Determining Donor Eligibility – Blood Donor vs. Stem Cell Donor

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Objectives

The learner will be able to:

- Define donor eligibility and suitability.
- Identify agencies/regulatory documents governing general blood donation criteria and stem cell donation criteria.
- Describe three criteria that are specific to peripheral blood stem cell donors.
Outline

Allogeneic, unrelated donors

○ Definitions
○ Governing Regulations
○ Routine Blood Donor Criteria
○ Stem Cell Donor Similarities
○ Additional Criteria for Stem Cell Donors
○ Differences in Criteria for Stem Cell Donors
○ 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 22nd Edition Standards and Glossary
Governing Regulations

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
Routine Blood Donor Criteria

Physical Exam
- Weight of 110 lb
- Acceptable BP and pulse
- Temp $\leq 99.5$
- Hgb $\geq 12.5$
- Plt $\geq 150,000$, if applicable

Questionnaire
- 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
Routine Donor Criteria, cont.

- Testing
  - Hepatitis B surface antigen (HBsAg)
  - Antibody to Hepatitis B core antigen (anti-HBc)
  - Antibody to HIV types 1, 2, and group O (HIV)
  - Antibody to Hepatitis C (anti-HCV)
  - Antibody to HTLV types I and II (anti-HTLV)
  - Antibody to T. cruzi (Chagas) – only done once
  - Syphilis screen
  - HCV NAT
  - HIV NAT
  - HBV NAT
  - West Nile Virus NAT
Stem Cell Donor Similarities

Physical Exam

- Weight of 110
- Acceptable BP and pulse
- Temp ≤ 99.5
- Hgb ≥ 12.5
- Plt ≥ 150,000

Questionnaire

- 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 Similarities, 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
- HLA typing
- CBC
- WNV
Additional Criteria for Stem Cell Donors

- 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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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
Additional Criteria for Stem Cell Donors, cont.

- Criteria specific to 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
Differences in Criteria for Stem Cell Donors, cont.

- 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
Resources

- **NMDP**
  - National Marrow Donor Program 22\textsuperscript{nd} 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
Sincere thanks to

- National Marrow Donor Program/Be the Match
Questions?