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TITLE: Blood Donor Eligibility and Donation Suitability

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Slide 1:

Hello, my name is **Chakri Gavva**. I am a **Transfusion Medicine Fellow at Bloodworks Northwest and the University of Washington**. Welcome to this Pearl of Laboratory Medicine on "**Blood Donor Eligibility and Donation Suitability**."

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Before I begin, I'd like to add a disclaimer that all information presented is current as of December 2017. A list of blood donor deferrals and deferral lengths will be included in the supplementary materials.

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The two primary objectives of this presentation are to understand the purpose of blood donor eligibility and donation suitability and to review the criteria for allogeneic blood donation.

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The main purpose of determining blood donor eligibility and donation suitability relates to ensuring the safety and potency of the blood supply as well as protecting the donor's

health. In other words, defining blood donor eligibility and donation suitability will help uphold the safety of the transfusion recipient and the safety of the donor.
The U.S. Food and Drug Administration (FDA), State regulations, and AABB Standards all play a part in determining blood donor eligibility and donation suitability.

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Let's start with donor eligibility. For a donor to be eligible to donate, they must be in good health, free of transfusion-transmitted infections, not be at risk of harm during the donation process, and free of risk factors that can potentially affect the safety or potency of the blood product. We will discuss more regarding these infections and risk factors later in the presentation.

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Prior to donation, the donor must undergo 4 separate steps: registration, reading the education materials, answering the Health History Assessment, and then a brief physical exam with a hemoglobin or hematocrit measurement. For a donor to be registered, they must provide proof of identity and a reliable postal address in case they need to be contacted post-donation. In addition, they must also provide a date of birth. The FDA minimum age to donate blood is 16 years old. However, it differs from state to state. For example, in some states such as Washington, 16 and 17 year olds can donate with parental consent whereas in other states such as Texas, 16 year olds need parental consent while 17 year olds do not. The prospective donor is also required to read education materials that both explains the donation process and informs the donor to not donate if they feel sick or have risk factors for sexually transmitted diseases such as HIV. Specifically, if someone believes they may be at risk of HIV and would like to get a free HIV test by donating, they absolutely should not donate and should instead be directed to where they can get tested appropriately.

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After reviewing the education materials, the prospective donor must answer the donor health history assessment. The purpose of this health history assessment is to identify potential factors that can affect the safety of the donor as well as the safety or potency of the blood component. The most widely used assessment currently is the AABB Donor History Questionnaire (DHQ). The most recent version is version 2.0. This questionnaire has been validated by the FDA. Blood Centers may insert additional questions after the DHQ, but they can not alter the DHQ because it has been validated as a whole. A link to the full DHQ 2.0 can be found in the references at the end of the presentation.

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Within the DHQ, there are a host of questions that are related to maintaining the safety and potency of the blood supply. There are different deferral lengths based on the donor's answers to the DHQ. If a donor is deferred, they are asked to come back to donate after their deferral length. Please refer to the supplementary materials for a list of deferrals, the deferral lengths, as well as a link to the AABB medication deferral list. The blood center must maintain records of all donors and their eligibility status.

The questions on the DHQ can be grouped into broad categories. There are questions that will defer a donor based on certain donor characteristics that can increase the risk of transfusion-transmitted infections. For example, the first 3 questions of the DHQ asks if the donor is feeling healthy and well, taking any antibiotics, or taking any other medications to treat an infection. If the donor is sick on day of donation or taking medications to treat an active infection, that can affect the safety of the blood component. There are other questions that ask about certain exposures such as travel history that are related to the risk of malaria. As an example, if a donor who has resided

for at least 3 consecutive years in the United States, which is considered a non-malarial endemic country, has recently traveled to a malaria-endemic area for greater than 24 hours, they are deferred for 12 months from the date of departure.

Donors may also be deferred if they have ingested certain medications. These medications have primarily been chosen if they are known teratogens or can affect the potency of the blood component. For example, donors are deferred for 1 month after their last dose of finasteride because it is a teratogen, and if that unit of blood is transfused to a pregnant patient, can affect the fetus. Donors are deferred for 7 days after ingestion of warfarin because that can affect the plasma levels of the vitamin K-dependent coagulation factors.

Donors may be deferred if they have recently received any live attenuated vaccines. For example, a donor is deferred for 4 weeks after the receipt of the varicella zoster vaccine. This is because the live attenuated virus could infect the transfusion recipient, especially if the recipient is immunocompromised. There are certain high risk behaviors that result in deferrals because they can increase the risk of transfusion-transmitted infections. One example is if a donor has ever used needles to inject drugs, steroids, or any non-prescribed medications because that is a risk factor for HIV or Hepatitis.

There are certain risk factors that can increase the risk of Creutzfeldt-Jakob disease (CJD) or variant CJD. The DHQ asks the length of time and years the donor has spent in the United Kingdom or other countries in Europe because this may place the donor at risk of variant CJD.

Although the DHQ asks about a history of cancer, there is no explicitly stated deferral length by the FDA or AABB with regards to cancer. It’s mostly up to individual blood center standard operating procedure (SOP) and medical director discretion. Most blood centers probably would not accept a donor who has a recent history of a hematological malignancy, but they may accept a donor with a history of pediatric leukemia in remission for many years.

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There are also questions related to maintaining donor safety. The first question on the DHQ asks how well the donor is feeling. Obviously, if a donor is not feeling well on the day of donation, you wouldn't want to remove 500 cc's of blood which may make the donor feel even worse. There are also deferrals based on how recently the donor has donated. This is primarily due to minimizing red cell loss for the donor. For example, if a donor has donated whole blood, they are not eligible to donate whole blood again until 8 weeks later. If a donor has donated double red blood cells by apheresis, they can not donate any blood products for another 16 weeks. If someone has been pregnant, they cannot donate until 6 weeks after they are no longer pregnant.
If a donor has a history of hemophilia or other bleeding condition that requires treatment, that is considered an indefinite deferral. In the past, they were deferred due to potential HIV risk. However, currently they are deferred due to both protection of the donor to minimize risk of bleeding during phlebotomy as well as maintaining the potency of the blood product. Other bleeding disorders that do not require treatment is up to the medical director to determine whether they are eligible or not to donate. And finally, there are questions that ask about the donor's history of heart or lung disease. This is primarily to protect the donor from any adverse events during the donation process. Individual blood centers have their own SOPs regarding this. For example, a medical director may choose to defer a donor who recently had a myocardial infarction whereas they may accept a donor who has a history of stable coronary artery disease and no functional limitations.

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After answering the DHQ, the donor undergoes a brief physical exam. Their temperature must be 37.5 degrees or less, systolic blood pressure between 90-180 mm Hg, diastolic blood pressure between 50-100 mm Hg, and pulse between 50 to 100 beats per minute and regular. With approval by a donor's physician and blood center medical director, they may be eligible to donate even if their vitals fall outside the stated range. Furthermore, the donor provides a self-reported weight. The FDA minimum weight for allogeneic whole blood donation is 110 pounds. And of course, there is also a

visual inspection of the donor antecubital skin to assess for any stigmata of intravenous drug use.

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And finally, the donor's hemoglobin or hematocrit is tested. This can either be a capillary point of care test or venous blood. Most blood centers use a point of care fingerstick sample. Of note, an earlobe puncture is not acceptable for hemoglobin/hematocrit determination. Prior to 2016, the minimum hemoglobin/hematocrit for both men and women donors was 12.5 g/dl or 38%. Since 2016, the minimum hemoglobin/hematocrit for men was raised to 13.0 g/dl or 39%. For women, the FDA allows centers to lower the minimum hemoglobin/hematocrit to 12.0 g/dl/36% if there are additional steps taken to ensure the health of a donor using a process approved by the FDA.. Most blood centers continue to use 12.5/38% for women donors.

Of note, a hemoglobin/hematocrit below the minimum cutoff is the most common reason for deferral at United States blood centers.

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After donation, the blood center must ensure the donation is suitable for release. This is based on if the donor is not currently deferred from donation upon review of donor records, and the donation will not affect the safety or potency of the blood supply based on both the donor health assessment and results of post-donation testing.

Slides 13 and 1:

With regards to post-donation testing, the blood supply is tested for 8 different diseases: Hepatitis B Virus (HBV), Hepatitis C Virus (Hepatitis C Virus), HIV, HTLV, Syphilis, Chagas, West Nile Virus, and most recently Zika virus. The types of tests used are listed on slides 13 and 14. Nucleic acid testing (NAT) has shortened the infectious window period for HBV, HCV, and HIV to approximately 22, 7, and 9 days respectively. This is the length of time where the donor is infected with the virus but is unable to be detected by current assays. Accordingly based on the incidence of the diseases and the

window periods, the theoretical risk of transmitting HBV, HCV, and HIV are approximately 1 in 1 million, 1 in 1.15 million, and 1 in 1.5 million per donated unit.

If a donor tests positive, they may not be indefinitely deferred depending on the pattern of results. For example, if a donor tests repeatedly reactive only for anti-Hepatitis B core antibody (anti-HBc), they may still be eligible for reentry if after a minimum of 8 weeks following the last positive anti-HBc test, a follow-up sample is negative for anti-HBc, HBV surface antigen (HBsAg), and HBV nucleic acid testing.

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Additional tests are performed on donor samples prior to release of the unit from the blood center. An ABO and Rh(D) type is performed on every donor. In addition, for the Rh(D) type, blood centers must perform the weak D test to ensure the unit is truly Rh(D) negative. Furthermore, a red blood cell (RBC) antibody screen is performed on donor samples. Some blood centers will not release blood products from donors with preformed RBC antibodies while others might still release them with an attached special tag identifying the antibody present.

Platelet bacterial testing and pathogen reduction is beyond the scope of this presentation. However, it is important to know that the FDA mandates that blood collection centers ensure that the risk of bacterial contamination of platelets is sufficiently controlled. In addition, AABB Standards state that blood collection centers have methods to detect bacterial contamination in platelet components or use pathogen reduction technology.

Lastly, it is mandated by the FDA that any plasma, apheresis platelets, and whole blood for allogeneic transfusion should come from males, females who have never been pregnant, or females who have been screened for human leukocyte antigen (HLA) antibodies since their most recent pregnancy and found to be negative. These measures were established to reduce the risk of transfusion-related acute lung injury

(TRALI). Some blood centers will screen for HLA antibodies in females who have been pregnant since their last donation while others may simply not collect plasma, apheresis platelets, or whole blood for allogeneic transfusion from previously pregnant females.

Slide 16: References

In the references, you can find a link to the donor history questionnaire. For further reading, please refer to the AABB technical manual, AABB standards, and the FDA Code of Federal regulations.

Slide 17: Disclosures

Slide 18: Thank You from www.TraineeCouncil.org

Thank you for joining me on this Pearl of Laboratory Medicine on "**Blood Donor Eligibility and Donation Suitability**."