Chapter 13: Stem Cell Donors

Purpose: To provide minimum necessary to determine a donor’s suitability to donate stem cells.

Scope: These guidelines apply to persons who are being evaluated for the purpose of donating stem cells.

I. Donor Evaluation and Selection Criteria
II. Donor Consent Forms
III. Notification of Allogeneic Donor’s MD of Abnormal Testing
IV. Notification of Donor of Abnormal Testing
I. Donor Evaluation and Selection Criteria

A. Autologous Donors: There are two reasons to perform a stem cell harvest

1. Patients who are at high risk for relapse in the marrow or blood but are currently negative for marrow involvement or peripheral smear abnormalities suggestive of malignancy. These are patients who are being harvested for later use of stem cells. Such patients will only be harvested if there is no evidence of malignancy and only if there is minimal risk of complications with the harvest.

2. Patients who have presented with malignancy in which the plan is to proceed immediately with transplant. For these patients transplant is a necessity so that additional risks will be taken to collect stem cells given the importance of the procedure.

B. Evaluation and Approval/Selection of Autologous Donors:

1. History and Physical within 3 months of the procedure: Goal of donor evaluation is to rule out medical conditions that would increase the risk of harvest or, in the case of a patient who is proceeding on to transplant, a process (such as an infection or cardiac problem) that would represent a contraindication to proceeding directly on to transplant.

2. Blood work within one month of donation: CBC with manual differential, CMP, HIV I/II, CMV, hepatitis B antigen, hepatitis B core antibody, hepatitis C antibody, STS, HSV I/II, Varicella, HTLV I/II, Chagas, WNV NAT, HCV NAT and Hep B NAT, TSH, HLA Class I, LDH, UA, PRA, PT/PTT/INR, ABO/Rh & Ab Screen. Pregnancy test on all female donors who are ≤65 years who have had a period or any vaginal bleeding in last year who have not had a hysterectomy. See Chapter 7 for additional testing for patients with Multiple Myeloma.

3. Testing within 2 months of donation: EKG, CXR, LVEF, PFT (DLCo Adj & FEV1) and 24 hr CrCl.

4. Donor Selection/Approval: Transplant coordinators will complete the Autologous Pre-Transplant Checklist with the data listed above and review this data with the patient’s physician. If abnormal values indicate that additional testing or evaluation are needed, this is specified and ordered by the physician. No patient or donor proceeds with stem cell collection until this form is signed by the physician indicating authorization to proceed.

a) Contraindications:

(1) Absolute Contraindications: HIV I/II (+), Active, serious infections or serious medical problems. Patients known to be allergic to G-CSF or to E coli derived recombinant protein products should undergo marrow harvest rather than HPC-A collection. Patients with known anesthesia intolerance cannot undergo bone marrow harvest. Prior to apheresis, the physician or Advanced Practice Practitioner (APP) should be notified of a WBC<3000; ANC,1500; platelet,100K or hemoglobin,10gm/dL prior to starting mobilization.

b) Relative Contraindications: Patients with severe abnormalities of PFT’s or ECHO or with severe medical problems should be evaluated by a specialist. This physician will then discuss the case with the transplant physician and a decision will be made as to the advisability of proceeding with the transplant.

C. Evaluation and Selection of Allogeneic Donors

1. Goal: Goal of donor evaluation is to exclude or investigate a donor condition that would increase the risk of harvest and to look for evidence of infection or malignancy that could be transmitted to the transplant recipient. Since we are dealing with healthy, normal individuals, donors will be excluded if medical problems produce any significant increase in risk of donation.

2. History and Physical within 3 months of the procedure: The history and physical looks primarily for medical conditions that would increase donor risk such as
significant cardiac or pulmonary problems. There will be detailed inquiries to examine the donor for increased risk of underlying transmissible infection.

3. Blood work within one month of donation: In addition to the testing listed above for autologous donors, the following testing is required: class I and II HLA typing is to be done first by low and then by high resolution; West Nile virus testing; blood type with antibody screen/isoagglutinin; STR.

4. Testing within 2 months of donation: EKG and CXR, unless already done for some other reason during that time.

5. Donor Selection: Transplant coordinators will complete the Allogeneic Pre-Transplant Checklist with the data listed above and review this data with the patient’s physician. If abnormal values indicate that additional testing or evaluation are needed, this is specified by the physician or APP and ordered by the coordinator. No donor proceeds with stem cell collection until this form is signed by the physician or APP indicating authorization to proceed.
   a) Contraindications:
      (1) Absolute Contraindications: HIV I/II (+). Donors known to be allergic to G-CSF or to E coli derived recombinant protein products should undergo marrow harvest rather than HPC-A collection. Donors with known anesthesia intolerance cannot undergo bone marrow harvest and should undergo peripheral blood stem cell harvest instead. With rare exception donors should not undergo apheresis if any component of the CBC is less than the following values: WBC<3000; ANC<1500; platelet<100k; hgb<10 gm/dL prior to starting mobilization.
      (2) Relative Contraindications: Donors with any significant medical problems that could increase the risk of donation must be evaluated by a medical specialist who, in consultation with the transplant physician, will make a decision regarding the safety of donation. Donors with any significant abnormality of the CBC should generally undergo a thorough evaluation, to include bone marrow biopsy, prior to being approved for donation. Treatment with G-CSF may exacerbate autoimmune diseases so that such patients should be treated with caution and should be aware of such potential contraindications. Further, donors with a history of DVT or venous thromboembolism may be at increased risk of these complications following therapy with G-CSF and should be informed of this although this should not be considered an absolute contraindication to stem cell collection.

II. Donor Consent Forms: See BM06-010 Obtaining Informed Consent from Patients and Donors

III. Notification of Allogeneic Donor’s MD of Abnormal Testing
   A. The donor’s MD will be notified of abnormal testing at the request of the patient. See recommendations below.
IV. Notification of Donor of Abnormal Testing
A. On the day of testing, all donors will receive a copy of all testing that was performed, regardless of whether testing was normal or abnormal.
B. Donors will be notified verbally and by letter of any significant abnormal test results.
C. The letter will not state what test was abnormal but it will advise the donor to contact their physician for follow up testing. They will be advised to bring copies of their testing to their physician when they are seen.
D. If it is emergent that their physician be notified of results, then we will obtain telephonic consent to do so and test results will immediately be sent and a call will be made to their physician.
E. If the patient does not have a physician, then a referral will be made to a physician for them.

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VI. See Also:
A. BM06-010 Obtaining Informed Consent from Patients and Donors
B. BM08-005 Donor Evaluation and Selection
C. BM08-045 Notification of Donor of Abnormal Testing