

FAQ: 2023 Donor Assessment Screening Changes

This document includes frequently asked questions about the donor assessment screening. The Food and Drug Administration (FDA) requires all U.S. blood centers to ask volunteer blood donors a specific set of questions before each donation. These questions help determine whether it is safe for the donor to donate and whether it is safe for a patient to receive that donor's blood.

Key Messages

- The updated donor history questionnaire is designed to be applied as broadly as possible to screen a large number of potential donors and identify the possibility of new exposures to certain viruses within the window period of testing platforms.
- Blood donor screening criteria is based on individual risk behaviors, not sexual or gender identity. Every donor is asked every question regardless of sex or gender identity.
- All blood donors, regardless of gender or sexual orientation, will be asked if they've had new and/or multiple sexual partners in the past three months. Note the following:
 - ✦ If they answer no to both questions, there is no risk of a newly acquired transfusion-transmitted infection. They will not be asked about the type of sexual contact and will move on to the next question.
 - ✦ If they answer yes to either, there is some risk of a newly acquired transfusion-transmitted infection. Therefore, they will then be asked if they've had anal sex with any of these partners. If they have, they will be required to wait three months from when they most recently had anal sex to donate.
 - ✦ If they have not had anal sex with a new and/or multiple partners and meet all other eligibility criteria, they will be able to donate.
 - ✦ Asking about anal sex in the context of new or multiple recent partners allows blood collectors to more precisely and reliably identify those who may have an increased risk of a newly acquired transfusion-transmissible infection.
- All donors, regardless of gender, will be asked if they are currently pregnant and if they have ever been pregnant.



What are the most notable changes for individual donor assessment questions?

All donors will be asked if they've had new and/or multiple sexual partners in the past three months. If they answer yes to either, they will then be asked if they've had anal sex with any of these partners.

If they have, they will be required to wait three months from when they most recently had anal sex to donate. If they have not and meet all other eligibility criteria, they will be able to donate.



Why do we ask every donor pregnancy related questions?

The updated questions allow us to simplify the donor questionnaire by asking all donors the same questions without regard to gender. Pregnancy related questions are asked for both donor safety and patient safety (in relation to prior pregnancies). Donors who have been pregnant may develop HLA antibodies. If donated blood contains these HLA antibodies, the platelets and plasma from these donations could have a negative effect on the patient who receives the transfusion. (Donated red blood cells are not affected by HLA antibodies.) HLA testing can help make transfusions even safer than before.

Why the focus on anal sex?

Statistically, anal sex has a significantly higher chance of HIV transmission per sex act than vaginal or oral sex.

This does not account for individuals' safe sex practices but is based on an evidence-based approach to overall risk.

Isn't all blood tested anyway? Why are screening questions necessary?

Yes, every donation is tested for an array of infections that could potentially be transmitted by blood transfusion. But no test is perfect, and there are some infections for which there is no reliable test available.

One reason we have such a safe blood supply is the layering of a donor screening questionnaire with donation testing.

Tests that are used on every blood donation have a limitation called the "window period." The window period is the time between when a donor has acquired a new infection and is able to transmit it, to the time a lab test can reliably detect the infection. If a donor has recently acquired an HIV or hepatitis infection, current testing methods may not pick it up. The Donor History Questionnaire is critical in helping identify people who may have had a recent new exposure to an infection of concern, such as HIV or hepatitis C.

Why are there questions about anal sex with multiple partners?

Data show that the risk of a new/recent infection of HIV that cannot be detected by current testing methods (particularly “window period” infections) increases with new sexual partners and multiple sexual partners.

Statistically, anal sex has a significantly higher risk of HIV transmission per sex act compared with vaginal or oral sex. Multiple sexual partners can increase the chance of HIV transmission.

Why are people who have used PrEP/PEP in the past three months deferred?

Pre-exposure prophylaxis (PrEP) is a highly effective medication regimen used for HIV prevention. In people taking PrEP or post-exposure prophylaxis (PEP), low levels of HIV may be missed by current testing methods. The blood community relies on accurate HIV testing as part of its multi-layered approach to safety.

There needs to be more research on how PrEP and PEP affect HIV testing. At this time, FDA recommends that individuals who take oral PrEP or PEP are deferred from donation for three months from their most recent use. For individuals who have received PrEP by injection, FDA recommends deferral from blood donation for two years from their most recent injection. This longer deferral for injectable forms of PrEP is due to the increased duration of effect that this form of the medications has.

This is an issue impacting blood operators worldwide. Tests used to detect HIV and other viruses are manufactured by independent companies, not blood collectors or regulatory bodies. Work to understand the true impact of PrEP and PEP medication regimens on HIV tests can only be completed in collaboration with or directly by the manufacturers of the test, who hold the licensing for these products.



How was it determined that it was safe to change to an individual donor assessment approach?

FDA determined, based on its review of currently available scientific data, that this change will not compromise the safety or adequacy of the United States blood supply. The new approach to donor screening will continue to defer those with a higher chance of acquiring a new HIV infection. Other criteria already in place identify additional risk factors for acquiring HIV, and these will continue to be applied.

Evidence from the ADVANCE Study, the TTIMS (Transfusion-Transmissible Infections Monitoring System), and other data assessed by the FDA support making this change. Currently

the risk of HIV being introduced to the blood system is extremely low. 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.



How does this change affect transgender donors?

The new Donor History Questionnaire is gender-neutral and will pose all questions to all donors regardless of their gender or sexual orientation. Transgender individuals are welcome to donate blood.

I'm non-binary, why do you still capture gender as part of my donor information?

For some items (such as donor hemoglobin), the donor eligibility criteria is based on gender. This gender can be self-identified. However, our computer system and apheresis instruments only allow for entry of male or female. Until that is changed, for donors who

identify as non-binary (neither male nor female), the donor's gender will be entered so that our system enforces the most conservative acceptability criteria.

Why are there not questions about condom use?

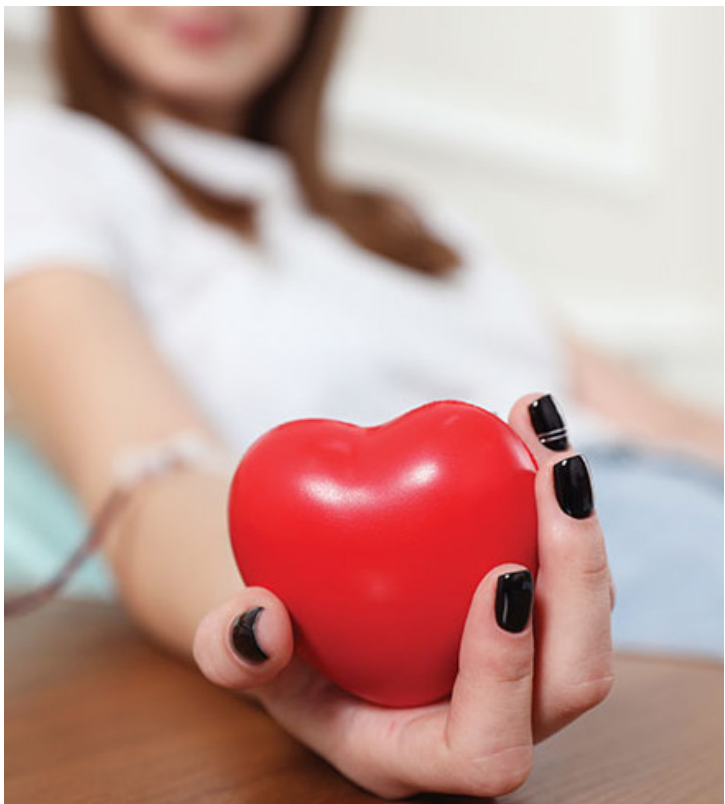
Condom use, while an excellent sexual health practice, isn't an evidence-based method of screening donors because condoms are not always effective and can break or slip.

It is important to note that our individual donor assessment screening questions are not comprehensive in asking about safe sexual practices, such as condom use, that can effectively mitigate the risk of acquiring HIV.

The updated donor history questionnaire is designed to be applied as broadly as possible to screen a large number of potential donors and identify the possibility of new exposures to certain viruses within the window period of testing platforms.

Is this eligibility change being made because of political correctness?

No. The blood community's goal is to be as inclusive as possible while maintaining the highest level of safety for the blood supply. Donor eligibility undergoes frequent revisions resulting in changes based on current scientific evidence.



I've heard that undetectable means untransmissible (U=U). Why can't HIV+ people donate if their viral load is undetectable?

It's amazing that HIV care has reached a point where people's viral loads can be undetectable.

Undetectable equals untransmissible only applies to sexual transmission of HIV. Unfortunately, this does not apply to the risk for transfusion-transmission. Even blood donated by those who have an undetectable viral load could potentially put a patient at risk for HIV following a blood transfusion.

The risk of transmission is much higher with a unit of blood due to the large volume of a blood transfusion and the much higher total amount of virus present.

Why do the questions not address receptive vs. insertive anal sex when they have such different risk profiles?

It is true that receptive anal sex is associated with a higher risk of HIV transmission per sex act than insertive anal sex.

However, in research studies involving asking donors about receptive anal sex, the term was not well understood and the question was inconsistently answered.

For the safety of the blood supply, it is important that donor screening criteria is easily understood by all donors.

What about people who are in exclusive relations with multiple people/ practice polyamory/polyfidelity? Why aren't they able to donate?

The blood community recognizes that some people may be in sexual relationships with multiple people where their partners are not new partners. At this point, there is insufficient evidence to inform criteria about people in exclusive relationships with more than one partner.



Why can't I have anal sex and donate blood? Is this just another version of the previous policy using "anal sex" instead of asking men if they've had sex with men?

The new individual donor assessment questions will only ask donors about anal sex if they have had a new sexual partner or have had multiple sexual partners in the past three months.

Donors who have one sexual partner they've been with three months or longer won't be asked about anal sex.

Donors who have anal sex with one partner who they've been with for three months or longer will be eligible, as long as they meet all other eligibility criteria.

Does it count as anal sex if I use sex toys/hands/fingers?

No, using sex toys/hands/fingers is not considered anal sex in the context of our donor screening criteria.

Are donors eligible if they have multiple partners if it's vaginal/oral sex?

The individual donor assessment screening criteria focus on anal sex in the context of new or multiple partners, rather than vaginal or oral sex. This is because, statistically, anal sex has a significantly higher chance of HIV transmission per sex act than vaginal or oral sex. Multiple sexual partners can increase the chance of HIV transmission. This does not account for individuals' safe sex practices but is based on an evidence-based approach to overall risk.

I'm monogamous. Can I donate and still have anal sex with my partner?

Yes. If you are having anal sex with one person you've been with for at least three months, you will be able to donate as long as you meet all other eligibility criteria. All donors are asked if they've had a new partner in the past three months, or multiple partners in the past three months. Donors who have one sexual partner they've been with three months or longer won't be asked about anal sex.