

The FDA must lift its discriminatory blood-donor policy

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With the nation's blood supply at its lowest point in a decade, and the American Red Cross declaring its first-ever national blood crisis earlier this month, it is time for the Food and Drug Administration (FDA) to do something the AMA and others have urged for years: remove its discriminatory ban that prevents many gay and bisexual men from becoming blood donors.

The existing ban requires gay or bisexual men to abstain from sex for a minimum of three months before they can donate blood. This policy was established in April 2020, when the FDA shortened the deferral time from one year to 90 days in response to a drastic decline in blood donations as the COVID-19 pandemic took hold and thousands of blood drives were canceled.

The current three-month deferral period singles out and bans blood donors based on their inherent attributes rather than the risk factors they present. For example, a man who has protected sex with another man in the three months prior to a blood donation cannot be a donor, but a man or woman who has unprotected sex with multiple partners of the opposite sex over the same time period remains eligible.

The roots of limitations against gay and bisexual blood donors date back to the HIV/AIDS crisis of the 1980s. In 1985, the FDA established a lifetime ban on donations by men who have sex with men (MSM) that remained in place until 2015, when the one-year deferral took effect. In shortening that period to 90 days in 2020, the agency said it expected the change would remain in place after the pandemic ends.

While that was a welcome change, the fact remains that further changes—including the removal of all categorical restrictions on MSM blood donations—are needed. The lifetime ban was imposed in an era when HIV was poorly understood, and it persisted for decades even as blood-screening technology improved dramatically. Today, every unit of donated blood is rigorously tested to detect any trace of HIV, syphilis, hepatitis, West Nile virus or other blood-borne diseases.

Evaluate all donors equally

At issue is the need to evaluate all potential blood donors on an equal basis based on their individual risk factors and without regard to their sexual orientation or gender identity. The FDA's Center for Biologics Evaluation and Research, which develops and regulates the standards for the collection of blood and blood products, should proceed further down the path it has already set out upon by ensuring that blood donation criteria are applied equitably across all segments of our population, including the LGBTQ+ community, based on the latest scientific evidence.

The American Red Cross, which supplies an estimated 40% of the nation's supply of blood and blood products, has stated its belief that blood-donor eligibility should not be based on sexual orientation, and has committed to achieving that goal. One effort that could speed that achievement is the ongoing Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study.

This important research may help shape FDA donor-eligibility requirements by changing the donor-history questionnaire and determining whether research-informed questions that better determine individual risk are just as effective in reducing the risk of HIV in donated blood as the existing 90-day deferral period. Results should be available later this year.

AMA policy supports using a rational, scientifically based deferral period for human tissue donations as well. FDA policy now requires a five-year deferral period for MSM seeking to donate human cells, tissues, and cellular and tissue-based products such as corneas. We have asked the FDA to change its tissue-donation policy to provide the same 90-day deferral period that applies to blood donations by MSM, and to use the ADVANCE Study or similar research to adopt individual risk assessment for donors.

In the meantime, as a Gallon Donor myself, I strongly encourage everyone to respond to the pressing need for blood donations by visiting the American Red Cross website and finding a donation site or blood drive near you. Blood cannot be manufactured or stockpiled, and a suitable supply depends solely on the good will of donors. The COVID-19 pandemic has cast an uncomfortable spotlight on many longstanding and too-often discriminatory policies that exist within our health system—and placed a new responsibility on all of us to work quickly to correct them.