

FDA Liaison Meeting for Cellular Therapy Organizations

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Status of Umbilical Cord Blood

- **Increased Utilization**
- **Retrospective series suggest that outcomes are equivalent to mismatched unrelated marrow transplants**
- **For many centers, cord blood is the preferred alternative donor source**

Factors Influencing Outcome of UCBT

- Cell number
- HLA disparity
- Patient and disease characteristics
- No clear effect of collection center, collection technique, or storage method on patient outcome

Cord Blood Banking Standards

- **ASBMT supports the development of standards for:**
 - **Maternal and donor selection/screening**
 - **Collection and processing**
 - **Banking**
 - **Release**
 - **Transport**

Cord Blood Banking Standards

- **FACT-NetCord have already begun the process of accreditation of centers in the United States and Europe**
- **Australia, AsiaCord, and WMDA are adopting FACT-NetCord standards**
- **Data collected by CIBMTR through the US Stem Cell Therapeutic and Research Act of 2005 will help define factors influencing outcome of UCBT**

Considerations for Cord Blood Bank Licensure

- Patients must have access to cord units with those characteristics (e.g., higher cell dose, closer HLA matching) associated with best patient survival
- 20% of units now originate outside of the U.S.; licensure may put an undue burden on non U.S. banks which would make it more difficult for patients to gain access these units
- Archived units collected under conditions that do not meet licensure standards must be available for potential use if they possess optimal cell number and matching

ASBMT Recommendations

- **Encourage accreditation of cord blood banks through FACT-NetCord**
- **Conduct further analysis to determine what cord blood banking procedures are associated with optimal patient outcome**
- **Allow patient's physicians to determine what cord blood unit(s) would be optimal, weighing issues of unit size, HLA match, and quality.**

The logo for the American Society for Blood and Marrow Transplantation (ASBMT). It features the acronym "ASBMT" in a large, white, serif font. A small "TM" trademark symbol is positioned to the right of the "T". The text is set against a solid red rectangular background.

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Considerations for HPC-A Licensure

- The majority of allogeneic transplants utilize peripheral blood, not bone marrow
- It remains unclear how licensure of HPC-A would clearly translate into improved patient safety
- Licensure of HPC-A would increase transplant costs to the public
- If domestic or foreign centers choose not to be licensed and decide not to collect HPC-A, that could negatively impact the donor pool for many of our patients.

Thank you!

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