

Apheresis Donor Guidelines

The Who, What, When, Where and Why

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Disclosures

- This talk contains manufacturer specific device information.
- I have no commercial or financial relationships to disclose.

Learning Objectives

- Following successful completion (while remaining awake) of this presentation, the participant shall be able to:
 - Give reasons for a stringent donor selection process.
 - Give two examples of regulatory agencies with oversight for apheresis donors.
 - List procedures in place for donor selection in an average blood center.
 - List applicable donation frequencies by donation type.
 - Distinguish issues of donor safety from recipient safety.

The Who (not the band...)

- Why is it important to select donors for apheresis procedures (or, more accurately, refuse some donors)?
 - Not all people are the same (duh!).
 - You can't judge a book by its cover.
 - You can't squeeze blood from a turnip.
- Safety first. (remember the Prime Directive)

Blood Collector's Prime Directive

Your (first) duty is to
safeguard the
health of your
donor.

Why is THAT my first priority?

1. No donors = no blood.
2. 'Bad' blood is worse than no blood.
3. Voluntary donation process.
4. Primum non nocere.
5. Bad choices >> bad outcomes >> no donors.
 - See No. 1 above
6. Federal Government says so.
7. AABB says so.

- Donors to avoid
 - Ineligible donors
 - Unsuitable donors
 - Inappropriate (for automated collections)

Sesquipedalian– given to, or characterized by, the use of long words

- Latin *sesquipedalis*, literally, a foot and a half long, from *sesqui-* + *ped-*, *pes* foot

21 CFR 640.3

- Code of Federal Regulations Title 21– Food and Drugs
- Chapter I– Food and Drug Administration Department of Health and Human Services
- Subchapter F– Biologics
- Part 640– Additional Standards for Human Blood and Blood Products
- Subpart A– Whole Blood
- Section 640.3 Suitability of donor

21 CFR 640

- Subpart A– Whole Blood
- Subpart B– Red Blood Cells
- Subpart C– Platelets
- Subpart D– Plasma
- Subpart F– Cryoprecipitate
- Subpart G– Source Plasma
- Subpart H– Albumin (Human)
- Subpart I– Plasma Protein Fraction (Human)
- Subpart J– Immune Globulin (Human)

21 CFR 640.3 Suitability of donor

■ (a) **Method of determining.** The suitability of a donor as a source of Whole Blood shall be determined by a qualified physician or by persons under his supervision and trained in determining suitability. Such determination shall be made on the day of collection from the donor by means of medical history, a test for hemoglobin level, and such physical examination as appears necessary to a physician who shall be present on the premises when examinations are made, except that the suitability of donors may be determined when a physician is not present on the premises, provided the establishment (1) maintains on the premises, and files with the Center for Biologics Evaluation and Research, a manual of standard procedures and methods, approved by the Director of the Center for Biologics Evaluation and Research, that shall be followed by employees who determine suitability of donors, and (2) maintains records indicating the name and qualifications of the person immediately in charge of the employees who determine the suitability of donors when a physician is not present on the premises.

(b) **Qualifications of donor; general.** Except as provided in paragraph (f) of this section and for autologous donations, a person may not serve as a source of Whole Blood more than once in 8 weeks. In addition, donors shall be in good health, as indicated in part by: (1) Normal temperature; (2) Demonstration that systolic and diastolic blood pressures are within normal limits, unless the examining physician is satisfied that an individual with blood pressures outside these limits is an otherwise qualified donor under the provisions of this section; (3) For allogeneic donors, a blood hemoglobin level which shall be demonstrated to be no less than 12.5 grams (g) of hemoglobin per 100 milliliters (mL) of blood; or a hematocrit value of 38 percent, and for autologous donors, a blood hemoglobin level which shall be demonstrated to be no less than 11.0 g of hemoglobin per 100 mL of blood or a hematocrit value of 33 percent.(4) Freedom from acute respiratory diseases; (5) Freedom from any infectious skin disease at the site of phlebotomy and from any such disease generalized to such an extent as to create a risk of contamination of the blood; (6) Freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations indicated above; and (7) Freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics.

(c) **Additional qualifications of donor; viral hepatitis.** No individual shall be used as a source of Whole Blood if he has (1) A history of viral hepatitis after the 11th birthday; (2) A history of close contact within 12 months of donation with an individual having viral hepatitis; (3) A history of having received within 12 months of donation, human blood or any derivative of human blood which the Food and Drug Administration has advised the blood establishment is a possible source of viral hepatitis.

(d) **Therapeutic bleedings.** Blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of this section, shall not be used as a source of Whole Blood unless the container label conspicuously indicates the donor's disease that necessitated withdrawal of blood.

(e) [Reserved]

(f) **Qualifications; donations within less than 8 weeks.** A person may serve as a source of Whole Blood more than once in 8 weeks only if at the time of donation the person is examined and certified by a physician to be in good health, as indicated in part in paragraph (b) of this section.

Read more: <http://cfr.vlex.com/vid/640-3-suitability-donor-19714870#ixzz1MH5J8l6Y>

AABB Standards for Blood Banks and Transfusion Services (27th edition)

- 5.4 Donor Qualification
 - 5.4.1 Allogeneic Donor Qualification
 - 5.4.2 Protection of the Recipient
 - 5.4.3 Protection of the Donor
 - 5.4.4 Autologous Donor Qualification
- 5.5 Additional Apheresis Donor Qualification Requirements
 - 5.5.1 Selection of Donors
 - 5.5.2 Automated Plasmapheresis Donation
 - 5.5.3 Automated Cytapheresis Donations
 - 5.5.4 Multiple Concurrent Apheresis Collection

AABB Reference Standard 5.4.1A- Requirements for Allogeneic Donor Qualification

- 1) Age– Conform to applicable state law, or ≥ 16 yrs
- 2) Whole Blood Volume Collected– Maximum of 10.5mL per kilogram of donor weight, including samples
- 3) Donation Interval– variable
 - 8 weeks (whole blood)
 - 16 weeks (2RBC)
 - 4 weeks (infrequent plasmapheresis)
 - ≥ 2 days after plasma-, platelet-, or leukapheresis
- 4) Temperature– $\leq 37.5\text{C}$ (99.5F) orally
- 5) Hemoglobin/ Hematocrit–
 - ≥ 12.5 g/dL / $\geq 38\%$; no earlobes!
 - 2RBC follow manufacturers instructions

AABB Reference Standard 5.4.1A (2)

6) Drug Therapy

- finasteride (Proscar, Propecia); isotretinoin (Accutane) [1 month]
- dutasteride (Avodart) [6 months]
- acitretin (Soriatane) [3 years]
- etretinate (Tegison) [permanent]
- Bovine insulin made in UK [indefinite]
- Anti-platelet meds (irreversible inhibition) [no platelets]
- aspirin and piroxicam (Feldane) [48 hours]
- clopidogrel (Plavix) and ticlopidine (Ticlid) [14 days]
- warfarin (Coumadin) (for transfusable plasma) [7 days]
- Hep B Immune Globulin [12 months]
- Antibiotics, other meds [defined by medical director]

AABB Reference Standard 5.4.1A (3)

7) Medical History and General Health

- The prospective donor shall appear to be in good health and shall be free of major organ disease (eg. heart, liver, lungs), cancer, or abnormal bleeding tendency, unless determined suitable by the medical director.
- The venipuncture site shall be evaluated for lesions of the skin. The venipuncture site shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood.
- Family history of Creutzfeld-Jakob disease (CJD) [indefinite]

8) Pregnancy— defer if pregnant within last 6 weeks.

9) Receipt of Blood, Blood Component or Human Tissue

- Dura mater or pituitary growth hormone (human origin) [indefinite]
- Blood, components, human tissue or plasma-derived clotting factor concentrates [12 months]

AABB Reference Standard 5.4.1A (4)

10) Immunizations and Vaccinations

- Receipt of toxoids, or synthetic or killed viral, bacterial, or rickettsial vaccines if donor is symptom-free and afebrile (anthrax, cholera, diphtheria, hep A, Hep B, influenza, lyme dz, paratyphoid, pertussis, plague, pneumococcal polysaccharide, Salk polio (inj), rabies, RMSF, tetanus, typhoid (inj)) [none]
- Receipt of recombinant vaccine (HPV) [none]
- Receipt of intranasal live attenuated flu vaccine [none]
- Receipt of live attenuated viral and bacterial vaccines (measles, mumps, Sabin polio (oral) , typhoid (oral), yellow fever) [2 weeks]
- Receipt of live attenuated viral and bacterial vaccines (rubella (German measles), varicella zoster) [4 weeks]
- Smallpox [refer to FDA guidance]
- Other vaccines, including unlicensed vaccines [12 months unless otherwise indicated]

AABB Reference Standard 5.4.1A (5)

11) Infectious Diseases

- History of viral hepatitis after 11th birthday [indefinite]
- Confirmed positive test for HBsAg [permanent]
- Repeatedly reactive test for anti-HBc on more than one occasion [indefinite]
- Repeatedly reactive test for HTLV on more than one occasion [indefinite]
- Present or past clinical laboratory evidence of infection with HIV, HCV, HTLV or as excluded by current FDA regulations and recommendation for the prevention of HIV transmission by blood and components [indefinite]
- History of babesiosis or Chagas' disease [indefinite]
- Evidence or obvious stigmata of parenteral drug use [indefinite]
- Use of a needle to administer nonprescription drugs [indefinite]
- Mucous membrane exposure to blood [12 months]
- Nonsterile skin penetration with instruments or equipment contaminated with blood or body fluids other than the donor's own. Includes tattoos or permanent make-up unless applied by a state-regulated entity with sterile needles and ink that has not been reused. [12 months]
- Sexual contact or lived with an individual who: [all 12 months]
 - Has acute or chronic Hep B
 - Has symptomatic Hep C
 - Is symptomatic for any other viral hepatitis
- Sexual contact with an individual with HIV infection or at high risk of HIV infection [12 months]

AABB Reference Standard 5.4.1A (6)

11) Infectious Diseases (cont)

- Incarceration in a correctional institution for more than 72 consecutive hours [12 months]
- Syphilis or gonorrhea [12 months]
 - Following diagnosis– must have completed treatment
 - Reactive screening test, no confirmatory testing
 - Confirmed positive test for syphilis (FDA reentry protocol applies)
- West Nile Virus [FDA Guidance]
- Malaria– irrespective of prophylaxis
 - Diagnosis of malaria [3 years]
 - Lived at least 5 consecutive years in malaria-endemic area (as defined by CDC) [3 years from departure]
 - Travel to a malaria endemic area [12 months after departing]

12) Travel

- The prospective donor's travel history shall be evaluated for potential risks.
- vCJD travel risk (as defined in most recent FDA Guidance) [indefinite]

- So... how do I translate the *entire* Code of Federal Regulations, the AABB Standards, my company's voluminous Donor Manual and the hopes and dreams of the Recruiting Department into a happy, healthy, smiling apheresis donor?

Easy

- You use a 20-120 minute, manual or semi-automated, computerized (or not) question-and-answer process involving extremely personal, invasive questions; poking, prodding and squeezing; and an apparent complete disregard for the honesty, accuracy, intelligence and goodwill of the donor.

The What

- Health History Questionnaire
 - DHQ vs. aDHQ (abbreviated)
 - aDHQ may be applied if Donor has donated twice before and within the last 6 months.
 - Most changes concern time- ‘Since your last donation, have you...’
 - Applies to changes in health and travel.
 - High risk questions remain.
 - Center specific questions
 - Aimed at new and emerging infectious diseases or research.

What is covered?

7) Medical History and General Health

- The prospective donor shall appear to be in good health and shall be free of major organ disease (eg. heart, liver, lungs), cancer, or abnormal bleeding tendency, unless determined suitable by the medical director.
- Family history of Creutzfeld-Jakob disease (CJD). [indefinite]
- Each center is free to interpret the meaning of this guidance. Many use the uDHQ: Are You...
 - Feeling healthy and well today?
 - Currently taking an antibiotic?
 - Currently taking any other medication for an infection?

8) Pregnancy— defer if pregnant within last 6 weeks

Health History (cont)

6) Drug Therapy

- finasteride (Proscar, Propecia); isotretinoin (Accutane) [1 month]
- dutasteride (Avodart) [6 months]
- acitretin (Soriatane) [3 years]
- etretinate (Tegison) [permanent]
- Bovine insulin made in UK [indefinite]
- Anti-platelet meds (irreversible inhibition) [no platelets]
- aspirin and piroxicam (Feldane) [48 hours]
- clopidogrel (Plavix) and ticlopidine (Ticlid) [14 days]
- warfarin (Coumadin) (for transfusable plasma) [7 days]
- Hep B Immune Globulin [12 months]
- Antibiotics, other meds [defined by medical director]

Health History (cont)

11) Infectious Diseases

- History of viral hepatitis after 11th birthday [indefinite]
- Confirmed positive test for HBsAg [permanent]
- Repeatedly reactive test for anti-HBc on more than one occasion [indefinite]
- Repeatedly reactive test for HTLV on more than one occasion [indefinite]
- Present or past clinical laboratory evidence of infection with HIV, HCV, HTLV or as excluded by current FDA regulations and recommendation for the prevention of HIV transmission by blood and components [indefinite]
- History of babesiosis or Chagas' disease [indefinite]
- Evidence or obvious stigmata of parenteral drug use [indefinite]
- Use of a needle to administer nonprescription drugs [indefinite]
- Mucous membrane exposure to blood [12 months]
- Nonsterile skin penetration with instruments or equipment contaminated with blood or body fluids other than the donor's own. Includes tattoos or permanent make-up unless applied by a state-regulated entity with sterile needles and ink that has not been reused. [12 months]
- Sexual contact or lived with an individual who: [all 12 months]
 - Has acute or chronic Hep B
 - Has symptomatic Hep C
 - Is symptomatic for any other viral hepatitis
- Sexual contact with an individual with HIV infection or at high risk of HIV infection [12 months]
- Incarceration in a correctional institution for more than 72 consecutive hours [12 months]
- Syphilis or gonorrhea [12 months]
 - Following diagnosis– must have completed treatment
 - Reactive screening test, no confirmatory testing
 - Confirmed positive test for syphilis (FDA reentry protocol applies)
- West Nile Virus [FDA Guidance]
- Malaria– irrespective of prophylaxis
 - Diagnosis of malaria [3 years]
 - Lived at least 5 consecutive years in malaria-endemic area (as defined by CDC) [3 years from departure]
 - Travel to a malaria endemic area [12 months after departing]



No deferral if tattoo applied in these states:

- Alabama
- Arkansas
- Delaware
- Georgia
- Hawaii
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Michigan
- Mississippi
- Montana
- New Hampshire
- New Jersey
- New Mexico
- North Carolina
- North Dakota
- Ohio
- Oklahoma
- Oregon
- South Carolina
- South Dakota
- Texas
- Tennessee
- Virginia
- West Virginia
- Wisconsin

Shots

10) Immunizations and Vaccinations

- Receipt of **toxoids**, or **synthetic** or **killed viral, bacterial**, or rickettsial vaccines if donor is symptom-free and afebrile (anthrax, cholera, diphtheria, hep A, Hep B, influenza, lyme dz, paratyphoid, pertussis, plague, pneumococcal polysaccharide, Salk polio (inj), rabies, RMSF, tetanus, typhoid (inj)) [**none**]
- Receipt of **recombinant** vaccine (HPV) [**none**]
- Receipt of **intranasal** live attenuated flu vaccine [**none**]
- Receipt of **live attenuated viral** and bacterial vaccines (measles, mumps, Sabin polio (oral) , typhoid (oral), yellow fever) [**2 weeks**]
- Receipt of **live attenuated viral** and bacterial vaccines (rubella (German measles), varicella zoster) [**4 weeks**]
- Smallpox [refer to FDA guidance]
- Other vaccines, including unlicensed vaccines [12 months unless otherwise indicated]

The What- Mini Physical Exam

- Height
 - Used by machine to calculate donor blood volume.
- Weight (≥ 110 lbs)
 - Also used for TBV
 - By Standard may collect 10.5mL/kg
- BP
 - FDA- 'within normal limits'
 - May be overridden by Medical Director.
- Pulse
 - Not required by FDA or AABB.
 - Added by most centers for purposes of donor safety.

Mini Physical Exam (cont)

- Temperature
 - FDA- 'normal'
 - AABB- $\leq 37.5\text{C}$ (99.5F) orally
- Hemoglobin or Hematocrit
 - 12.5 g/dL or 38%
 - General donor guideline
 - Apheresis procedures may have higher requirements.
- Platelet count
 - Specimen must be obtained before procedure.
 - $\geq 150,000$ per μL

Special qualifications

- 2RBC
 - 5.5.3.5.2 The volume of red cells removed from apheresis donors shall not exceed a volume predicted to result in a donor hematocrit of $<30\%$ or a hemoglobin <10 g/dL after volume replacement.
- FDA does not set specific requirements for individual 2RBC systems, but does qualify those systems with specific criteria that a blood center must use as a minimum guide.

MCS+ 8150 (Rev H)

DONOR ACCEPTANCE CRITERIA

Allogeneic Donors

Allogeneic donors for the 2-RBC Protocol should meet all applicable guidelines for standard allogeneic whole blood donations. In addition, each donor must meet the following minimum requirements as listed below, including a 112-day minimum interval between donations.

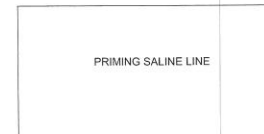
Allogeneic Male Donors:

weight: at least 130 lb.
height: at least 5'1"
hematocrit: at least 40%
hemoglobin: at least 13.3 mg/dl

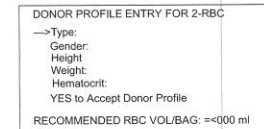
Allogeneic Female Donors:

weight: at least 150 lb.
height: at least 5'5"
hematocrit: at least 40%
hemoglobin: at least 13.3 mg/dl

Lastly the saline line is primed. At the start of the saline prime the blood pump turns briefly to complete filling the AS-3 into the red cell bags. Once the saline has been primed, the middle pump will reverse direction momentarily. The following screen is displayed:



Once a successful Prime has been completed, the MCS+ displays,



The MCS+ is now ready to begin the Two Unit Red Cells/ AS-3 procedure.

DONOR ACCEPTANCE CRITERIA

Allogeneic Donors

Allogeneic donors for the 2-RBC Protocol should meet all applicable guidelines for standard allogeneic whole blood donations. In addition, each donor must meet the following minimum requirements as listed below, including a 112-day minimum interval between donations.

Allogeneic Male Donors:
weight: at least 130 lb.
height: at least 5'1"
hematocrit: at least 40%
hemoglobin: at least 13.3 mg/dl

Allogeneic Female Donors:
weight: at least 150 lb.
height: at least 5'5"
hematocrit: at least 40%
hemoglobin: at least 13.3 mg/dl

P/N 39220-00

LN 832 AS-3 Set

Autologous Donors

Since autologous donation is a medically prescribed procedure, follow the center's Standard Operating Procedure, which has been approved by the medical director, to determine autologous donor acceptance for the 2-RBC Protocol.

Haemonetics recommends that autologous donors for the 2-RBC Protocol meet all applicable guidelines for standard autologous whole blood donations. In addition, each donor should meet the following minimum requirements:

weight: at least 130 lb.
hematocrit: at least 36%
hemoglobin: at least 12 mg/dl

Recommended Maximum Target Collection Volumes

In addition to the above donor guidelines, Haemonetics recommends that the total RBC donation volume be adjusted based on the donor's gender, weight, and hematocrit. Refer to pages 6-12 and 6-13 for recommended maximum total RBC donation volumes.

Note: To determine donor eligibility and maximum red blood cell collection volume for RBC apheresis, Haemonetics recommends using an instrument, for which the FDA has granted pre-market clearance, for use of measuring hematocrit or hemoglobin to determine donor eligibility for blood donation.

Note: The center should document methods for determining donor eligibility and target collection volumes in its Standard Operating Procedures (SOPs). Procedures for determining the donor's eligibility relative to hematocrit or hemoglobin should be validated in accordance with the Center's SOPs.

Note: Follow the center's Standard Operating Procedure, approved by the medical director, to determine the appropriate target RBC collection volumes.

Note: The MCS+ is capable of automatically calculating recommended collection volumes based on donor parameters, for informational purposes. Press PROTOCOLS at any time during the procedure to access the DONOR PROFILE entry screen described on page 6-14.

6-11

Maximum Target Absolute Red Cell Volume

Note: When not using the 190 ml default value, Haemonetics recommends observing the following maximum target RBC collection volumes according to the donor's gender, weight, height and hematocrit or hemoglobin, and whether the donor is autologous or allogeneic.

Maximum Target Red Cell Volumes

For Allogeneic Male Donors:

Donor Weight Predonation	Donor Height	Donor Hematocrit Predonation	Donor Hemoglobin Predonation	Max Total Absolute RBC Volume ⁽¹⁾
130 - 149 lb.	≥ 5'1"	≥ 40 to < 41% ≥ 41 to < 42% ≥ 42%	≥ 13.3 - 13.6 mg/dl ≥ 13.7 - 13.9 mg/dl ≥ 14.0 mg/dl	360 ml 370 ml 380 ml
150 - 174 lb.	≥ 5'1"	≥ 40 to < 41% ≥ 41 to < 42% ≥ 42%	≥ 13.3 - 13.6 mg/dl ≥ 13.7 - 13.9 mg/dl ≥ 14.0 mg/dl	400 ml 410 ml 420 ml
175 lb. and over	≥ 5'1"	≥ 40 to < 41% ≥ 41 to < 42% ≥ 42%	≥ 13.3 - 13.6 mg/dl ≥ 13.7 - 13.9 mg/dl ≥ 14.0 mg/dl	420 ml 420 ml 420 ml

Maximum Target Red Cell Volumes

For Allogeneic Female Donors:

Donor Weight Predonation	Donor Height	Donor Hematocrit Predonation	Donor Hemoglobin Predonation	Max Total Absolute RBC Volume ⁽¹⁾
150 - 174 lb.	≥ 5'5"	≥ 40 to < 41% ≥ 41 to < 42% ≥ 42%	≥ 13.3 - 13.6 mg/dl ≥ 13.7 - 13.9 mg/dl ≥ 14.0 mg/dl	360 ml 370 ml 380 ml
175 lb. and over	≥ 5'5"	≥ 40 to < 41% ≥ 41 to < 42% ≥ 42%	≥ 13.3 - 13.6 mg/dl ≥ 13.7 - 13.9 mg/dl ≥ 14.0 mg/dl	400 ml 410 ml 420 ml

⁽¹⁾ Recommended Maximum RBC Bag 1, RBC Volume + RBC Bag 2, RBC Volume. This is the sum of the machine settings for the target volume of absolute RBCs in the two RBC product bags. For each bag, this number equals the total RBC product volume multiplied by the RBC product hematocrit at the end of the procedure.

Maximum Target Red Cell Volumes

For Autologous Male Donors:

Donor Weight Predonation	Donor Hematocrit Predonation	Donor Hemoglobin Predonation	Max Total Absolute RBC Volume ⁽¹⁾
130 - 149 lb.	36 - 39%	12.0 - 13.2 mg/dl	320 ml
	40% and over	≥ 13.3 mg/dl	360 ml
150 - 174 lb.	36 - 39%	12.0 - 13.2 mg/dl	360 ml
	40% and over	≥ 13.3 mg/dl	400 ml
175 lb. and over	36 - 39%	12.0 - 13.2 mg/dl	400 ml
	40% and over	≥ 13.3 mg/dl	420 ml

Maximum Target Red Cell Volumes

For Autologous Female Donors:

Donor Weight Predonation	Donor Hematocrit Predonation	Donor Hemoglobin Predonation	Max Total Absolute RBC Volume ⁽¹⁾
130 - 149 lb.	36 - 39%	12.0 - 13.2 mg/dl	280 ml
	40% and over	≥ 13.3 mg/dl	320 ml
150 - 174 lb.	36 - 39%	12.0 - 13.2 mg/dl	320 ml
	40% and over	≥ 13.3 mg/dl	360 ml
175 lb. and over	36 - 39%	12.0 - 13.2 mg/dl	360 ml
	40% and over	≥ 13.3 mg/dl	400 ml

⁽¹⁾ Recommended Maximum RBC Bag 1, RBC Volume + RBC Bag 2, RBC Volume. This is the sum of the machine settings for the target volume of absolute RBCs in the two RBC product bags. For each bag, this number equals the total RBC product volume multiplied by the RBC product hematocrit at the end of the procedure.

The What (continued)

- Relationship between donor statistics and reaction rates
 - Wiltbank TB, Giordano GF. **Faint and prefaint reactions in whole-blood donors: an analysis of pre-donation measurements and their predictive value**; Transfusion 2008; 48:1799-1808
 - Associations with female gender, young age, first-time donor status and blood volume.

Males 16-22 years old

Height $\geq 5'0''$

Minimum Weight ≥ 110 lbs

Females 16-22 years old

Height	4'10"	4'11"	5'0"	5'1"	5'2"	5'3"	5'4"	5'5"	5'6"
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Minimum Weight	146	142	138	133	129	124	120	115	110
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The When

- Donation-deferral pairings AABB 5.4.1A (3)
 - 8 weeks (whole blood)
 - 16 weeks (2RBC)
 - 4 weeks (infrequent plasmapheresis)
 - ≥ 2 days after plasma-, platelet-, or leukapheresis
- Unsuccessful automated procedure with ≤ 200 mL RBC loss– no (extra) deferral.
- Unsuccessful automated procedure with > 200 mL RC loss– 8 weeks deferral .

The When (continued)

- Infrequent vs Frequent Plasmapheresis
 - Infrequent Program
 - Donation interval \geq 4 weeks
 - Usual donor qualification rules apply
 - Frequent Donation Program
 - Interval $<$ 4 weeks
 - Minimum of 2 day interval and maximum twice per week
 - Requires testing and evaluation by Medical Director (21CFR640.65 and 21CFR640.63 apply)
 - Q 4 months
 - Syphilis, total plasma or serum protein, SPE or quantitative immuno-diffusion

The When (continued)

■ Limitations

■ Frequency

- 2 times per week
- once in 7 days with multiple products
- 24 Platelet donations per year
- 12 Plasma donations per year

■ Losses

- RBC loss- 1540 mL per year (calculated)
- Plasma loss- 12 L (\leq 175#); 14.4 L ($>$ 175#)

The Where

- Veinous selection
 - Automated procedures use smaller needles but require better veins.
 - Listen to the donor.
- Standards 5.4.1A
 - The venipuncture site shall be evaluated for lesions of the skin. The venipuncture site shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood.

The Why

- Donor Safety vs. Recipient Safety
 - Not equivalent in meaning
 - Not equivalent in importance
- A donor is voluntarily submitting to an invasive medical procedure; his/her health must be managed proactively.
- A patient who receives blood is doing so out of necessity and, hopefully, by choice. He/she must undertake some risk inherent to their medical condition.

Additional Considerations

- Current ID testing of donated blood
 - Hepatitis B Surface Antigen (HBsAg)
 - Antibodies to the Hepatitis B Core (Anti-HBc)
 - Antibodies to the Hepatitis C Virus (Anti-HCV)
 - Antibodies to the Human Immunodeficiency Virus, Types 1 and 2 (Anti-HIV-1, -2)
 - Antibodies to Human T-Lymphotropic Virus, Types I and II (Anti-HTLV-I, -II)
 - Syphilis
 - Antibodies to Trypanosoma cruzi
 - Nucleic Acid Amplification Testing (NAT)
 - HIV, HCV, WNV, (\pm)HBV

- Over 80% of respondents in a survey said they don't donate blood because they weren't asked.
- Consider yourself asked.
- Please donate blood if you are able.

**Thank you
for your
time and attention**