Qualifying HPC Donors for Unrelated Bone Marrow Transplantation

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Objectives

The learner will be able to:
- Define donor eligibility and suitability.
- Identify agencies/regulatory documents governing stem cell donation criteria in the United States.
- Describe three criteria that are specific to peripheral blood stem cell donors.
Outline

Allogeneic, unrelated donors

- Definitions
- Governing Regulations
- Stem Cell Donor Criteria
- Exceptions to Eligibility
- Summary
- Q & A
Definitions

- Eligibility – a determination whether a potential allogeneic cellular therapy donor meets all donor screening and testing requirements related to transmission of infectious disease as defined by applicable laws and regulations. *

- Suitability – the medical fitness of a potential allogeneic cellular therapy donor to proceed to donation, based on established criteria relative to medical risk associated with donation, as determined by medical evaluation and physician judgment.

*National Marrow Donor Program 23rd Edition Standards and Glossary*
BLOOD DONOR
- CFR – 600 and 800 Series
- Multiple FDA guidance documents
- AABB Standards for Blood Banks and Transfusion Services
- State and local regulations

STEM CELL DONOR
- CFR – 1270 Series
- FDA guidance document – *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*
- AABB Standards for Cellular Therapy
- FACT-JACIE International Standards for Cell Therapy
- NMDP Standards
Feb. 2016 FDA guidance document on management of Zika risk

March 2016 - Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products
Stem Cell Donor Criteria

- Physical exam
  - Weight of 110
  - Acceptable BP and pulse
  - Temp $\leq 99.5$
  - Hgb $\geq 12.5$
  - Plt $\geq 150,000$
Stem Cell Donor Criteria, cont.

- Travel history – risk of malaria, CJD
- HIV/AIDS risk
- Hepatitis risk
- History of diseases including cancer, heart, lung, babesiosis, Chagas, syphilis, gonorrhea and bleeding disorders
- History of previous transfusion, transplant or graft
- Medication history
- History of tattoos or piercings
- Pregnancy status, if applicable
Stem Cell Donor Criteria, cont.

- Similar questions plus:
  - Hospitalizations
  - Anesthesia problems
  - Pregnancy in 6 month window period
  - Back and neck problems
  - Head injuries
  - West Nile Virus history

- Time frame for evaluating conditions tends to be longer
Stem Cell Donor Criteria, cont.

- Testing – within 30 days of donation and repeated on the day of donation
  - HBsAG
  - Anti-HBc
  - HBV NAT
  - HCV NAT
  - Anti-HCV
  - Antibody to HIV types 1, 2, and group O (HIV)
  - HIV NAT
  - Anti-HTLV-1/2
  - CMV
  - Syphilis
- Antibody to T. cruzi (Chagas) – only done once
- HLA typing
- WNV
Evaluation by a physician to include complete medical history and physical exam:

- Height and weight
- Vital signs
- Medication history
- Health history including pregnancy assessment, previous deferrals, contraindications to marrow or apheresis donation, or any potential for increased risk of anesthesia
- Physical evidence or risk of communicable diseases (e.g. dementia – indicative of CJD, generalized fever or rash – indicative of sepsis or systemic infection, etc.)
- GU focus looking for physical evidence of infection if donor reports any high-risk behavior
Additional Criteria for Stem Cell Donors, cont.

- Extensive donor testing
  - Chest x-ray
  - Urinalysis
  - Electrocardiogram
Additional Criteria for Stem Cell Donors, cont.

- Lab testing

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<th>Hematology</th>
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<td>Hgb/Hct</td>
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<td>Antibody screen</td>
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Additional Criteria for Stem Cell Donors, cont.

- **Non-medical factors**
  - Current living situation
  - Recent stressors in his/her life
  - Situational factors such as recent legal problems, family crisis, language barriers, financial problems, etc.
  - Indicators of possible psychological issues
    - Slow speech or movements
    - Forgetfulness or difficulty with comprehension
    - Anxiety/panic attacks
    - Previous suicide attempts
Additional Criteria for Stem Cell Donors, cont.

- Specific psychological disorders
  - Schizophrenia
  - Mental retardation
  - Dementia
  - Depression
  - Substance abuse
  - Eating disorders
  - Personality disorders
Criteria specific to peripheral blood stem cell donors

- Current treatment with lithium
- Presence of sickle cell disease (HgbS)
- History of head injury or concussions*
- Current pregnancy/breastfeeding (contraindication for filgrastim)
- Sensitivity to filgrastim or E. coli-derived products
- History of autoimmune disorders
- History of DVT or pulmonary embolism
- History of iritis or episcleritis
- Plt count < 150 at time of baseline assessment
  - Mild thrombocytopenia defined as Plt 130-149
  - Defer if < 130
Differences in Criteria for Stem Cell Donors

- Question 7 and 8 re. pregnancy
  - Likely in the next 6 months?
  - # of pregnancies - used by transplant center for donor selection
- Questions 4, 12 and 13 re. hospitalizations and experience with anesthesia
- Question 15 re. back, neck, hip or spine problems
- Question 25 addresses “other conditions” and includes an assessment for head injuries
Questions 26 and 27 re. West Nile Virus
Question 32 re. CNS diseases or dementia with unknown causes
Questions 52 and 53 re. MSM risks
Questions 56 and 57 re. travel or residence in African countries
Exceptions to Eligibility

- Exceptions to specific criteria for individual donors are allowed under certain circumstances by NMDP, AABB, FACT, and FDA.
- Decision of what will be allowed is dependent on what the criteria is and what the risk is to the donor and/or recipient.
- Donor must be notified of clinically significant abnormal findings.
- DC and AC MDs determine if findings constitute unacceptable risk for donor and if donor donates, the finding is reported to NMDP.
- TC MD determines if abnormal finding poses unacceptable risk to recipient, and approves in writing (recipient is also notified and counseled).
Exceptions to Eligibility, cont.

- Specific labeling requirements apply when
  - Donor testing/screening is not performed - NOT EVALUATED FOR INFECTIOUS SUBSTANCES
  - Donor testing/screening is incomplete or donor presents with risk factors/clinical evidence - WARNING: Advise recipient of communicable disease risks and NOT EVALUATED FOR INFECTIOUS SUBSTANCES
  - Donor testing/screening is abnormal – WARNING: Reactive test results for (name of disease agent or disease)
Resources

- CFR - 1270
- AABB Standards for Cellular Therapy, 6th Edition
- FDA – Guidance for Industry *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).* August 2007
- FACT-JACIE International Standards for Cellular Therapy – Product Collection, Processing and Administration, Fifth Edition
- WMDA Standards
- WMDA Donor Medical Suitability Recommendations
NMDP

- National Marrow Donor Program 22nd Edition Standards and Glossary
- F00280 – Donor Health History Screening Questionnaire
- A00329 – Rationale and Action Guide for Health History Questionnaire at HR/CT/WU
- A00262 – Assessment Tool at HR/CT/WU
- A00328 – Assessing Non-Medical Factors Affecting Donor Suitability
- A00220 – Physical Assessment Requirements for Marrow and Peripheral Blood Stem Cell Donors
- F00806 – Addendum to Physical Examination
- A00560 – Rational and Action Guide: Zika Virus Infection Assessment
Sincere thanks to
- National Marrow Donor Program/Be the Match
Questions?