America's Blood Centers®
It's About Life.

Frequently Asked Questions about the FDA's Move to Individual Donor Assessments

What are the changes to the regulations?

In May 2023, the U.S. Food and Drug Administration (FDA) published final guidance on recommendations for evaluating donor eligibility using individual assessment of health history to reduce the risk of HIV transmission by blood and blood products. The previous blanket deferrals for gay and bisexual men and for women who have sex with them are eliminated.

The donor history questionnaire used to screen all prospective blood donors will now ask all donors a series of questions about their sexual history as a way of identifying donors with a potentially high-risk for HIV. These questions include:

- Whether the individual has had multiple sexual partners in the past three months.
- Whether the individual has had any new sexual partners in the past three months.
- If the answer is yes to either of the above questions, the individual will then be asked about a history of anal sex in the past three months.

Based on these questions, a temporary deferral of prospective donors may occur.

- If donors have had a new sexual partner or more than one sexual partner and had anal sex in the past three months, they will be deferred from donation for three months.
- Donors who have not had new or multiple sexual partners in the past three months will not be asked about anal sex and may be eligible to donate, provided all other eligibility criteria are met.
- Donors who have had new or multiple sexual partners without anal sex may be eligible to donate provided all other eligibility criteria are met.

Donors who have taken medications to prevent or reduce the likelihood of HIV infection (PrEP or PEP) will be deferred for three months for oral medication or two years for injectable medication. These medications may delay detection of HIV by licensed screening tests for blood donations, potentially resulting in false negative results.

Donors should not stop taking any medication regimen prescribed by their provider in order to to donate blood.

Why are these changes happening?

The FDA's final guidance proposes a shift that will create equitable donor eligibility standards for blood donors by using the same sexual behavior-based questions in all pre-donation screenings.

These proposed changes are in line with current policies in countries like the United Kingdom and Canada, which have made similar changes in recent years.

The FDA evaluated and utilized data from ongoing surveillance of the U.S. blood supply and results from studies conducted by other countries. The FDA also sponsored a recent study, Assessing Donor Variability and New Concepts in Eligibility (ADVANCE), to evaluate data among domestic populations.

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This guidance has been updated previously two times, first when the lifetime ban for gay and bisexual men was lifted in 2015, and then again when the 12-month deferral for gay and bisexual men was reduced to three months in 2020.

Is this change politically motivated?

No.

Having a safe and adequate blood supply from volunteer blood donors is in the best interests of all patients requiring blood transfusions.

The blood community has united in support of this change and has advocated for this change for many years due to the excellent safety record of current infectious disease tests and more recent data on the risks associated with transmission of HIV.

The previous time-based deferral alienated a subset of the population due to its focus on sexual orientation rather than individual sexual behavior.

The new guidance proposes screening protocols that will be applied to all donors regardless of sexual orientation, assessing all donors equally for potential high-risk behavior.

Will this impact the safety of blood products for patients?

No.

Based on the data available to the U.S. Food and Drug Administration today, the decision was made with confidence that it would continue to support a safe and robust blood supply.

The new screening protocols will apply a set of screening questions about sexual behavior to all donors vs. a small subset of donors, which supports safety screening methodology.

Will this help overcome blood shortages?

We don't know.

Currently more than 60% of adults in the U.S. are eligible to voluntarily donate blood, yet only 3% donate each year.

Donation rates among donors under 50 years of age continue to decline and less than 20% of donations come from individuals from communities of color, leading to concerns about the long-term resiliency of the blood supply.

A donor screening process that equitably applies to all donors may help support a robust blood supply.

It is too early to tell how many donors will or will not be deferred with the new criteria.

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Why can't people on PrEP or PEP donate while taking this preventative medication?

Medications taken to prevent or reduce likelihood of HIV infection (PrEP or PEP) will result in deferral for three months (oral medication) or two years (injectable medication) as they may delay detection of HIV by licensed screening tests for blood donations, potentially resulting in false negative results.

Dr. Peter Marks of The U.S. Food and Drug Administration indicated in a January 27, 2023 press conference that the FDA will continue to monitor data for possible changes in the future.

The U.S. Food and Drug Administration and blood centers across the country recommend that donors continue medications as prescribed by their physicians and that they should not discontinue or delay taking medications to be eligible to donate blood.

To see a full list of medications that result in deferral from blood donation, contact your local community blood center.

Why is this sexual behavior-based screening protocol necessary?

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 protocols.

Will blood centers still ask donors about gender identity?

Most blood centers will still ask gender identity questions because it helps determine which blood components can be made from a single donation.

For example, blood centers cannot make plasma products from a donor that has had a history of pregnancy (without additional testing) or positive genetic markers in their plasma that can cause Transfusion Related Acute Lung Injury (TRALI) among patients receiving transfusion.

With no knowledge of gender, blood centers must use the most stringent gender-based criteria for hemoglobin (HGB) and total blood volume (TBV). This would mean that all females must have a minimum HGB of 13.0 rather than 12.5 and lead to unnecessary deferrals. The same is true TBV, which is used to determine eligibility to donate some apheresis products. This would limit the number of females eligible for those apheresis procedures. Both scenarios would have a detrimental impact on the blood supply.

These gender-related questions may not defer a donor from giving.

How can I learn more about donating blood and when I might become eligible to give?

For questions regarding your individual eligibility to donate, you can find a local donation center by contacting your local community blood center.

To contact your local community blood center and learn more about your eligibility to donate blood, visit AmericasBlood.org