

New blood donation rules empower more LGBTQ+ people to give and expand the blood supply

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For decades, LGBTQ+ patients have faced stringent requirements to donate blood—most gay and bisexual men were not allowed to donate at



all. Now, however, many more of them will be able to give this selfless gift. The U.S. Food and Drug Administration, which regulates blood donation in this country, has reworked the donor-screening criteria, and in the process opened the door to donation for more Americans.

The previous restriction on accepting blood from men who have sex with men (MSM) dates back to the early days of the AIDS epidemic, when blood donations weren't able to be screened for HIV, leading to cases of transfusion-transmitted HIV. In 1985, the FDA instituted a lifetime ban on blood donation for MSM, effectively preventing gay and bisexual men from donating. (Also included were women who have sex with MSM.)

Twenty years later, the agency rescinded the ban—but added a restriction that only MSM who had been abstinent from sex for at least one year could donate. In 2020, the FDA shortened the "deferral" period to 90 days of abstinence. While the changes were welcome news for those who had been unable to donate, they still <u>prevented many MSM</u> from giving blood.

As he wrote in an op-ed for the Philadelphia Inquirer last year, Kevin B. Johnson, MD, the David L. Cohen University Professor of Pediatrics, Informatics, Computer Science and Communication at Penn, was one of them. He and his husband were shocked to learn when they went to donate blood during a shortage early in the COVID-19 pandemic, that despite being married and monogamous for close to 17 years, they could not donate unless they were celibate for three months.

"It is time to move quickly to a policy under which all donors are evaluated equally and fairly, and to encourage local blood collection facilities to comply with that policy," Johnson wrote last year.

Now, such changes are underway. As the pandemic wound down, the



FDA moved forward with plans to re-evaluate its donation criteria. The first big change was <u>removal of an indefinite ban</u> on people who lived in or spent significant amounts of time in the United Kingdom, Ireland, and France, a measure that aimed to protect the U.S. blood supply against Creutzfeldt-Jakob disease (CJD; also known as "mad cow disease"), a terminal brain condition caused by hard-to-detect prions that occurred in those countries in the 1980s and 1990s.

Extensive and careful evaluation of epidemiological studies and statistical analysis has shown that the risk of CJD transmission is no longer a concern. The changes to eligibility for LGBTQ+ patients are related to advances in medical and <u>social science</u>, and have also been very thoroughly studied to ensure that the changes will maintain the safety of the blood supply without being discriminatory.

"In the decades since HIV was first recognized, there have been advances in testing methods for detection of the virus, changes in how we process blood products, public health advances, and extensive study of the evolving risk of disease transmission given these advances," said Sarah Nassau, MD, vice chair of Pathology and Laboratory Medicine at Lancaster General Hospital.

They also draw on rethinking the reliability of the guidelines. For example, while the rules partially or fully prevented gay and bisexual men from donating blood, they did not erect similar barriers to other people engaging in anal sex, or people who have multiple partners. "Specifying the sexual orientation of the person rather than a behavior in which they engaged was discriminatory and not evidence based," points out Judd David Flesch, MD, vice chief of Inpatient Operations in the Department of Medicine at Penn Presbyterian Medical Center and codirector of the Penn Medicine Program for LGBT Health.

What the revised regulations mean



The revised regulations shift the criteria from being identity-based to being based on an individual's behavior. Rather than targeting exclusion criteria specifically at men who have sex with men, the new rules ask all potential donors about their recent sexual practices and partners. This allows for, say, a gay man in a longstanding, monogamous relationship to donate, whereas a woman who has had anal sex with new and/or multiple partners would be temporarily deferred from donating.

The updated regulations do include some specific restrictions related to HIV, including a permanent ban for any person who has tested positive or been treated for an HIV infection, and a required waiting period for people taking pre-exposure or post-exposure prophylaxis (PrEP) against HIV. The use of PrEP "makes it harder to detect the virus with our testing methods," explained Nassau.

"The PrEP ban is the most controversial part of the new guidelines," said Flesch. "Hopefully, future studies can provide reassurance that this population, too, can safely donate."

While the FDA's changes to the regulations have been published, newly eligible donors will still need to be patient for their chance to donate blood. That's because blood banks, and blood-collection organizations like the American Red Cross, have to rework their questionnaires and materials for assessing donors, train and educate staff, update their computer systems, and develop new policies and procedures, a process that may take several months. "This is a complex and highly regulated field, for safety's sake, so changes inevitably take longer than many of us would like," admits Nassau, who oversees LGH's Blood Bank. "We are working hard to update everything so we can implement the new guidelines as soon as possible."

Nevertheless, the reworked rules are worth waiting for. Practically, they may expand the pool of potential donors, and shore up a national blood



supply that sometimes runs perilously low. From <u>natural disasters</u> to the COVID-19 pandemic to mass-casualty incidents, blood is often in high demand, and the more people who are eligible to donate, the better. For instance, Flesch points to the 2016 shooting at Pulse, a gay nightclub in Orlando, Florida, which killed 49 people and injured 53 others. Despite an urgent call for <u>blood donations</u> in the shooting's immediate aftermath, the FDA's restrictions at the time stymied many queer men who wanted to help.

"I 100% support blood drives," said Flesch, who is gay, "but they have historically been a reminder that, as much as I'd like to, I can't contribute to this community effort because of my identity."

The FDA's recent changes make the blood-donation system more equitable. Now, donors will be evaluated not for who they are, but for the medical risks associated with their activities. "A strategy that focuses on an individual's behavioral risk rather than their identity is a better approach, and overdue," according to Nassau.

Empowering a new culture of giving

What's more, removing this barrier may have deep psychological and emotional meaning for gay and <u>bisexual men</u> who were previously unable to donate. For example, Flesch says that as a high school student, he donated blood "routinely"; but once he became sexually active, that door was effectively closed to him.

"I suspect that there's a large generation of people who have grown up where blood donation has been forbidden to them, and it hasn't even actually occurred to them that they could do it," he adds. Now, though, more LGBTQ+ people can participate more fully in efforts to help their communities.



Updating blood donation criteria represents progress for health care as a whole, especially for greater inclusivity of the LGBTQ+ community. Historically, the health care system has not always been welcoming to this population, which contributes to a sense of mistrust, fear, and reluctance to seek care, according to Flesch. "So any step that's taken that reduces the stigmatization is a step in the right direction," he says. "Regardless of what it does for the number of people who actually engage in blood donation, just the removal of the stigmatizing language in the policy is an excellent positive step."

Provided by University of Pennsylvania

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