

National Marrow Donor Program® (NMDP) Screening of International Donors

Fran Rabe

A decorative graphic consisting of several light blue circular nodes connected by thin, curved lines, creating a network-like pattern across the lower half of the slide.

U.S. Importation of Peripheral Blood Stem Cells (PBSC-Primary)

- Calendar Year 2005: N=390

Country	Number	Country	Number
Germany	318	Australia	4
Great Britain, Netherland	13 each	Italy, Taiwan	3 each
France, Norway	9 each	Belgium, Cyprus, Switz.	2 each
Sweden	8	Australia, Canada, Israel, Wales	1 each

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PBSC Donor Screening

- NMDP defines donor screening requirements
 - Health history questionnaire
 - Infectious disease testing
 - Physical exam
- Screening is administered by the Donor Center (DC)/Apheresis center (AC)
- Eligibility status is determined by applicable DC/AC

PBSC Donor Screening

- Health History

- Core required health history screening questions are required to be administered
- Questions shall be translated into the appropriate language by the center
- Questions are not required to be asked exactly as provided by the NMDP

PBSC Donor Screening

- Health History

- Information is communicated to NMDP
- Donors, which indicate possible infectious disease risk for the patient based on the HHQ, IDMs, PE or other records, are considered ineligible
- “Urgent Medical Need” documentation is obtained from Transplant Center (TC) by NMDP, where applicable

PBSC Donor Screening

- Infectious Disease Testing

- Profile:
 - HIV Ab, NAT, HBV SAg and core Ab, HCV Ab, HTLV I/II Ab, STS, CMV
- Laboratory:
 - CLIA accredited
- Test kits:
 - FDA approved/cleared

PBSC Donor Screening

- Infectious Disease Testing

- All results acceptable except HIV confirmed positive
 - Donor declared ineligible, where applicable, per current FDA 1271 requirements

PBSC Donor Screening

- Physical Exam

- Required to perform comprehensive exam
 - Content specified by NMDP.
 - Donor declared as ineligible if criteria is not met.

U.S. Importation of Cord Blood

Calendar Year 2005: N= 21

Spain 12

France 4

Germany 2

Taiwan 2*

Switzerland 1

*Note: These products were from a Member Bank

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Factors That Impact Screening Process of Cord Blood Donors

- Collection of the cord blood occurred prior to or after 5/25/05
- Cord Blood Bank is a NMDP “Member” versus NMDP “Non-Member” Bank

Cord Blood “Member” versus “Non-Member” Banks

- Member banks:
 - Must meet comprehensive NMDP application criteria
 - Audited by NMDP
 - Bank must be registered with FDA as a Tissue Establishment
 - Cord listed on NMDP Registry
 - NMDP facilitates transplant

Cord Blood “Member” versus “Non-Member” Banks

- Non-member banks:
 - Must meet NMDP application criteria
 - Must have local government regulatory oversight or be accredited by AABB, NetCord/FACT, or be ISO certified. (Specifics of government. oversight not stated or evaluated).
 - Bank must be registered with FDA as a Tissue Establishment
 - Cord not listed on NMDP Registry
 - NMDP facilitates transplant

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Cord Blood Member and Non-Member Banks

- Cord blood collected after 5/25/05:
 - Donor eligibility determination performed by cord blood bank
 - “Urgent Medical Need” documentation is obtained from TC by NMDP, where applicable

Cord Blood Member Bank

- Health History Screening

- Cord blood collected prior to 5/25/05:
 - Required to have been screened using "Grandfathered Questions"
 - Required to move from Grandfathered Questions to v. 3 as soon as possible and must implement within 6 months of signing member bank contract

Cord Blood Member Bank

- Health History Screening

- Cord blood collected after 5/25/05 – Current members:
 - Required to have been screened using comprehensive set of questions (V. 3)
- Cord blood collected after 5/25/05 – New applicant members:
 - If bank did not use V. 3,; must indicate questions that were not asked
 - Donor is declared as ineligible

Cord Blood Non-Member Banks - Health History Screening

- Cord blood collected before 5/25/05:
 - Not required to ask specific questions
 - Labeling indicates product was collected prior to 5/25/05 and eligibility declaration does not apply

Cord Blood Non-Member Bank - Health History Screening

- Cord blood collected after 5/25/05:
 - Comprehensive documentation of questions administered
 - Acceptable responses include yes, no, not asked
 - “Urgent Medical Need” documentation is obtained from TC by NMDP, for answers indicating risk or where questions were not asked

Cord Blood Member Banks- Bacterial Testing

- Cord blood collected before 5/25/05:
 - Not provided for distribution if positive for growth and collected after 2004. Product prior to 2004 with positive cultures are available for distribution
 - Cord blood unit would be considered “exceptional”
- Cord blood collected after 5/25/05
 - Not provided for distribution if positive growth

Cord Blood Non-Member Banks- Bacterial Testing

- Cord blood collected before 5/25/05:
 - Positive growth units available for distribution
 - Units are “exceptional”
- Cord blood collected 5/25/05:
 - Positive units declared as ineligible

Cord Blood Member Banks

- Infectious Disease Testing

- Cord blood collected prior to 5/25/05:
 - Must test for HBV, HCV, HIV, HTLV I/II, STS, CMV
 - Laboratory must be CLIA approved and use FDA approved test kits
 - Positive (screen and/or conf.) donors are listed as an "exception donor". (CMV and STS screen positive are not exception donors.)
 - HIV screen or confirmed positive not listed

Cord Blood Member Banks

- Infectious Disease Testing

- Cord blood collected after 5/25/05:
 - Must test for HBV (Ag and core AB), HCV, HIV (Ab and NAT), HTLV I/II, STS, CMV.
 - Laboratory must be CLIA approved and use FDA approved test kits
 - No screen positive donors listed on Registry accept HBcAb, STS (conf. neg.), CMV
 - Declared ineligible where applicable, per FDA 1271 requirements

Cord Blood Non-Member Banks

- Infectious Disease Testing

- Cord blood collected prior to 5/25/05:
 - Must test for HBV, HCV, HIV, STS, CMV
 - Laboratory does not need to be CLIA approved or use FDA approved test kits
 - All results acceptable except HIV screen or confirmed positive

Cord Blood Non-Member Banks - Infectious Disease Testing

- Cord blood collected after 5/25/05:
 - Must test for HBV (Ag and core AB), HCV, HIV (Ab and NAT), HTLV I/II, STS, CMV.
 - Laboratory must be CLIA approved and use FDA approved test kits
 - Positive donors declared as ineligible, where applicable, per FDA 1271 requirements
 - Exceptions to above requirements; donor declared as ineligible

Cord Blood Member Banks

- Physical Exam

- Cord blood collected prior to 5/25/05:
 - Required to perform PE. Content not specified.
- Cord blood collected after 5/25/05:
 - Required to perform maternal exam. Content specified by NMDP.
 - Donor declared as ineligible if criteria are not met. If components of exam incomplete, cord is not listed on Registry

Cord Blood Non-Member Banks

- Physical Exam

- Cord blood collected prior to 5/25/05:
 - Not required to be performed
- Cord blood collected after 5/25/05:
 - Information from comprehensive exam requested
 - If comprehensive exam not performed or components missing, donor declared as ineligible

Questions ?

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