I. Blood Collection

A. Donor Screening

1. All blood and blood components used for transfusion come from volunteer blood donors.
2. A screening process must be performed to ensure that the donor is healthy.
3. Use qualified, professional employees, clean, neat, well lit facility are critical.

B. Blood Bank Versus Blood Center

1. Blood Bank or transfusion service is usually located in the hospital.
   a. Perform compatibility and other serological testing necessary for transfusion of blood and blood components.
   b. Prepares components for transfusion.

2. Blood center may be an independent off site facility or may be located in a hospital.
   a. Responsible for donor selection, donor drawing, serological testing of donor blood, preparation, storage and distribution of components.
   b. May provide specialized services such as HLA typing and harvesting, preparation and storage of tissue such as bone.

C. Standards, Regulations and Governing Bodies

1. The blood banking industry in the US is very regulated and many agencies are involved in setting the standards and guidelines for practice.

2. The Food and Drug Administration (FDA - http://www.fda.gov/) is the governmental agency responsible for ensuring the safety of the nation’s blood supply by mandating all facilities comply with their standards.
   The 2 following agencies fall under the “umbrella” of the FDA.
   b. Code of Federal Regulations (CFR- http://www.gpoaccess.gov/cfr/) mandates that all blood collection facilities comply with "Current Good Manufacturing Practice (cGMPs) for Blood and Blood Components".

2. American Association of Blood Banks (AABB- http://www.aabb.org) is the professional organization which sets standards for practitioners in the field of transfusion medicine.
   a. Provides minimum standards for blood centers and transfusion services.


4. The Joint Commission-http://www.jointcommission.org/) inspects all operations of healthcare organizations every other year, including the laboratory.

5. The Clinical and Laboratory Standards Institute (CLSI-http://www.nccls.org) is an organization that provides published standards for clinical laboratory science in all areas of practice, e.g., a standard format for procedure manuals. Effective January 2005 will be called Clinical and Laboratory Standards Institute.
D. Donor Screening

1. **Serves 2 purposes:**
   a. Assess health of potential donor to ensure donation will not harm them.
   b. Protect potential recipient by preventing selection of donors who may have infectious diseases.

2. Will have one of four outcomes: *acceptance, temporary deferral, indefinite deferral or permanent deferral*. “Indefinite” deferrals are for those conditions for which a test to definitively determine infectious status is not available. For the purposes of this lecture guide “indefinite” and “permanent” will be synonymous.

3. **Three components** of donor screening:
   a. Registration
   b. Medical History
   c. Physical Examination

4. Donor selection is based on a limited physical exam and medical history.
   a. Performance should be done in a way to maintain privacy, allay apprehension and allow time for discussion.
   b. Upon successful completion of the screening process the donor will go on to the actual phlebotomy.

E. Registration of the Donor

1. Must obtain complete and accurate demographic information about each donor.
2. Records must be kept 5 years or 6 months after component expires.
3. Information to be obtained from donor
   a. Date of current donation
   b. Date of previous donation
   c. Full name or previous names
   d. Address
   e. Phone number
   f. Gender
   g. Age and/or date of birth.
      1) At least 17 years of age.
      2) Elderly accepted if they meet all requirements
      3) Autologous donation
   h. Reason for previous deferrals
   i. Written informed consent must be obtained.

3. Additional useful information:
   a. Additional identification information such as social security or drivers license number
   b. Name of patient or group to be credited
   c. Race
   d. Unique characteristics of the donor

4. Information which **must** be provided to the prospective donor.
   a. Educational materials about high risk activities for exposure to HIV, must document.
   b. Warnings about possible donor reactions to donation, first time donors may need more extensive information.
   c. Information on tests that will be done and notification of results.
   d. Post phlebotomy care instructions.
F. Medical History

1. Blood donation - should not donate more than 525 ml every 8 weeks, for hemapheresis it is 48 hours.

2. Have they been deferred as a donor before and, if yes, what was the reason.

3. AABB has simplified and standardized this process by providing a "Uniform Medical History Questionnaire for Whole Blood Donors" http://tinyurl.com/6yo3k

4. Reasons for deferral and time limits of deferral are changing constantly, must keep procedures up to date.

4. Permanent deferral:
   a. Men and women who have engaged in sex for drugs or money since 1977.
   b. Men who have had sex with another male, even one time, since 1977.
   c. People who have used IV drugs (even once).
   d. Taking clotting factors for a bleeding disorder such as hemophilia.
   e. People with clinical or laboratory evidence of HIV infection.
   f. Hepatitis after age 11.
   g. Cancer: Leukemia and lymphoma, individuals who had treatment and have been disease free for 5 years may be acceptable after evaluation by a qualified physician.
   h. Creutzfeldt Jakob disease (CJD): The following individuals are permanently deferred:
      1) Received pituitary growth hormone of human origin
      2) Received a transplant of brain covering (dura mater) or corneal transplant.
      3) Family member with CJD.
      4) Spent a cumulative of 3 months or more between 1980-96 in the UK.
      5) Taken Bovine Insulin imported from countries in which “Mad Cow Disease” has been found, permanent
   i. Individuals who have ever had the following parasitic blood diseases: Chagas Disease or Babesiosis.
   l. People who have ever had a positive test for one or more of the following:
      1) HBsAg
      2) Hepatitis C
      3) HTLV I/II
      4) HIV
   m. Donor who donated only unit of blood given to a patient who then developed post transfusion hepatitis, or has been involved in 2 or more cases of post transfusion hepatitis.

5. Defer for 12 months

   a. Recipient of blood, blood components or had tissue or organ transplant.

   b. High risk behaviors:
      1) Women who have had sex with men who have had sex with another man, even one time, since 1977.
      2) Has had sex with someone who was given drugs or money for sex.
      3) Has had sex with any person who is a past or present IV drug user.
      4) History of syphilis or gonorrhea.
      5) Had sex with someone who has taken clotting factors on regular basis.
      6) Sexual partner of someone who is HIV positive.

   c. Received an injection of hepatitis immune globulin (HBIG).
   d. Acupuncture, tattooing, or ear piercing done under questionable circumstances.
e. Accidental needle exposure or non-sterile skin penetration with instruments contaminated with blood or body fluids.
f. Rabies vaccine given following the bite of a rabid animal.
g. Recent inmate of a prison, juvenile detention or mental institution for more than 72 consecutive hours.
h. Close contact with AIDS or hepatitis patient which is defined as donors who share living quarters or are a sexual partner of a person with viral hepatitis or AIDS.
i. Traveled to a malarial endemic area, components free of RBCs are exempt.
j. Intra nasal use of cocaine

6. Temporary deferral

a. Immunizations
1) Measles (rubeola), mumps, yellow fever, oral polio, typhoid - 2 weeks
2) German measles (rubella), Varicella zoster (chicken pox) - 4 weeks
3) Smallpox - 2 months
4) Rabies, HBIG - 1 year
5) NOTE: There is no deferral for toxoids or killed vaccines (including Hepatitis B vaccine).

b. Medications
1) Aspirin, piroxicam (Feldene) - defer platelet donors for 3 days.
2) Isotretinoin (Accutane) or - 1 month
3) Finasteride (Proscar) (Propecia) - 1 month
4) Acitretin (Soriatane) - 3 years
5) Etretinate (Tegison) - permanent
6) Dutasteride (Avodart) - 6 months.

c. Existing pregnancy or pregnancy in last 6 weeks is cause for deferral except under extremely unusual circumstances.
d. Lived in malarial endemic area or had malarial infection - 3 years
e. West Nile virus - deferred for 28 days from onset of symptoms or until patient is symptom free for 28 days. NOTE: Recent article recommending 56 day deferral.

7. Other illnesses or medications are evaluated on an individual basis.

G. Physical Examination

1. General appearance
2. Weight - 110 lbs.
3. Temperature - 37.5 C or 99.5 F
4. Pulse - 50 - 100 beats per minute and regular
5. Blood pressure
   a. Systolic - less than or equal to 180 mm Hg
   b. Diastolic - less than or equal to 100 mm Hg
6. Determination of hemoglobin level
   a. allogeneic (regular) donors 12.5 g/dL
   b. autologous donors 11.0 g/dL
   c. Hemoglobin determination by copper sulfate with a specific gravity of 1.053 for allogeneic, 1.049 for autologous is a qualitative screening test.
7. Hematocrit may be performed instead of, or in addition to, the hemoglobin.
   a. allogeneic (regular) donor - 38%
   b. autologous donor - 33%
8. Skin at venipuncture site must be free of lesions and needle marks.
H. Confidential Unit Exclusion (CUE)

1. Donors must be given the confidential opportunity to inform blood collection facility not to use their blood for transfusion.

2. Self exclusion opportunity is given to donor upon completion of history and physical, and prior to going into the donor room.

3. Ballot system, uses bar code labels.

4. Encourage donor to call blood center if they change their mind about acceptability.

5. Donor should be informed that their blood will be tested and they will be notified of abnormal results.

I. Donor categories

1. The terms "allogeneic", "homologous" and "random donor" are used to describe blood donated by an individual to be given to anyone.

2. **Therapeutic bleeding (phlebotomy)** is the term used when blood is collected from a patient for medical reasons.

3. **Autologous donation** is the term used for patients who donate their own blood prior to an elective procedure for use by the patient if excessive bleeding occurs.
   a. Very popular for orthopedic, vascular, urologic and cardiac procedures.
   b. Requires doctors order for number of units. Can collect up to 5 to 6 units.
   c. Autologous units are not allowed to "crossed over".
   d. If donor has positive serology must be labeled biohazard and stored separately.

4. **Recipient specific designated donations**
   a. Rare donors
   b. Mother and babies
   c. Single donor for components

5. **Directed donor** is a donor population created due to the public’s fear of AIDS, the patient selects his own donors.

6. Hemapheresis is removal of 1 or more blood components such as plasma, platelets, or WBCs from a donor, the unused portion is returned to the donor.

7. Bone marrow processing and progenitor cell collection is the newest type of tissue harvesting.
   a. Bone marrow (usually autologous) is processed while patient is in remission and frozen.
   b. Stem cell newest therapy which is replacing bone marrow transplants.
      1) Stem cells harvested from peripheral blood by apheresis.
      2) Patient irradiated and stem cells reinfused.
      3) Infused stem cells will engraft and produce "normal" cells.
J. Collection of Blood

1. Phlebotomy performed by well trained personnel.
2. Materials and instruments are sterile, single use and disposable, blood containers must be pyrogen free, sterile and FDA approved.
3. Identification of donor very, very critical.
   a. Identify donor record with the donor
   b. Attachment of numbered labels
   c. Labeling processing tubes
   d. Final recheck
4. Preparing Venipuncture Site
   a. Select large firm vein in area free of lesions.
   b. Preparation of venipuncture site is critical, prepare to a state of surgical cleanliness using iodine solution.
5. Collecting the unit
   a. Gloves should be available and do not have to be worn except:
      1) by personnel in training
      2) during collection of autologous units
      3) if phlebotomist has cuts, scratches or breaks in the skin
   b. Collected from a single venipuncture using a 16 or 17 gauge needle.
   c. During collection mix blood with anticoagulant frequently.
   d. Monitor amount collected carefully by weighing or visual inspection, maximum volume is 450 +/- 45 mls.
   e. Collection should be completed within 15 minutes if platelets will be prepared.

K. Adverse donor reactions

1. Syncope is a general term used for fainting.
   a. Signs/symptoms may include: weakness, sweating, dizziness, pallor, loss of consciousness, convulsions and/or involuntary passage of urine or feces, skin feels cold, blood pressure falls and pulse rate often slows significantly.
   b. Remove tourniquet and withdraw needle
   c. Move donor to area of privacy for treatment
   d. Call physician if treatment does not lead to rapid recovery
2. Hyperventilation caused by excessive respiration, have donor rebreathe into a paper bag.
3. Nausea and vomiting
4. Twitching or muscular spasms occurs most commonly with loss of consciousness and occurs in one half of donors who lose consciousness.
5. Hematoma
6. True convulsions are rare
   a. Call someone to help you immediately
   b. Make sure donor has adequate airway
   c. Notify blood bank physician
7. Serious cardiac difficulties are exceedingly rare but if they do occur call for medical aid and/or an emergency care unit immediately (ambulance). If donor is in cardiac arrest begin CPR immediately and continue until emergency personnel arrive.

8. Record any donor reactions.

L. Care of the Donor After Phlebotomy

1. Check arm and apply bandage.
2. Have donor remain reclined in donor chair for a few minutes.
3. Allow donor to sit up when his/her condition appears satisfactory, check phlebotomy site to make sure bleeding has stopped, and have patient remain seated for 10 - 15 minutes.

4. Donor instructions for post-phlebotomy care.
   a. Eat and drink before leaving.
   b. Do not leave until released by staff.
   c. Drink more fluids in next 4 hours.
   d. No alcohol until you have eaten.
   e. Do not smoke for one half hour.
   f. If bleeding continues raise arm and apply pressure.
   g. If faint or dizzy lie down or sit down with head between your legs.
   h. If symptoms persist return to blood bank or see your doctor.
   i. Cautions about returning to work.
   j. Remove bandage.
   k. Restoration of normal blood volume occurs in approximately 3 days.

5. Thank donor and offer refreshments, watch for signs of donor reaction.
6. Note reactions (if any) or if donor leaves without permission.

M. Processing donor blood

1. All reagents used for testing must meet or exceed appropriate FDA regulations.

2. Records - **Cannot rely on previous records**
   a. All test results and interpretations must be recorded immediately upon completion of testing.
   b. Record system must be such that any unit can be traced from its source to final disposition.
   c. All lab records pertaining to an individual unit must be retrievable, including investigation of adverse affects.
   d. Records should be retained for 5 years or 6 months after expiration date.

3. General considerations in donor processing
   a. Numbers on blood bag, processing tubes and donor records should be rechecked prior to processing.
   b. ABO group and D type, including weak D, must be determined using appropriate testing procedures. **CANNOT RELY ON PREVIOUS RECORDS.**
   c. Donor with history of transfusion or pregnancy should be tested for unexpected antibodies.

4. Testing for diseases which may be transmitted by transfusion:
   a. Hepatitis B Surface Antigen (HBsAg)
   b. Hepatitis B core antibody (HBc)
   c. Hepatitis C - anti-HCV
   d. HIV - anti-HIV-1, anti-HIV-2 and HIV(p24) antigen
   e. Human T-cell lymphotrophic virus -HTLV-I/II
   f. Syphilis - RPR
g. Nucleic Acid Amplification Test - NAT-tests that detect viral nucleic acids are more sensitive than current screening tests is expected to reduce the pre-antibody sero-conversion window period.
   1) For HIV from current 22 days to about 12 days.
   2) For HCV from 70 days to 10 to 14 days.
   3) West Nile Virus (WNV)

5. For transfusion units must be non-reactive, negative or within normal range, if unit must be transfused prior to testing it must be conspicuously labeled and doctor must sign release form.

6. Additional optional tests which may be performed include CMV testing, special antigen typing and test for sickle cell trait.

7. Labeling donor units
   a. Proper name of component.
   b. Unique donor number.
   c. ABO group, D type (not required for plasma components).
   d. Interpretation of antibody tests and results of unusual tests, ie, CMV.
   e. Type and volume of anticoagulant and the volume of the unit (not required for CRYO).
   f. Required storage temperature
   g. Expiration date.
   h. Name and address of the collecting facility and/or facility that prepared the component.
   i. Reference to the Circular of Information. http://tinyurl.com/3cnuvw
   j. Appropriate donor classification
   k. Results of tests for infectious diseases.
   l. Essential instructions or precautions which must include:
      1) "this product may transmit infectious agents"
      2) "properly identify intended recipient"
      3) "federal law requires a prescription"

l. Additives, sedimenting agents and cryoprotective agents added.
m. Pooled components must include the name of the component, a unique identification number, number of units in the pool, ABO and D type of all units and the final volume.

8. The only repeat testing required by the transfusion service is confirmation of the ABO and D type of red cell blood products.
   a. Discrepancies must be reported to the collecting facility and must be resolved prior to issue.
   b. Repetition of other tests on donor units is not required or recommended.

9. Donor samples must be stored in the transfusion service at 1-6 C for at least 7 days after transfusion.