

Combined Work Group Presentation

Realizing the Potential of Cord Blood & Scientific Factors Necessary to Define a Cord Blood Unit as High Quality

Tom Price
Joanne Kurtzberg

May 29, 2014
Advisory Council on Blood Stem Cell Transplantation

Work Group on Realizing the Potential of Cord Blood—Initial Charge

“The Work Group (WG) will identify important gaps and strategic opportunities with regard to more fully realizing the potential of cord blood in such areas as clinical research, technology development, and the economics of public cord blood banking. At least initially, the WG should focus on the cord blood role in transplantation for hematopoietic reconstitution.”

Realizing the Potential of Cord Blood

- **Original charge**
 - Identify gaps and opportunities in the areas of:
 - Clinical research
 - Technology development
 - Economic issues, especially related to cord banks
- **What was accomplished**
 - Basic charge was fulfilled (May 2012 presentation to ACBSCT).
 - Cord blood economic issues remain
 - Did not recommend that TNC threshold be increased

Work Group on Realizing the Potential of Cord Blood

Members

- Michael Boo
- Colleen Delaney
- Nancy DiFronzo
- Brian Freed
- Dennis Gastineau
- Adrian Gee
- Liana Harvath
- Mary Hennessey
- Joanne Kurtzberg
- Bertram Lubin
- Mutsuko Holiman
- Thomas Price
- Donna Regan
- Pablo Rubinstein
- John Rudrud

Participants

- Stephen Sprague
- Edgar Milford, Chair ACBSCT
- HRSA Staff
 - Robyn Ashton
 - Randy Gale
 - Shelley Grant
 - Nawraz Shawir
 - Patricia Stroup
 - Passy Tongele

Work Group on definition of a high quality CBU

Charges Accomplished

- ✓ **Exclusion Rules**
- ✓ **Clarify cell count requirements**
- ✓ **Kit Model**
- ✓ **Synchronizing accreditation requirements and HRSA NCBI criteria**
- ✓ **Expiration dates and stability**
- ✓ **Standardization of CBU release criteria**
- ✓ **Minimum donor age?**
- ✓ **Overwrap requirement**

Work Group on Scientific Factors Necessary to Define a Cord Blood Unit as High Quality

Members

- Claudio Anasetti
- Robert Chow
- Bob Hartzman
- Liana Harvath
- Joanne Kurtzberg
- Bert Lubin
- Rebecca Pentz
- Larry Petz
- Thomas Price
- Donna Regan
- Pablo Rubinstein
- Machi Scaradavou
- Susan Stayn
- John Wingard

Participants

- Edgar Milford, Chair ACBSCT
- HRSA Staff
 - Robyn Ashton
 - James Bowman
 - Richard Durbin
 - Randy Gale
 - Shelley Grant
 - Nawraz Shawir
 - Patricia Stroup
 - Passy Tongele
 - Anita Wabeke

Combined Work Group Presentation
Realizing the Potential of Cord Blood
&
Scientific Factors Necessary to Define a Cord Blood
Unit as High Quality

Liana Harvath, Ph.D.
Joanne Kurtzberg, M.D.

May 16, 2013
Advisory Council on Blood Stem Cell Transplantation

Realizing the Potential of Cord Blood

- **Conference call 3/14/14**
 - **Presentation of cord blood usage trends by Mike Boo**
 - Use of CB seems to be trending down---down ~10% worldwide in 2013
 - Greatest growth among cell sources 2008-2012 was in haplos
 - Not clear if increased use of haplos responsible for downward CB trend
 - No action items identified for the work group
 - **Cord bank economic issues now in HRSA court**
 - **Proposal to merge work groups**
- **Next steps**
 - **Monitor trends in cord blood use; identify barriers to proper use**
 - **Revisit the TNC threshold issue**
 - **Consider HRSA reimbursement practices**

Recommendations

- **Merge the two committees**
 - Significant overlap in discussion items
 - Members of the two committees are essentially the same—all agree that merger makes sense
 - New name?
- **Revisit the committee charge**
 - Continue to evaluate the characteristics of a high quality cord blood unit
 - Revisit again the recommended minimum TNC threshold
 - Expand to include considerations other than hematopoietic reconstitution
 - Use of cord blood in graft engineering, immunotherapy, etc
 - Use of cord blood in regenerative medicine