

Does the blood community support this final guidance?

ConnectLife, WNY's only community blood bank, supports the Food and Drug Administration's (FDA) final guidance establishing a blood donor screening process based on individual donor assessments. This change prioritizes the safety of the nation's blood supply while welcoming new individuals as potential blood donors. This change aligns the United States with other countries who have implemented similar changes, including Canada and the United Kingdom.

How does this change impact the safety of the blood supply?

The safety of our local blood supply is our top priority. This change is supported by multiple layers of safety, including extensive testing of blood donations as well as a donor health questionnaire. The data from countries that have already implemented this change – including Canada and the United Kingdom – have shown that making this change does not put the safety of the blood supply at risk.

How does the individual donor assessment approach differ?

Under the guidance, all prospective donors will be asked about new or multiple sexual partners in the past three months. If they report a new sexual partner or more than one sexual partner in the past three months, they would then be asked if they engaged in anal sex over the prior three months. Those 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 temporarily deferred from donation. A prospective donor who does not report having new or multiple sexual partners or anal sex in the past three months may be eligible to donate, provided all other eligibility criteria are met.

By asking all potential donors the same questions about their sexual behavior, this change reflects the fact that diseases caused by infectious agents such as HIV could be contracted by anyone, regardless of their sexual orientation. Additionally, these questions are only the first layer of safety and followed by extensive and sensitive tests for a variety of infections.

How does this change increase inclusivity in the blood donation process?

This new policy is a major step forward in the ongoing work of bringing equality and fairness to America's blood donation policies while maintaining the safety of the blood supply. By basing a person's ability to donate on their individual donor assessment rather than sexual orientation, more gay and bisexual men will now be able to safely donate blood without abstaining from sex.

What does this guidance mean for prospective donors taking medications like PrEP and PEP?

Prospective donors taking oral medications to prevent HIV transmission like PrEP will be subject to a three-month deferral, while those taking injectable PrEP will be deferred for two years from the date of the most recent dose.

This deferral is for anyone taking the medication and is not based on any characteristic of the individual taking the medication. It is just one of many medications that can result in an individual being unable to donate blood while taking the medication and for some time after.

Should those individuals on PrEP and PEP stop taking this medication to be able to start donating blood under these new guidelines?

The FDA and blood centers across the country are recommending that donors continue medicine regimes as prescribed by their physicians and do not discontinue or delay taking medications to be eligible to donate blood.

Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research at FDA, indicated in a January 27th press conference that the FDA will continue to examine the issue for possible changes in the future.

How soon will impacted donors be able to give blood?

ConnectLife has started working on implementing this change so we can welcome newly eligible donors. This process will take some time. We will be making an announcement soon.

Why does it take so long for blood centers to implement this guidance?

Since the FDA accepted an updated donor history questionnaire to reflect the final guidance, ConnectLife can now begin implementing necessary computer changes. ConnectLife will also be training our staff on these new guidelines and new standard operating procedures. It is important that this process is conducted with appropriate due diligence.