Laboratory 1 Donor History

Objectives

1. Review donor qualifications.
2. List four conditions, which would permanently defer a donor.
3. List four conditions, which would temporarily defer a donor.
4. List the deferral time-periods for immunizations.
5. State the reason for deferral for sexually transmitted diseases.
6. Explain why donors who have spent 3 months or more in the United Kingdom are indefinitely deferred as blood donors.
7. List the two broad reasons for performance of the donor interview and physical exam.

Discussion

Careful donor selection plays a major role in determining whether a unit of donor blood will be therapeutically effective and free of transmissible disease.

There are three parts in the selection of eligible blood donors. The first part involves obtaining a brief oral medical history. The interview must be conducted by qualified personnel in a manner that assures auditory privacy (visual privacy is also recommended), that allays apprehensions, and allows time for any necessary discussion or explanation. Answers to questions must be recorded as "yes" or "no" with details added as indicated. Results of tests must be recorded. Some very specific questions will be necessary but a great deal of pertinent information can be obtained by asking some general or leading questions in simple language that the donor can understand. If a potential donor passes the oral medical history interview, they must then undergo a very limited physical exam.

The third component of the donor selection involves having the donor review the blood donor education materials and the medication deferral list. The details of the physical exam will be covered in the next laboratory exercise.

Based on the answers to specific questions the interviewer must evaluate the responses and determine whether the potential donor is eligible to donate blood. **The questions asked serve two purposes:**

- Ensuring the donation of blood or blood components will not compromise the health of the potential donor.
- Potential donor's blood will not transmit a disease state to the potential recipient.

Donors may donate one unit of whole blood every 8 weeks. Donation intervals for other types of products (double red cell unit, apheresis platelets, etc.) will vary.

- Whole blood or red blood cells 8 weeks
- Two unit red cell unit 16 weeks
    - Male – must be at least 17 years of age; 5'1" tall, and at least 130 pounds
    - Female – must be at least 19 years of age; 5'5" tall, and at least 150 pounds
- Plateletpheresis – Wait at least seven days between platelet pheresis donations
- Plasmapheresis– once every 4 weeks, (need mostly AB plasma, why?)

The minimum age of the donor is 16 according to the AABB. Some states may require parental consent or a higher age. There is no maximum age limit.

The potential donor's past and present health status will aid in making this determination. There are certain situations in which a potential donor will be accepted (past carcinoma in situ of the cervix). Some conditions will require a certain time of deferral (12 months if rabies vaccine has been administered). Other conditions, which will result in a permanent deferral of a donor (AIDS, hepatitis B, hepatitis C, etc.). It is of critical importance that the interviewer knows the type of deferral, which must be recommended for a variety of conditions.

What does the term "donor deferral" mean?

Individuals disqualified from donating blood are known as "deferred" donors. A prospective donor may be deferred at any point during the collection and testing process. Whether or not a person is deferred temporarily or permanently will

depend on the specific reason for disqualification (e.g., a person may be deferred temporarily because of anemia, a condition that is usually reversible). If a person is to be deferred, his or her name is entered into a list of deferred donors maintained by the blood center, often known as the "deferral registry." If a deferred donor attempts to give blood before the end of the deferral period, the donor will not be accepted for donation. Once the reason for the deferral no longer exists and the temporary deferral period has lapsed, the donor may return to the blood bank and be reentered into the system. (From AABB website)

There are three defined areas of deferral:

1. Indefinite Deferral – Prospective donor is unable to donate blood for someone else for an unspecified period of time due to current regulatory requirements. The indefinite deferral would no longer apply if regulatory requirements changed and the donor qualified for re-entry based on results of improved testing methods or a change in the impact of the relevant transfusion transmitted infection, also referred to as RTTI. Indefinitely deferred donors may be eligible to donate autologous blood.
2. Permanent Deferral – Prospective donor is deferred from donation with no possibility for reentry. Permanently deferred donors may be eligible to donate autologous blood. Example of permanent deferral: A prospective donor states that he/she has Creutzfeldt-Jakob Disease. Additionally, some permanent deferrals may result from the testing performed on a previous donation. Permanently deferred donors may be eligible to donate autologous blood.
3. Temporary Deferral – Prospective donor is deferred from donation for a specified period of time. Temporarily deferred donors may be eligible to donate autologous blood. Example of temporary deferral: A prospective donor who received a transfusion within the last three months would be deferred for three months from the date of the transfusion.

Those who may be permanently deferred include:

- Anyone with a positive test for HIV (AIDS virus) or taken medicines to treat an HIV infection
- Anyone who has had hepatitis since his or her eleventh birthday - reevaluate on a case by case basis
- Anyone who has had babesiosis or Chagas disease
- Anyone who has taken Tegison for psoriasis
- Anyone who admits risk factors for Crueutzfeldt-Jakob disease (CJD)
- Anyone who voluntarily admits risk factors for vCJD
- If you received an injection of cadaveric pituitary human growth hormone (hGH) you cannot donate. Human cadaveric pituitary-derived hGH was available in the U.S. from 1958 to 1985. Growth hormone received after 1985 is acceptable.
- If you have been diagnosed with vCJD, CJD or any other TSE (transmissible spongiform encephalopathies) or have a blood relative diagnosed with genetic CJD (e.g., fCJD, GSS) you cannot donate.
- If you have a blood relative diagnosed with familial prion disease
- Anyone with diabetes since 1980, ever used bovine (beef) insulin made from cattle from the UK
- Hepatitis B and/or C positive at any age
- Received a dura mater graft
- Most cancers - Survivors of blood cancers, like leukemia and lymphoma, as well as other blood disorders, are permanently deferred.
- Anyone who has ever had Ebola
- Active tuberculosis or are being treated for tuberculosis

There are some additional general guidelines to follow when making decisions about donor deferral.

- **Twelve (12) month deferrals**
    - Skin graft or tissue transplant (including corneas)
    - Hepatitis exposure
    - Donor who has had sexual contact with any person who has received clotting factor concentrates
    - Donor has been in contact with persons who, in the past or present, have used needles to take drugs, steroids or anything not prescribed by their physician
    - Heart surgery
    - Pacemaker or implanted defibrillator
    - Rabies vaccine after animal bite

  - Travel to Iraq
  - Donor incarcerated in a facility for more than 72 consecutive hours
- **Three month deferrals**
  - Three months after any type of organ transplant
  - History of sex with a person who has had a positive HIV test
  - Women who have sex with men who have had sex with men – eligible to donate if they have not had sex with another man in 3 months
  - Donors who exchange sex for money or drugs (prostitutes) or engaged in non-prescription drug use or non-prescription IV drug use
  - Donors that have had sexual partners engaged in non-prescription injection drug use.
  - Men having sex with men – eligible to donate if they have not had sex with another man in last 3 months, unless in a monogamous relationship
  - HIstory of contact with blood of another through a needlestick or contact with an open wound or mucous membranes
  - Any individual who has a history of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes.
  - Transfusion of blood or blood products
  - Ear/body piercing-persons who have had ear or body piercing during the previous 3 months; acceptable if performed under sterile conditions, with a single use device, must be healed without signs of infection.
  - Tattoos - wait three months if the tattoo was applied in a state that does not regulate tattoo facilities. A tattoo is acceptable if it was applied by a state-regulated entity using sterile needles and ink that is not reused. A donor may donate the same day if in a Texas regulated facility.
  - History, diagnosis, or treatment of syphilis or gonorrhea
  - Travel to a malaria area-donors who have been to an area where malaria is considered endemic will be deferred for 3 months after departure from that area regardless of whether they took anti-malaria prophylaxis.
- **Temporary deferrals**
  - Certain medications (see list)
  - Aspirin - two full days
  - Certain conditions such as pregnancy – six (6) weeks after delivery
  - Heart attack, angina, bypass, angioplasty - wait six months
  - West Nile virus-no longer symptomatic-120 day wait
  - Zika virus-Potential donors with any of the following risk factors should donate after the end of the defined risk period noted below:
    - Travel to or residence in countries on the CDC Zika travel information list within the last four weeks
    - Diagnosis of Zika virus infection wait 120 days
  - Monkeypox -21 days after exposure or infection
- Three year wait after being treated for malaria
- Three year wait after living more than 5 years in a country where malaria is found
- FDA does not recommend using COVID-19 laboratory tests to screen routine blood donors. •
  - The blood establishment's responsible physician must evaluate prospective donors and determine eligibility (21 CFR 630.5). The donor must be in good health and meet all donor eligibility criteria on the day of donation (21 CFR 630.10). The responsible physician may wish to consider the following:
    - Individuals diagnosed with COVID-19 or who are suspected of having COVID-19, and who had symptomatic disease, refrain from donating blood for at least 14 days after complete resolution of symptoms
    - Individuals who had a positive diagnostic test for SARS-CoV-2 (e.g., nasopharyngeal swab), but never developed symptoms, refrain from donating at least 14 days after the date of the positive test result, or individuals who are tested and found positive for SARS-CoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, can donate without a waiting period and without performing a diagnostic test (e.g., nasopharyngeal swab)

- **Vaccines**
  - Hepatitis B immune globulin shot (HBIG) - 3 month deferral
  - Hepatitis B vaccination-Wait 21 days after immunization for hepatitis B as long as you are not given the immunization for exposure to hepatitis B.
  - Two (2) weeks – Red measles (rubeola), mumps, oral polio, oral typhoid, or the yellow fever vaccine.
  - Four (4) weeks – German measles (rubella), chicken pox (varicella zoster), MMR, Zostavax-the live shingle vaccine
    - NOTE: The above defer time limits for rubeola and rubella are followed when the vaccines are given separately. If the MMR is given, the donor must be deferred for four weeks.
    - Shingrix vaccine is acceptable if you are symptom-free and fever-free.
  - NO DEFERRAL if symptom-free – anthrax, cholera, diphtheria, influenza, Tdap, tetanus, Lyme disease, paratyphoid, polio injection, routine rabies or HPV vaccine (Ex: Gardasil).
  - Individuals who have received rabies post-exposure prophylaxis with vaccine and/or immunoglobulin defer for 12 months after exposure.
  - Unlicensed vaccines-1-year wait
  - Smallpox – Wait 8 weeks (56 days) from the date of having a smallpox vaccination as long as you have no complications. Complications may include skin reactions beyond the vaccination site or general illness related to the vaccination. If a person develops complications, wait 14 days after vaccine complications have resolved or 8 weeks from the date of having the smallpox vaccine, whichever is the longer time period. (Some blood centers may choose to use a simpler but stricter deferral scheme than the one proposed by the FDA in which all donors who have been in contact with a person who received the smallpox vaccination are deferred for 56 days regardless of when the rash or sore was resolved.)
  - Smallpox vaccination – close contact with someone who has had the smallpox vaccine in the last eight weeks and you did not develop any skin lesions or other symptoms. Eligible to donate.
  - Smallpox/Monkeypox Vaccine - Must know the name of the vaccine to determine if you are eligible to donate. If you do not know the name of the vaccine, the wait is 8 weeks to donate as a precaution.
    - **ACAM2000 vaccine:** This is an older vaccine which is administered in a single dose by inoculation (pricking the skin surface several times with a needle). If you receive the ACAM2000 smallpox/monkeypox vaccine, which is a live virus vaccine containing infectious agents then the following apply:
      - **Smallpox/Monkeypox vaccination and did not develop complications** Wait 8 weeks (56 days) after receiving the vaccination to donate blood as long as you have no complications. Complications can include skin reactions beyond the vaccination site or general illness related to the vaccination.
      - **Smallpox/Monkeypox vaccination and developed complications** Wait 14 days after all vaccine complications have resolved or 8 weeks (56 days) from the date of having had the smallpox vaccination whichever is the longer period of time. Discuss your particular situation with the health historian at the time of donation. Complications can include skin reactions beyond the vaccination site or general illness related to the vaccination.
    - **Jynneos vaccine:** This is a new vaccine that is administered in 2 doses (shots) given 4 weeks apart. If you receive the newer smallpox/monkeypox vaccine called Jynneos, which is a nonreplicating live virus vaccine, which does not contain infectious agents, your eligibility to donate blood is determined based on exposure to Monkeypox.
      - If you received this vaccine after an exposure to Monkeypox, you cannot donate for 21 days after your last exposure.
      - If there is no exposure to monkeypox and you received this vaccine, there is no deferral.
  - **COVID-19 Vaccine**
    - Acceptable if you were vaccinated with an Inactivated or RNA based COVID-19 vaccine manufactured by AstraZeneca, Janssen, Moderna, Novavax or Pfizer providing you are symptom-free and fever-free.
    - Wait 14 days if you were vaccinated with a live attenuated COVID-19 vaccine.
    - Wait 14 days if you were vaccinated with a COVID-19 vaccine but do not know if it was an inactivated or RNA based vaccine or a live attenuated vaccine.

What tests are performed on blood after it has been donated?
After blood is drawn, it is tested for ABO group (blood type) and Rh type (positive or negative), as well as for any unexpected red blood cell antibodies that may cause problems for the recipient. Screening tests performed are listed below:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody (anti-HBc)
- Hepatitis C virus antibody (anti-HCV)
- HIV-1 and HIV-2 antibody (anti-HIV-1 and anti-HIV-2)
- HTLV-I and HTLV-II antibody (anti-HTLV-I and anti-HTLV-II)
- Serologic test for syphilis
- Babesiosis (*Babesia microti*) NAT ***In some states, not required by all states, check with FDA
- Antibody test for *Trypanosoma cruzi*, the agent of Chagas' disease
- Cytomegalovirus (CMV)-CMV antibody detection*
- Nucleic acid testing (NAT) for the following:
    - hepatitis B virus (HBV) deoxyribonucleic acid (DNA),
    - HCV ribonucleic acid (RNA),
    - HIV-1 (RNA),
    - West Nile virus (WNV) RNA, and
    - Zika virus (RNA), - discontinued in May 2021

Human Leukocyte Antigens (HLA) Antibody Testing (implemented in 2016) HLA testing is performed on donations from female donors who indicate they have ever been pregnant (first-time donors) or donors who have had a pregnancy since their prior HLA-negative donation (repeat donors) as a mitigation for HLA-antibody-mediated Transfusion-Related Acute Lung Injury (TRALI). Donors who test HLA reactive by the FDA-licensed screening test for HLA class I and II antibodies are further tested to determine their ongoing suitability via Luminex using a validated cutoff for donor screening. Donors testing negative in duplicate can be reinstated.

As of August 2023, the following are new from the FDA guidance:

- All potential donors will see new non-gendered questions when they come to donate.
- All potential donors, regardless of gender or sexual orientation, will be asked the same questions and be assessed for blood donation eligibility based on individual risk factors.
- The FDA's previous blood donation eligibility criteria based on sexual orientation, which restricted sexually active gay and bisexual men from giving blood, has been eliminated.
- Under the new 2023 FDA guidance, a potential donor who has had anal sex in the past three months, but no new or multiple sexual partners, may be eligible to donate, provided all other eligibility criteria are met.

Questions that will be asked of all potential donors:
Screening questions focus on the risk of recent HIV infection, which is more likely to be missed by routine testing than a longstanding infection.

The screening questions ask everyone — regardless of gender, sex, or sexual orientation — whether in the past three months they have

- had a new sexual partner and engaged in anal sex
- had more than one sexual partner and engaged in anal sex
- taken medicines to prevent HIV infection (such as pre-exposure prophylaxis, or PrEP)
- exchanged sex for pay or drugs, or used nonprescription injection drugs
- had sex with someone who has previously tested positive for HIV infection
- had sex with someone who exchanged sex for pay or drugs

- had sex with someone who used nonprescription injection drugs.

When is a waiting period recommended before giving blood?

- Answering no to all of these screening questions suggests a person has a low risk of having a recently acquired HIV infection. No waiting period is necessary.
- Answering yes to any of these screening questions raises concern that a potential donor might have an HIV infection. A three-month delay before giving blood is advised.
- A waiting period before giving blood is recommended for people who take medicines to prevent HIV infection, called PrEP (pre-exposure prophylaxis). PrEP might cause a test for HIV to be negative even if infection is present. The new guidelines recommend delaying blood donation until three months after the last use of PrEP pills, or a two-year delay after a person receives long-acting, injected PrEP.

*These tests are not required for all transfusions but are often performed by blood centers or for special needs patients (CDC website).

Medication Deferral List This is the most recent list of medications that may cause a deferral from donation. We will supply this PDF during the lecture.

Side note: Must wait two days to donate plasma, if the donor has taken aspirin. No deferral for whole blood.

A blood donation facility may go above and beyond this donor history as it is defined in this paperwork. It is always up to the medical director of the facility.

Name _____ Date _____

Laboratory 1 Donor History
Study Questions

Each correct answer is worth 1.0 unless otherwise indicated.

1. How often may a donor donate a single unit of whole blood?

A potential donor has had the medical history interview. List the deferral time for each situation listed below. (Refer to your lecture guide, laboratory for donor history, and textbook).

2. The donor had surgery and received two (2) units of blood.
3. The donor wishes to donate platelets but took aspirin last night for a headache.
4. The donor had leukemia, but has been in remission for 10 years.
5. The donor recently (four months ago) had a baby.
6. The donor recently had a tattoo from a licensed facility.
7. The donor recently got out of prison after two years of incarceration.
8. The donor traveled to a malaria endemic country for a 2-week vacation.
9. Donor admits to having been a prostitute in 1983.
10. Donor received pituitary growth hormone of human origin in 1968.
11. Donor is taking accutane for treatment of acne.
12. Donor was diagnosed with gonorrhea three months ago.
13. Donor received a hepatitis B immune globulin shot one month ago.
14. Donor was given the booster vaccine (third dose) for the COVID Moderna vaccine.
15. The donor is taking Plavix.
16. The donor had a heart attack three and one half months ago.

17. The donor traveled to Iraq nine months ago.
18. The diagnosis of a Zika viral infection.
19. The donor had West Nile Virus 2 years ago.

List the deferral times for the following immunizations.

20. Measles (rubeola)
21. Immune serum globulin (HBIG) following blood exposure
22. Hepatitis B vaccine
23. German measles (rubella)
24. Mumps
25. Oral Polio
26. Yellow fever
27. Smallpox with no complications
28. Cholera
29. COVID-19 vaccine with Pfizer
30. Shingrix vaccine

31. What are the minimum and maximum age requirements for qualifying as a routine blood donor? (2 points)
    a. Minimum

    b. Maximum

32. The questions asked during the donor interview (medical history) serve two purposes, state these two purposes. (2 points).
    a.

    b.