



Health Resources and Services Administration, Division of Transplantation - Overview ACBSCT Meeting

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Healthcare Systems Bureau (HSB)

Health Resources and Services Administration (HRSA)

Vision: Healthy Communities, Healthy People



Presentation Overview

- HRSA Division of Transplantation (DoT) Oversight Responsibilities
- Statutory Framework: The Stem Cell Therapeutic and Research Act of 2005, as amended
- HRSA's Contracts for the C.W. Bill Young Cell Transplantation Program (CWBYCTP) and National Cord Blood Inventory (NCBI)
- Appropriations for the CWBYCTP and NCBI
- FY 2019 Data for CWBYCTP and NCBI
- FY 2020 Special Engagement with CWBYCTP and NCBI Contractors
- Cooperative Efforts of Federal Agencies



HRSA Division of Transplantation

Oversight Responsibilities

- Primary federal entity responsible for oversight of the U.S. solid organ and blood stem cell transplant systems and for initiatives to support organ and blood stem cell donation and transplantation in this country
- Oversight exercised according to statutory requirements, federal regulations, and federal contracts
- HRSA staff serve as ex-officio, non-voting members of the:
 - Board of Directors of the National Marrow Donor Program (NMDP)/Be The Match and Organ Procurement Transplantation Network (OPTN)
 - Committees and working groups of the NMDP/Be The Match, Center for International Blood and Marrow Transplant Research (CIBMTR) and OPTN



Statutory Framework

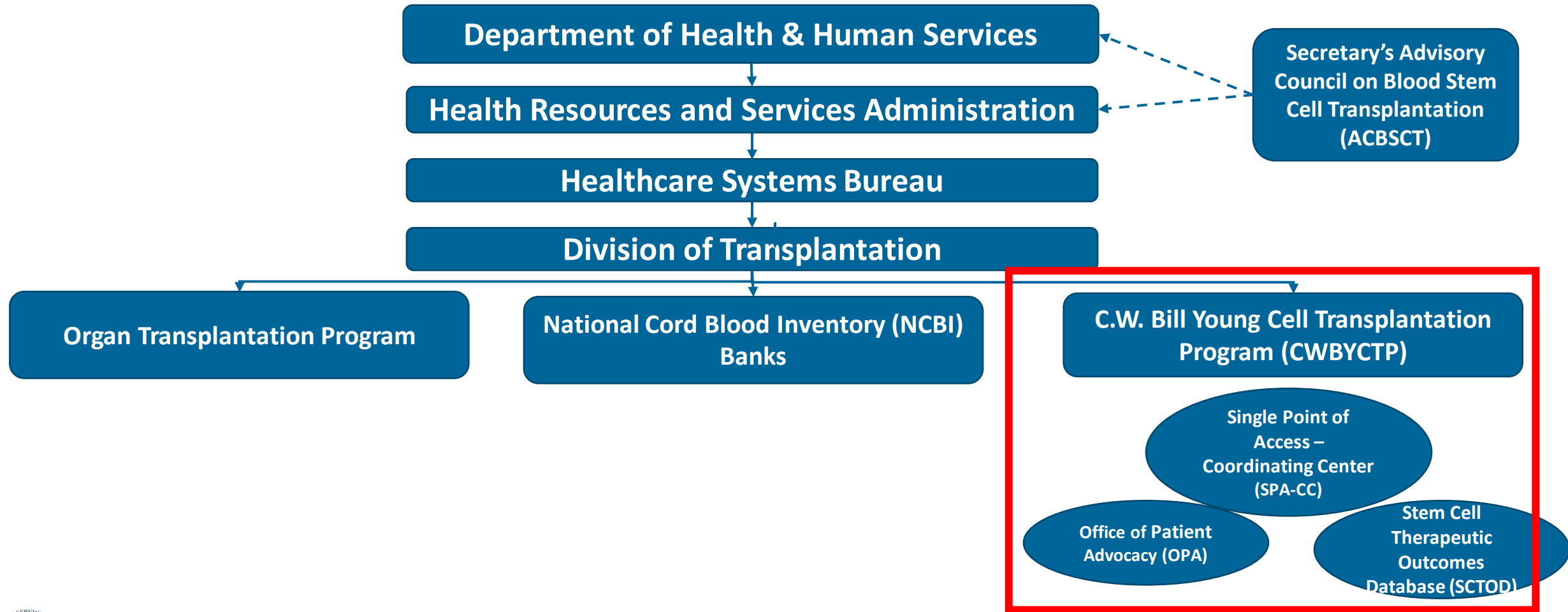
Stem Cell Therapeutic and Research Act

- Stem Cell Therapeutic and Research Act of 2005, P.L. 109-129, as amended by P.L. 111-264 (section 379(a)(1)) and P.L. 114-104, Stem Cell Therapeutic and Research Reauthorization Act of 2015 authorizes:
 - C.W. Bill Young Cell Transplantation Program (CWBYCTP)
 - National Cord Blood Inventory (NCBI)
 - Secretary's Advisory Council on Blood Stem Cell Transplantation (ACBSCT)
- Goals
 - *CWBYCTP*: To increase the number of bone marrow and cord blood transplants for recipients suitably matched to biologically unrelated donors
 - *NCBI*: Contract 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)
 - *ACBSCT*: Advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services and the HRSA Administrator on matters carried out by both CWBYCTP and the NCBI Program



HRSA's Program Oversight

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



C.W. Bill Young Cell Transplantation Program Contracts

- Provides support to patients who need *unrelated* bone marrow or umbilical cord blood transplants

Office of Patient Advocacy (OPA)

- Provides information, resources and support for bone marrow transplant patients and families from diagnosis through survivorship

Single Point of Access (SPA)/Coordinating Center (CC) (SPA-CC)

- Recruits potential marrow donors and works with cord blood banks that collect cord blood units (CBUs), lists CBUs on a single, searchable electronic system and facilitates the distribution of donated CBUs and adult bone marrow that are suitably matched to patients

Stem Cell Therapeutic Outcomes Database (SCTOD)

- Collects and makes data about bone marrow and cord blood transplantation available for research to improve outcomes

National Cord Blood Inventory Program Contractors



National Cord Blood Inventory Program – HRSA Issued New Contracts in 2019 and 2020

- Bloodworks (Seattle, WA)
- Cleveland Cord Blood Center (Cleveland, OH)
- LifeSouth Community Blood Centers (Gainesville, FL)
- New York Blood Center (New York City, NY)
- University of Texas – MD Anderson Cancer Center (Houston, TX)

- In 2020, HRSA awarded a new NCBI contract to-Carolina's Cord Blood Bank at Duke University (Durham, NC)



Appropriation Level by Fiscal Year	C.W. Bill Young Cell Transplantation Program	National Cord Blood Inventory (NCBI)
2019 Enacted	\$24,609,000	\$16,266,000
2020 Enacted	\$30,009,000	\$17,266,000
2021 President's Budget	\$30,009,000	\$8,266,000



Fiscal Year 2019 Data for the CWBYCTP and NCBI

- As of September 30, 2019 (end of FY 2019), the Program's registry included over 22 million adult volunteer donors
- More than 3.9 million (approximately 18%) self-identified as belonging to a specific under-represented racial or ethnic population
- HRSA contracted with cord blood banks to deliver more than 100,000 cord blood units (over 65% of the minimum statutory goal of at least 150,000)
- Over 60 percent of the contracted cord blood units are from under-represented racial or ethnic populations
- The total number of cord blood units (CBU) available through the C. W. Bill Young Cell Transplantation Program ~~is~~ exceeds 240,000 (NCBI and non-NCBI CBU)



Fiscal Year 2019 Data for the CWBYCTP and NCBI (cont'd)

- The total number of transplants facilitated in FY 2019 was 6,426 (compared to 6,188 in FY 2018 - a 5% increase)
- The total number of transplants for domestic individuals was 5,329 in FY 2019 (compared to 5,019 in FY 2018 - a 6% increase)
- The total number of transplants for members of underrepresented racial and ethnic populations in FY 2019 was 1,004 (compared to 992 in FY 2018 – a 1% increase)
- The total number of CBU (NCBI and non-NCBI) released for transplantation in FY 2019 was 848 (compared to 949 in FY 2018 - an 11% decrease)



Cooperative Efforts Among Federal Agencies

- HRSA chairs a Hematopoietic Stem Cell Transplantation (HSCT) Work Group (WG), which meets twice per year, is comprised of various government agencies, primarily within the U.S. Department of Health and Human Services (HHS), and was created to provide a platform to discuss issues regarding hematopoietic blood stem cell transplantation.
- The HSCT WG includes representatives from various institutes in the National Institutes of Health (NHLBI, NCI, NIAID), Centers for Disease Control and Prevention (CDC); Centers for Medicare and Medicaid Services (CMS); Food and Drug Administration (FDA); Veterans Administration (VA), and Department of Defense - Navy.
- The HSCT WG historically focused on the state of HRSA's contractual authority as it relates to unrelated blood stem cell transplantation; however, given the expansion in the field of cellular therapy, the HSCT WG's discussions have broadened.



Cooperative Efforts Among Federal Agencies (cont'd)

- NIH shares some of its relevant research studies; the FDA shares information regarding its regulatory processes; CMS provides information regarding coverage determinations for blood stem cell transplantation; and the U.S. Navy shared information regarding its Department of Defense Marrow Donor Program and its involvement in laboratory research and contingency planning.
- Other collaborations include Department of State (to assess foreign policy implications in facilitating blood stem cell transplants through the CWBYCTP) and Department of Homeland Security (to assist with timely transports of blood stem cell products, including during public health emergencies).



COVID 19 – Special Engagement with CWBYCTP and NCBI Contractors

- HRSA collaborated with its contractors for the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory to understand the impact of COVID-19 on meeting contractual obligations.
- HRSA offered its contractors partial stop work orders
- HRSA worked with contractors and Federal agencies (e.g., Department of State, Department of Defense, Office of Management and Budget) to provide support.



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