PERSPECTIVE

We Need Blood and I Am Not Allowed to Help

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This summer I became a physician at the height of the coronavirus disease 2019 (COVID-19) global pandemic. While I will be fighting on the front lines, I will not be able to donate blood to fight the growing national crisis for blood donations. Additionally, if I become infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and survive, I will not be able to donate my convalescent plasma, a potentially important treatment. This is because I am a gay man.

On April 2, 2020, the US Food and Drug Administration (FDA) amended its restriction on blood donations from gay men. They reduced the period that men who have sex with men (MSM) must abstain from sex from 1 year to 3 months to be allowed to donate. I am not celebrating. While the FDA claims that this change was in response to new data, the timing of this change is revealing. It took a global pandemic to overcome a discriminatory fear of gay blood. Yet the science shows that even 3-month of abstinence for all MSM is not needed, and these rules are putting lives at risk.

Earlier this year, as a fourth-year medical student, I was on an infectious disease rotation and had a new intensive care unit consult for an immunocompromised patient in septic shock. Under treatment with proper antibiotics, the patient quickly recovered, but the underlying illnesses continued to be life-threatening. What the patient needed most was frequent blood transfusions, but the COVID-19 pandemic is creating a dire national shortage.

Donors are staying home in response to shelter-in-place orders by their local and state governments. In March 2020, the blood banks were rely on announced critical shortages. I wanted to help, and ironically would medically benefit from doing so owing to iron overload in my blood as a consequence of being a carrier for hemochromatosis. However, because I am gay, my blood is deemed too dangerous. Instead, as a treatment for my iron overload, I must obtain a specialist referral to an infusion center, where, after the requisite copay, my blood is extracted and thrown away.

Back in 1983, early in the AIDS epidemic, the FDA banned gay men from donating blood to reduce the transmission of HIV. The FDA amended the rule in 2015 to permit gay men to donate blood as long as they had abstained from sex with other men for at least 12 months. This forced gay men to forgo donating, abstain from sex, or even lie to circumvent a seemingly discriminatory rule. The change on April 2 shortened this period to 3 months for all MSMs, but that is still not necessary. And here is the scientific reason: MSM are indeed at a higher risk of contracting HIV, and although all donated blood undergoes 2 separate tests for HIV—antibody testing and nucleic acid testing—there is a risk of a false-negative test result immediately after becoming infected (ie, the "window period"). According to the American Red Cross, there is "an approximate period of 7 to 10 days when an infected donor may not be detected."[1] Thus, by imposing a 3-month deferral period, the FDA has created an excessive and needless buffer.

The memory of the HIV/AIDS epidemic prior to current advances in testing and treatment, superimposed on the longstanding societal marginalization of homosexuality, has led to a policy that continues to exaggerate the risk of undetected HIV among many MSM. In fact, the pretest probability of having undetected HIV among many MSM is quite low. A minority of MSM in the United States are infected with HIV, and of those about half have suppressed or undetectable viral loads, making transmission risk to their sexual partners negligible.[2] For those who can transmit HIV, there is a 0.1% to 1.4% chance of transmission from unprotected sexual intercourse,[3] and that risk can be reduced with condom use, knowledge of a partner's sexual history, and/or daily preexposure prophylaxis (PrEP) use which, in and of itself, reduces the transmission risk by 99%.[4] Furthermore, MSM engaged in primary care are encouraged to undergo HIV screening every 3 to 6 months while sexually active, per CDC guidelines.[5]

The resulting low pretest probability of many MSM having or being capable of unknowingly transmitting HIV, combined with the excellent test characteristics of blood donor screening, makes HIV transmission in this setting exceedingly unlikely. In a letter to the FDA, cosigned by hundreds of physicians, HIV experts Deborah Cohan and Monica Hahn criticize the FDA's policy change for not going far enough. In particular, a broad ban "does not take into account the actual behavior in question."[6] They cite the near 100% sensitivity of nucleic acid testing 10 days after infection to declare that it *is* possible to "uphold the utmost safety of the blood supply and simultaneously promote equity and reverse historical discrimination in blood donation."[6,7]

To ensure that everyone who needs access to life-saving blood transfusions can get them, the FDA should consider 3 important changes. First, the FDA should immediately shorten the deferral time to more closely match the window period of 10 days. Second, they should prioritize completing a study of an HIV risk assessment questionnaire for MSM blood donors.[8] By scientifically determining which questions to ask, the FDA can write a policy based on risky behavior rather than broadly banning a marginalized group. As a result, some MSM may be identified as low enough risk such that the deferral period could be completely eliminated. (It must be taken into account that if PrEP use is included to determine low-risk behavior, it could unintentionally perpetuate racial disparities among donors because African American men currently have less access to PrEP.[9]) Finally, with the implementation of these recommendations, the FDA should reconsider the use of

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individual nucleic acid testing rather than minipool, where blood from several donors is pooled together for testing. Although more expensive, individual nucleic acid testing can further shorten the window period and improve safety.[10]

The FDA needs to urgently finish the job of making commonsense changes to their restrictions on blood donations from MSM. This is not an academic exercise on fairness, but an imperative for patient safety. After I began my residency, the nearest children's hospital announced a significant shortage of my blood type and urged its clinicians to take steps to reduce its use. Once again, I would love to help, but I am barred from doing so. COVID-19 has exposed the weaknesses in our health care system, and our blood banks have critical shortages. Our response should be guided by science rather than fear. Patients depend on it.

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