

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

Fran Rabe



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

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

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

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

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

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

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 ?

Contact Fran Rabe, NMDP Program Manager
RA/QA

612-362-3490

frabe@nmdp.org

NATIONAL MARROW DONOR PROGRAM[®]

Creating Connections. Saving Lives.[™]