



Program Report to the Advisory Council on Blood Stem Cell Transplantation

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Presentation Overview

- Review legislative authority for Stem Cell Therapeutic and Research Reauthorization Act of 2010
- Review Appropriation level for Program and NCBI
- Update on C.W. Bill Young Cell Transplantation Program (Program) and National Cord Blood Inventory (NCBI)
- Discuss importance of balancing Program and NCBI funds
- Share information on current and future efforts to increase cord blood unit collection and transplantation
- Introduce the Blood Stem Cell Transplantation Team

C.W. Bill Young Cell Transplantation Program (Program)

- Authorized by Stem Cell Therapeutic and Research Act of 2005 (P.L. 109-129)
 - Reauthorized October, 2010 (P.L. 111-264)
 - Current authorization expires September, 2015
- Goals are to increase:
 - Number of unrelated-donor transplants
 - Recruitment of potential marrow donors
 - Patient and donor advocacy services
 - Public and professional education re transplantation
 - Analysis and reporting of transplant outcomes data
- Opportunity to help more patients obtain transplants, other therapies, with blood stem cells

Current status of the Program

- The Program serves a growing number of patients in need of unrelated donor transplantation
 - As of September 30, 2014 (end of FY 2014), the Program's registry included approximately 12.4 million adult donors
 - More than 3.25 million (26 percent) self-identified as belonging to a racial/ethnic minority

Current status of the Program cont'd

- The total number of cord blood units (cbus) available through the Program in FY 2014 exceeded 200,000 (NCBI and non-NCBI cbus)
- The total number of transplants facilitated in FY 2014 was 6,253 (compared to 6,283 in FY 2013 - a 0.5% decrease)
- The total number of domestic transplants was 4,882 in FY 2014 (compared to 4,886 FY 2013 - a 0.1% decrease)
- The total number of cord blood transplants (NCBI and non-NCBI) was 960 in FY 2014 (compared to 1,102 in FY 2013 - a decrease of 13%)
- The total number of cord blood units (NCBI and non-NCBI) shipped in FY 2014 was 1,359 (compared to 1,575 in FY 2013 - a decrease of 13.7%)

Appropriation Level by Fiscal Year	C.W. Bill Young Cell Transplantation Program	National Cord Blood Inventory (NCBI)
2013 Final	\$21,877,000	\$11,147,000
2014 Final	\$22,154,000	\$11,238,000
2015 Enacted	\$22,109,000	\$11,266,000
2016 President's Budget	\$22,109,000	\$11,266,000

Balancing the use of Program and NCBI funding

- Balancing the use of Program and NCBI funds is important as Congress expects all authorized functions of the Program and NCBI to be successful
- Conducting cord blood bank site visits to better understand the needs of the banks (particularly with decreased cord blood utilization)
- Conducting site visits to transplant centers, donor centers, apheresis centers, and recruitment organizations to observe and better understand the roles and needs of the organizations involved with facilitating unrelated blood stem cell transplants
- Providing financial support for FY 2016 (through CBCC) to select NCBI banks to make cord blood units (cbus) more rapidly available through the Program
- Identify special projects that will likely not only increase the number of cbus that are collected annually but also increase the number of cord blood transplants

Balancing the use of Program and NCBI funding (cont'd)

- Balancing the use of NCBI funds across the 13 cord blood banks (cbbs) that are actively funding.
- Establishing funding priorities
 - Cbbs collecting all or higher percentage of minority units (particularly from Asians and Black/African Americans)
 - Cbbs that have obtained an FDA Biologics License Application (BLA)
 - Cbbs that offer the government significant discounts/price per unit
 - Financial stability of cbbs
 - Cbbs that are able to expand cord blood collections and produce more cbus annually.

Current Priorities for Public Cord Blood Banking and Transplantation

The goals:

- Continue building the public inventory and meeting the needs of diverse patient populations and our statutory goal for inventory size
- Ensure continued access to umbilical cord blood as a source of blood stem cells
 - Licensed and unlicensed units
- Understand the reasons for the decrease in cord blood utilization

Current Priorities for Public Cord Blood Banking and Transplantation

- Assess current initiatives established to assist with increasing cord blood unit collection and transplantation
 - Remote collections pilot project
 - Expanding cord blood collections at new or existing hospitals
 - Task force to assist with difficult or stalled patient searches
- Establish new initiatives, in consultation with Advisory Council on Blood Stem Cell Transplantation, and other HHS agencies

Together we will soar





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