Transplantation (BMT) Patients; and (4) Acute Myeloid Leukemia: Treatment Options, Including BMT, Care, and Support.

In an effort to address the challenge of lack of access to Hematopoietic Stem Cell Transplantation for patients diagnosed with MDS, the CIBMTR, NMDP, American Society for Blood and Marrow Transplant Research, and other organizations partnered with the Centers for Medicare & Medicaid Services to develop a Coverage with Evidence Development study entitled “Assessment of Allogeneic Hematopoietic Stem Cell Transplantation in Medicare Beneficiaries with Myelodysplastic Syndrome and Related Disorders.” This ongoing study (end date undetermined and based on patient accrual) was approved by Centers for Medicare & Medicaid

Services in December 2010, and it has enrolled a total of 1,439 patients (see Table 2 below for the number of patients registered by FY).

Table 2: Number of Patients 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 2010-2015^{†*}

Fiscal Year	Related Donor	Unrelated Donor	Total
2010	43	61	104
2011	43	91	134
2012	69	146	215
2013	89	210	299
2014	114	214	328
2015	110	249	359

[†]In previous reports to Congress, this table reported only first allogeneic transplants, which understated the number of overall transplants performed. It is now modified to include all allogeneic transplants performed at U.S. transplant centers for MDS.

^{*}The numbers reported in this table may have changed from previous reports. This change is a result of information reported in the above note and an internal audit.

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

In FY 2015, the CWBYCTP hosted a 2-day working forum entitled “[Aligning Quality and Value in Hematopoietic Cell Transplant](#)” to bring stakeholders together to discuss ways to account for cost and quality when measuring the value of blood stem cell transplantation. The forum consisted of over 100 stakeholders from the stem cell transplantation community, including patient advocacy organizations; medical and program directors from transplant centers; payers; and leadership from the American Society of Blood and Marrow Transplantation (ASBMT), the Foundation for the Accreditation of Cellular Therapy, and the CIBMTR.

Nationally-recognized speakers discussed their perspectives on how the blood stem cell transplantation field could develop approaches to measure quality and improve value for patients. Many approaches centered on coordination of care, public accountability, process improvement, and the overall patient experience. Meeting participants made a number of recommendations including the need for timely referral to a specialist at a transplant center, the need for timely insurance provider approval for transplants, and the need to investigate how the blood stem cell community could leverage data from CIBMTR and other sources to identify utilization patterns and improve transplant outcomes.

2. Professional education and outreach through medical education: Bone Marrow Transplantation Curriculum Modules (English, Spanish)

The CWBYCTP offered 16 education modules developed by the NMDP to encourage more physicians to choose the field of Hematopoietic Stem Cell Transplantation. The NMDP and the 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. Data will be collected in FY 2016 to determine how often the site is accessed for educational outreach.

3. Public and professional outreach and education

The CWBYCTP performed public outreach and education activities on college campuses with an emphasis on Historically Black Colleges and Universities, as well as Hispanic-Serving Institutions. The CWBYCTP also engages families of current patients searching for a match with the intent of increasing the number of volunteer adult marrow registrants listed on the adult donor registry. Family members are important advocates and partners in raising awareness about the unrelated donor registry.

Additionally, the CWBYCTP developed and disseminated post-transplant guidelines and care plans that referring physicians can apply when their patients return to their care after undergoing transplantation.

B. CWBYCTP Accomplishments and Statistical Highlights

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

- By the end of FY 2015, the CWBYCTP included approximately 13.6 million volunteer adult marrow registrants who are willing to be matched for any patient in need.
 - More than 3.4 million of the registrants (approximately 25 percent) self-identified as belonging to an underrepresented racial or ethnic population.
- In FY 2015, a total of 360,765 potential volunteer adult marrow registrants of bone marrow or peripheral blood stem cells between the ages of 18-44 were added to the registry.
 - 182,921 (51 percent) of these registrants self-identified as belonging to an underrepresented racial or ethnic minority group.

The results of efforts of the CWBYCTP to increase the number of unrelated blood stem cell transplants are as follows:

- The total number of transplants facilitated grew 1.9 percent from 6,253 in FY 2014 to 6,373 in FY 2015.
- The number of transplants facilitated for domestic patients grew 3.8 percent from 4,892 in FY 2014 to 5,078 in FY 2015.

Increasing the number of blood stem cell sources of umbilical cord blood and volunteer adult marrow registrants, particularly those from underrepresented racial and ethnical diverse populations, 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 number of transplants performed overall for minority patients increased by 8 percent from 990 in FY 2014 to 1,069 in FY 2015 (see Table 3). While the number of transplants for Asian patients from FY 2014 to 2015 shows a decrease of less than 1 percent, the number of preliminary searches, formal searches, and transplants for this group has grown since 2010. Transplants for minority patients represent 16.8 percent of the 6,373 transplants that were facilitated by the CWBYCTP in FY 2015.

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

Race/Ethnicity	FY 2014	FY 2015	Percent Change
African American	302	353	16.9%
Asian	239	237	-0.8%
Hispanic/Latino	411	437	6.3%
All Minorities	990	1,069	8.0%

C. Transplant Survival Rates

The CWBYCTP strives to support patients from the time of diagnosis through all aspects of transplant and throughout life after transplant; therefore, the CWBYCTP not only establishes goals for the number of transplants that are facilitated, but also examines the outcomes of such transplants. The CWBYCTP established an ambitious long-term goal of increasing the 1-year survival rate of unrelated blood stem cell transplant patients from 62 percent in FY 2003 to 69 percent in FY 2010. To achieve this goal, the CWBYCTP:

- Engaged in education efforts regarding the appropriate timing for referring patients to a specialist at a transplant center and to the resources that are available to transplant candidates and their providers;
- Provided training to transplant centers about best practices for donor-recipient tissue matching and provided education about the various sources of blood stem cells available (i.e., adult donors and cord blood);

- Improved the speed at which donor searches are performed, which enabled more patients to proceed to transplant at the clinically optimal time;
- Refined transplant protocols and patient selection criteria to better determine which patients will benefit from transplant;
- Developed tools to support transplant patients as they transition into long-term survivorship; and
- Increased the number of adult volunteer donors and CBUs available through the CWBYCTP.

The 1-year survival rate increased from 62 percent in FY 2003 to 71 percent in FY 2013. The next long-term goal that addresses the 1-year survival rate is established for FY 2017, and the outcome data for the FY 2017 goal will not be available until FY 2019, as it takes 1 year to accrue the data post-transplant and 1 year to generate the report. This data will be reported in a future report.

IV. National Cord Blood Inventory Program Overview

The NCBI Program contracts CBBs to meet the statutory goal to build a public inventory of at least 150,000 new, high-quality, genetically diverse CBUs, which are to be made available to patients through the CWBYCTP. Donated CBUs that are not available for clinical transplantation are made available for research that has been reviewed and approved by experts in the field of transplant. The costs to recruit, collect, test, and cryopreserve CBUs and make them available for listing through the CWBYCTP varies by CBB. In FY 2015, the average cost for banks collecting for the NCBI Program was \$3,787 per unit.

HRSA awards contracts to public CBBs through the competitive Request for Proposal process, where CBBs are reimbursed 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 units to be reimbursed per year as well as the racial/ethnic background of donors. Setting racial/ethnic diversity goals helps to ensure continued growth in the variety of tissue types that are available for transplantation.

HRSA conducts annual reviews of each contractor's progress. The results of the reviews provide the basis for funding decisions. Subject to the availability of funds, options to support the banking of additional CBUs are exercised for contractors who have demonstrated the ability to meet the CWBYCTP's goals as identified by the authorizing statute (i.e., the ability to collect and store diverse, high-quality CBUs for unrelated donor transplantation). Funding decisions have aimed to ensure that progress is made 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 number of CBUs purchased for the NCBI Program through FY 2015.

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	6,458
Total	\$118,095,531	\$112,104,036	93,654

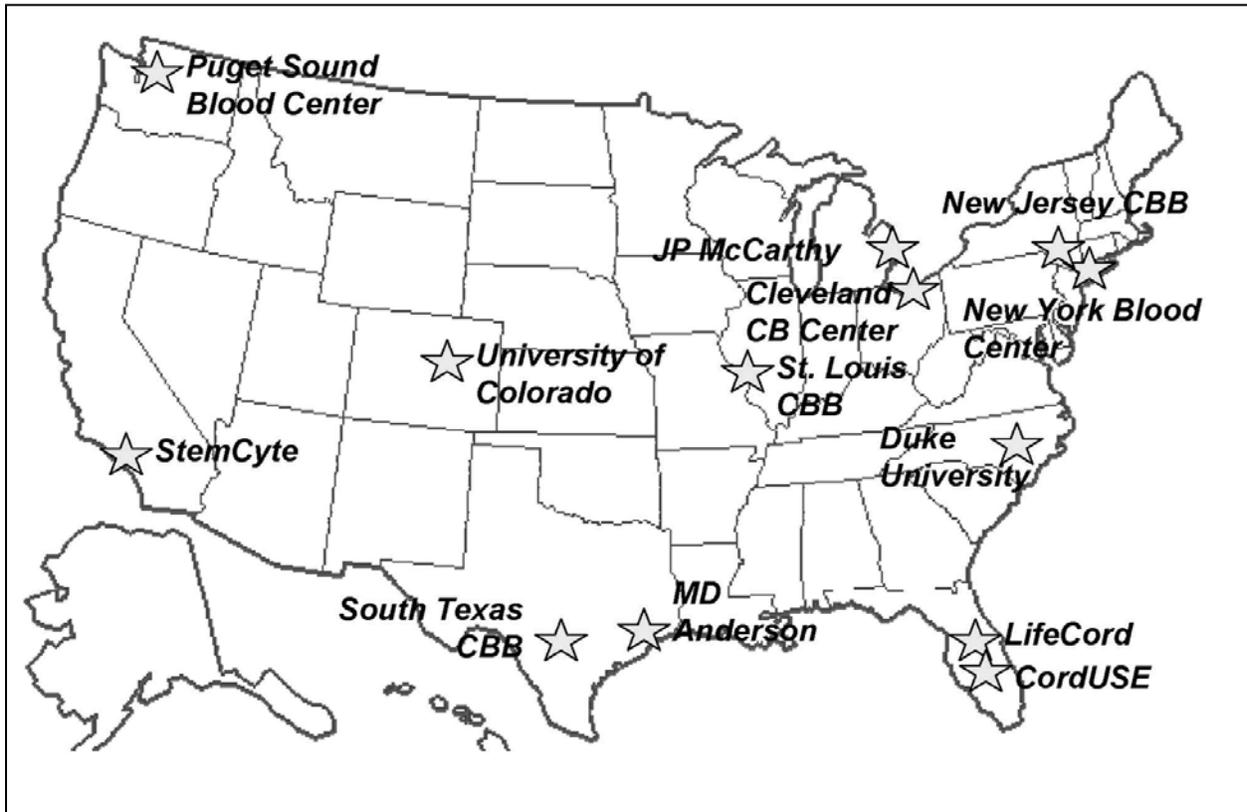
+Administrative costs account for the difference between the level of appropriations and total funds awarded.

*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.

Since the inception of the NCBI Program through FY 2015, HRSA has awarded 18 NCBI Program contracts with 13 different contractors (5 contractors hold 2 contracts each), and has provided funds to store nearly 80,000 NCBI units, 60 percent of which were from minority donors. Figure 2 identifies organizations holding an NCBI Program contract as of the end of FY 2015. 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 patients in need.

Figure 2: National Cord Blood Inventory Banks



As of the end of FY 2014, HRSA has contracted with 13 umbilical CBBs to collect, test, store, and distribute CBUs for the NCBI. Those contractors are 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, 2015, 79,276 CBUs that have been funded by the NCBI (also known as NCBI CBUs) were available through the program (see Table 6). This represents an increase of 9,373 (13 percent) since the 2014 report to Congress. A cumulative total number of units of cord blood will be collected with all funds awarded during the period FY 2007 – FY 2015 (see Table 6). Since 2007, 4,367 (44 percent) NCBI CBUs have been selected for transplantation compared to 9,980 total cord blood transplants (NCBI and non-NCBI) during the same time period (see Table 7).

In addition to directly growing the NCBI inventory, the support provided to NCBI-contracted banks has played an important role in stimulating the collection and banking of many other

(non-NCBI) units. These CBUs may not meet the minimum cell content threshold established for the NCBI, but may be a suitable source of blood stem cells for smaller patients where an acceptable cell dose can still be achieved using smaller units. Additionally, NCBI banks have provided to researchers more than 53,025 non-NCBI units for a wide variety of research endeavors.

The NCBI continues to grow in size and diversity with over 7,000 new CBUs being added each year and made available to patients through the CWBYCTP. Increasing the diversity of the NCBI offers an increased chance for transplantation for those patients who lack a suitably tissue-matched relative and cannot find an adequately matched unrelated donor through the CWBYCTP. At least 50 percent of the newly added CBUs come from racially and ethnically underrepresented donor populations on the registry. Between FYs 2007 and 2015, nearly 80,000 new units of cord blood were added to the NCBI, and 37 percent of those units were from donors who identified as White non-Hispanic or Latino. See Table 5 for a breakdown of CBUs by race and ethnicity that have been contracted by FY.

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

Fiscal Year	AI/AN⁺	AA[*]	Asian	NH/PI[#]	White	Hispanic/ Latino	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	1	1,183	558	9	1,691	1,760	1,256	6,458
Total	106	13,701	4,907	141	34,804	27,689	12,306	93,654
% of Total	0.1%	14.6%	5.2%	0.2%	37.2%	29.6%	13.1%	100%

+American Indian/Alaska Native

*African American

#Native Hawaiian/Pacific Islander

%Multi-racial

Table 6: Cord Blood Collections

Fiscal Year	Cumulative Units Made Available¹
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

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	1056
2010	530	1153
2011	690	1180
2012	714	1191
2013	714	1102
2014	544	1359
2015	609	1393
Total	4,367	9,980

* Includes NCBI and Non-NCBI CBUs.

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

The CWBYCTP continued a demonstration project by working with five accredited CBBs to develop comprehensive plans to increase the number of cord blood collections at new or existing birthing sites in racially and ethnically diverse communities. The cord blood banks sought to educate and obtain consent from expectant mothers for the collection and banking of their

¹Due to the lag between when CBUs are collected and when they have been fully tested and qualified for listing on the public registry, all of the units collected with funds from a given FY will not be made available on the registry during that same FY.

umbilical CBUs. Data were collected from the selected CBBs (i.e., LifeCord CBB, MD Anderson CBB, Cleveland Cord Blood Center, New Jersey CBB, and Carolinas CBB) and analyzed quarterly to assess impact.

The CBBs demonstrated their ability to overcome the challenges (e.g., delays getting into new collections sites, timing constraints in obtaining institutional review board approvals), that were initially faced with the demonstration project in 2014. As of September 30, 2015, there were 10 new or existing collection sites and a total of 850 CBUs added with 55 percent being recorded as Asian and African American CBUs. In 2015, the CBU collection rates increased from 466 to 850 CBUs, and the CBBs began sharing best practices with each other. A continuation of this demonstration project is planned in FY 2016 with an added component to provide additional funding for CBUs that have a Total Nucleated Cell count above 150×10^7 .

C. FY 2016 Demonstration Program: Explore Cord Blood Options for Transplant Centers with Difficult Donor Searches

In an effort to minimize treatment delays, the CWBYCTP proposes to perform a demonstration project in FY 2016 to identify patients with difficult searches (i.e., unlikely to have fully matched donors). The demonstration project will help to determine the feasibility of providing transplant centers with cord blood selection information and advice. Transplant centers will be provided with a search strategy if they do not have a fully-matched donor option, which will include cord blood recommendations and clinical expertise from an established cord blood transplant physician, if desired. Transplant centers will be assessed based on how often they follow recommended advice, how often physicians with cord blood expertise are consulted, and transplant center satisfaction with the service.

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 the ACBSCT. The ACBSCT advises the Secretary and the HRSA Administrator on matters related to the CWBYCTP and the NCBI Program. The first meeting of the ACBSCT was held in January of 2008, and by the end of FY 2015, there have been 15 subsequent meetings. As soon as the authorizing statute was signed by the President on December 20, 2005, HRSA began the process of establishing the ACBSCT according to the requirements of the Federal Advisory Committee Act. However, due to the statutory requirements, time, and effort required for the establishment of an Advisory Committee under the Federal Advisory Committee Act, the first meeting was convened in January of 2008.

Since its inception, the 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 2015, 27 recommendations had been submitted 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 an opportunity to make public comments. The charter for the ACBSCT, membership roster, agenda for upcoming meetings, and meeting summaries are available on the CWBYCTP website at <http://bloodcell.transplant.hrsa.gov>.

In September 2015, the ACBSCT made a recommendation to HRSA to work with the NCBI banks and the blood stem cell transplantation community to develop recruitment and collection strategies that will result in banking CBUs with the highest possible Total Nucleated Cell count without impairing access for racial and ethnic minorities needing cord blood transplants. As of September 30, 2015, this work is ongoing. More information regarding this or other recommendations made by the Advisory Council may be found at http://bloodcell.transplant.hrsa.gov/about/advisory_council/recommendations/index.html.

Summary and Conclusions

This report reflects the status of the CWBYCTP and the NCBI Program. It provides information on contracts awarded and funding by the CWBYCTP and NCBI. The report outlines the number of potential volunteer adult marrow registrants and CBUs that are available for searching patients. The report outlines the number of unrelated blood stem cell transplants that have been facilitated for all patients, and it also provides the information broken down by domestic patients and those from underrepresented racial and ethnic minority populations. The report outlines activities to support increasing patient access to transplantation as a potential treatment and identifies a future demonstration project that is planned to assist physicians with identified potential stem cell products (e.g., adult volunteer donors and umbilical CBUs). The report also highlights the importance of monitoring and establishing goals on transplant outcomes in addition to assisting patients in getting to transplant. The FY 2013 goal of achieving a 69 percent 1-year post-transplant survival rate was exceeded. The report also provides recommendations made by the ACBSCT since the last report. Future annual congressional reports will continue to provide information on the progress of the CWBYCTP and the NCBI Program.