

Below are answers to common questions about the FDA's groundbreaking change moving to individual donor assessments for blood donor screening. For specific questions about your eligibility or to learn more, we encourage you to <u>contact your local community blood center.</u>

What criteria was used to determine that transitioning to an individual donor assessment approach was safe?

Evidence from the ADVANCE Study, the TTIMS monitoring system, and other scientific data assessed by the FDA support making this change. The new approach to donor screening will continue to defer those with a higher risk of acquiring a new HIV infection while making the eligibility process more equitable. Other criteria already in place identify additional risk factors for acquiring HIV, and these will continue to be applied. All available evidence confirms that an individual donor assessment approach to screening will continue to ensure the highest safety and quality for the blood supply.

Can I donate blood if I'm in a monogamous relationship and engage in anal sex with my partner?

Yes, if you have been in a monogamous relationship for at least three months and engage in anal sex, you will still be eligible to donate blood as long as you meet all other eligibility criteria. If you have had one sexual partner for three months or longer, you won't be asked about anal sex during the donor screening process.

Why is there a specific focus on anal sex?

Statistically, anal sex carries a higher risk of HIV transmission per sexual act compared to vaginal or oral sex. This focus is based on evidence-based scientific research that evaluates overall risk rather than individuals' safe sex practices.

Are individuals eligible to donate if they have multiple partners, but engage in vaginal or oral sex?

Yes. Donor screening criteria primarily focus on anal sex in the context of new or multiple partners due to the significantly higher risk of HIV transmission associated with anal sex compared to vaginal or oral sex. This is rooted in evidence-based scientific research that acknowledges the increased risk of HIV transmission with multiple sexual partners.

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FREQUENTLY

ASKED QUESTIONS

Why do blood centers inquire about anal sex with multiple partners?

Research demonstrates that the risk of a new or recent HIV infection increases with new and multiple sexual partners, which may not be detectable by current testing methods. As statistically demonstrated, anal sex has a significantly higher risk of HIV transmission per sexual act compared to vaginal or oral sex, and having multiple sexual partners can further elevate the risk of HIV transmission.

Why are individuals taking PrEP and PEP deferred from donating?

It's because these medications are so good at what they are designed to do! Despite excellent dual testing protocols for sexually transmitted viruses, there is a short window of time that a new infection may not be detectable by antibody or Nucleic Acid Testing (NAT) protocols.

If HIV positive individuals have an undetectable viral load, why can't they donate?

While it's fantastic that HIV care has advanced to the point where viral loads can become undetectable, the "undetectable equals untransmissible" concept only applies to sexual transmission of HIV. Unfortunately, this does not extend to the risk of blood transfusion-transmission as the concentration of the virus in blood could still pose a risk to the recipient.

Why can't individuals in exclusive relationships with more than one partner donate blood?

The FDA currently lacks sufficient data to support changes to the eligibility criteria based on the transmissible disease risk for individuals in exclusive relationships with multiple partners. This signifies the need for more research and does not imply any judgment on the sexual practices of individuals in such relationships.

Why do blood centers still ask donors about gender identity?

Most blood centers will still ask gender identity questions for the safety of the donor. For example, gender may impact the amount of product removed during an apheresis collection. Donor gender can also impact the level of hemoglobin required for a donor to safely donate blood. In absence of this information, blood centers would have to utilize the most conservative levels which would mean some donors that could safely donate blood would be unable to do so. Additionally, some centers may utilize gender to determine which blood components can be made from a single donation. For example, blood centers may not make plasma products from "female" donors (without additional testing) because of a greater risk of Transfusion Related Acute Lung Injury (TRALI) among patients receiving transfusion.

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