TuSalud

UPDATE: More Gay and Bi Men Can Now Donate Blood

The American Red Cross started screening all donors using a questionnaire to evaluate behavior-based risk. Folks on PrEP may not donate.

August 9, 2023 By Trent Straube

UPDATE: On August 7, the American Red Cross began using the Food and Drug Administration's more inclusive assessment for all blood donors, regardless of gender or sexual orientation. Under the new FDA policy, all donors are screened with a questionnaire to evaluate behavior-based risk. This means more gay and bisexual men will be allowed to donate blood.

"The Red Cross celebrates this significant progress and also recognizes there is more work to be done to make blood donation even more inclusive," noted the organization in a statement titled "LGBTQ+ Donors." The American Red Cross provides about 40% of the nation's blood and blood components.

Other blood centers are adopting the policy, including OneBlood, a nonprofit based in Orlando, Florida, that sends donated blood to hundreds of hospitals, primarily in Southern states. As CNN reports, OneBlood will begin using the FDA's risk assessment on Monday, August 21.

Below is the original article about the FDA's new policy, including details about who is still not allowed to donate blood.

UPDATE MAY 11, 2023: More gay and bisexual men will be able to donate blood now that the Food and Drug Administration (FDA) has ended its policy of requiring men who have sex with men to abstain from sex for three months before donating blood, according to a May 11 press release from the FDA.

Under the new policy, all potential donors will answer a questionnaire that evaluates each person's individual risk, regardless of their sex or gender. Gay and bisexual men in monogamous relationships can now donate blood. According to the FDA, people who report the following will not be eligible to donate blood:

- Anyone who had a new sexual partner in the past three months

- Anyone with more than one sexual partner in the past three months
- Anyone who had anal sex in the past three months
- Anyone taking HIV medications to treat or prevent HIV, including pre- and post-exposure prophylaxis (PrEP and PEP).

Regarding the rules based on PrEP, PEP and HIV meds, the FDA explains:

> "Though these antiretroviral drugs are safe, effective, and an important public health tool, the available data demonstrate that their use may delay detection of HIV by currently licensed screening tests for blood donations, which may potentially give false negative results. Although HIV is not transmitted sexually by individuals with undetectable viral levels, this does not apply to transfusion transmission of HIV because a blood transfusion is administered intravenously, and a transfusion involves a large volume of blood compared to exposure with sexual contact. As stated in the guidance, individuals should not stop taking their prescribed medications, including PrEP, or PEP, in order to donate blood. The FDA remains committed to evaluating additional data and new technological developments as they become available to inform our donor eligibility recommendations."

The FDA issued draft guidelines on the new policy earlier this year. Below is POZ's original January 27, 2023, article about the proposed policy, which is now finalized.

JANUARY 27, 2023: The Food and Drug Administration (FDA) is considering allowing more gay and bisexual men to donate blood. More specifically, it proposes ending the current policy on who can and cannot donate blood and switching to "gender-inclusive, individual risk-based questions to reduce the risk of transfusion-transmitted HIV," according to an FDA press statement.

Currently, men who have sex with men can donate blood and plasma if they haven't had sex in the previous three months. Instead of enforcing this blanket ban—which prohibits monogamous, HIV-negative gay and bisexual men from donating blood—the FDA proposes using a questionnaire to assess a person's risk. The questionnaire would apply to everyone, regardless of sexuality or gender.

Under the new policy, people living with HIV, even if they maintain an undetectable viral load, are still banned from donating blood, as are HIV-negative people taking pre-exposure prophylaxis (PrEP), the daily pills and long-acting injectables to prevent HIV.

The ban on PrEP users has some AIDS advocates pushing the FDA for further updates (see their

statements at the end of this article).

Before it finalizes the new policy, the FDA is seeking public comment. You can read the draft guidelines on FDA.gov and comment on them via Regulations.gov. The FDA will consider comments submitted within 60 days.

In its press statement, the FDA spells out several changes in the new policy. Under the new proposed guidance:

- The time-based deferrals for men who have sex with men (MSM) and women who have sex with MSM would be eliminated.

- The current donor history questionnaire would be revised to ask all prospective donors about new or multiple sexual partners in the past three months.

- Prospective donors who report having a new sexual partner, or more than one sexual partner in the past three months, would then be asked about a history of anal sex in the past three months.

- All prospective donors who report having a new sexual partner or more than one sexual partner and had anal sex in the past three months would be deferred from donation.

- Under this proposal, a prospective donor who does not report having new or multiple sexual partners, and anal sex in the past three months, may be eligible to donate, provided all other eligibility criteria are met.

Other considerations in the guidance include:

- No change in the donor deferral time periods for other HIV risk factors, including for individuals who have exchanged sex for money or drugs or have a history of non-prescription injection drug use.

- Any individual who has ever had a positive test for HIV or who has taken any medication to treat HIV infection would continue to be deferred permanently.

- Blood establishments would still be required to test all blood donations for evidence of certain transfusion-transmitted infections, including HIV, hepatitis B and hepatitis C.

Proposed guidance related to PrEP or post-exposure prophylaxis (PEP):

- Those taking oral medications to prevent HIV infection such as PrEP or PEP would be deferred for three months from their most recent dose.

- Those taking injectable PrEP to prevent HIV infection would be deferred for two years from their most recent injection.

- Some blood establishments currently have deferral policies related to the use of medications to prevent HIV infections.

- The available data demonstrate that the use of PrEP and PEP may delay detection of HIV by licensed screening tests for blood donations, potentially resulting in false negative results.

“This marks a monumental shift and ends a long and painful era of blanket discrimination against gay men,” said Carl Schmid, executive director of the HIV+ Hepatitis Policy Institute, in a separate press statement. “No longer will eligibility to donate blood be based on sexual orientation. Instead, every person, no matter their sexuality, will be reviewed individually in order to determine their eligibility to donate. While this long-overdue change is being made based on the science and the facts, which have been clear for years, it is the result of the leadership of the Biden administration that continues to tear down discriminatory government policies.”

“These changes are 40-plus years in the making, and are a tremendous leap forward toward elevating science over stigma,” said Sarah Kate Ellis, president and CEO of GLAAD, in a statement from the LGBTQ advocacy group. “GLAAD and leading medical experts have long been advocating for guidelines that see and treat LGBTQ people the same as any other person, including as potential donors who want to help others. The announcement today will ease historic discrimination against LGBTQ Americans, help alleviate the national blood shortage, and opens the

door for all eligible LGBTQ people to give blood and save lives. The U.S. moves closer to joining the growing list of countries that already welcome blood donations from gay and bi men without restrictions. LGBTQ leaders will continue to advocate until the FDA enacts those science-based, safe and stigma-free guidelines."

A statement from the Human Rights Campaign (HRC), another leading LGBTQ advaocacy group, also praised the FDA's proposed changes but added that "it's not the end of the road; there is much more that needs to be done, and we urge the Biden administration to prioritize removing remaining barriers and ask the FDA to move expeditiously while ensuring the safety of the blood supply and a blood donation policy in-line with the science."

NMAC (formerly the National Minority AIDS Council), which fights HIV through the lens of race, shed light on potential changes to better the FDA's proposed requirements.

"This change by the FDA is a welcome step towards eliminating the outdated and discriminatory ban on men who have sex with men donating blood," said NMAC executive director Paul Kawata in a released statement. "It moves away from broad bans on large groups to a science-based approach based on the circumstances of each individual potential donor. But it's just a step. There is much more that needs to change, including focusing on a potential donor's new sexual partners, not total number. And the ban on those who use pre-exposure prophylaxis (PrEP) to prevent HIV acquisition is also troublesome and could lead to potential donors ending or suspending their use of PrEP. We hope that the FDA will revisit these issues and, ultimately, completely eliminate the ban on all men who have sex with men from donating blood."

Before 2020, FDA recommendations required gay and bi men to abstain from sex for 12 months before donating blood, but when COVID-19 struck and resulted in a blood shortage, the FDA eased the policy to a three-month deferral.

In December, the FDA signaled that it was about to ease its restrictions, as it is now doing. Read the backstory—including the advocacy and science behind the move—in this POZ article.

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http://beta.docker.tusaludmag.com/article/fda-proposes-lifting-rules-blood-donations-gay-bi-men