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PEARLS OF LABORATORY MEDICINE

Blood Donor Eligibility and Donation Suitability

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Disclaimer

- All information is current as of December 1, 2017.
- Please refer to the supplementary material (posted along with the transcript) for full details of donor deferral lengths.



Objectives

- Understand the purpose of defining blood donor eligibility
- Review criteria for allogeneic blood donor eligibility and donation suitability



Purpose of determining blood donor eligibility and donation suitability

- 1) Ensure safety and potency of blood supply
- 2) Protect the health of the donor

- In accordance with:
 - U.S. Food and Drug Administration (FDA) Code of Federal Regulations Title 21
 - State regulations
 - AABB voluntary accreditation standards



Donor Eligibility

- To be eligible to donate
 - Be in good health
 - Free of transfusion-transmitted infections
 - Free of risk factors that can affect the safety and potency of the blood product
 - Free of risk factors that can affect the donor's health during donation



Pre-Donation

- Registration
- Education
- Health history assessment
- Brief physical exam with hemoglobin or hematocrit measurement



Pre-donation

- Donor Health History Assessment
 - Purpose is to identify potential factors that can affect both the safety of the donor and the safety and potency of the blood product
 - AABB Donor History Questionnaire (DHQ) → most widely used assessment; As of 2/2016, version 2.0*
 - Validated by the FDA

*Link to full DHQ 2.0 can be found in the references

DHQ 2.0

- Maintain safety and potency of the blood supply*
 - Defer based on donor characteristics that increase risk of transfusion-transmitted infections
 - Defer based on donor exposures that increase risk of transfusion-transmitted infections (e.g. travel history)
 - Defer based on specific donor medications*
 - Defer based on receipt of specific vaccinations
 - Defer based on high risk behaviors that increase risk of transfusion-transmitted infections
 - Defer based on risk factors that increase risk of Creutzfeldt-Jakob Disease (CJD) or variant CJD
 - Defer based on history of cancer → up to Medical Director discretion

*Please refer to the supplementary materials for a list of deferrals and a link to the medication deferral list.



DHQ 2.0

- Maintain Donor Safety*
 - Defer based on how well the donor is feeling
 - Defer based on how recently the donor donated
 - Defer based on recent pregnancy
 - Defer based on history of bleeding condition → Up to Medical Director discretion (Hemophilia or other bleeding condition that requires treatment is an indefinite deferral)
 - Defer based on history of heart or lung disease → Up to Medical Director discretion

*Please refer to the supplementary materials for a list of deferrals



Pre-donation

- Physical Exam
 - Temperature $\leq 37.5^{\circ}\text{C}$
 - Systolic BP: 90- 180 mm Hg; Diastolic BP: 50 – 100 mm Hg
 - Pulse: 50 to 100 beats per minute without irregularities
 - Minimum weight for whole blood donation: 110 pounds (reported by donor)
 - Visual inspection of donor antecubital skin



Pre-donation

- Labs (for allogeneic whole blood donation)
 - Men: Minimum hemoglobin/hematocrit 13.0 g/dL / 39%
 - Women: Minimum hemoglobin/hematocrit 12.5 g/dL / 38%;
Or 12.0 g/dL / 36% if additional steps are taken to ensure health of donor using a process approved by FDA
- Low hemoglobin/hematocrit is the most common reason for deferral at United States blood centers



Donation Suitability

- For a donation to be suitable:
 - The donor is not currently deferred from donation upon review of donor records.
 - Based on the donor health assessment, the donation will not affect the safety or potency of the blood product.
 - Based on post-donation testing, the donation will not affect the safety of the blood product.





Infectious disease testing of whole blood donations*

- 1) Hepatitis B Virus (HBV)
 - surface antigen, Anti-HBc, HBV DNA
- 2) Hepatitis C Virus (HCV)
 - Anti-HCV antibody, HCV RNA
- 3) Human Immunodeficiency Virus (HIV)
 - HIV I/II antibody, HIV-1 RNA
- 4) Human T-cell Lymphotropic Virus (HTLV) antibody
 - Anti-HTLV I/II antibody

*Please refer to the supplementary materials for deferral lengths



Infectious disease testing of whole blood donations*

- 5) Syphilis
 - Nontreponemal assays (e.g. rapid plasma reagin) or treponemal assays
- 6) Trypanosoma cruzi (Chagas) antibody
 - Only mandated to perform once per lifetime of a donor
- 7) West Nile Virus RNA
- 8) Zika RNA

*Please refer to the supplementary materials for deferral lengths



Additional required testing

- All donations
 - ABO/Rh(D) typing
 - Red blood cell antibody screen
- Platelet bacterial testing
- Transfusion-related acute lung injury (TRALI) mitigation
 - Plasma, apheresis platelets, and whole blood for allogeneic transfusion from males, never-pregnant females, or females who have a negative human leukocyte antigen (HLA) antibody screen since their most recent pregnancy



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4. AABB. AABB Full-Length Donor History Questionnaire (DHQ). <http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx> (Accessed December 2017).
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