

# Blood and Blood Product Donation Policy Statement

## POSITION

ASTHO recommends FDA update its blood donor guidance to align with the current evidence base for the following reasons:

- 1) Current policy does not consider protective factors, such as the number of recent sexual partners and/or knowledge of partner’s HIV status.
- 2) Current blood donation deferral policy is discriminatory as it is not applied equally to all groups. It is rooted in outdated science, which perpetuates stigma against gay, bisexual, and other men who have sex with men (MSM), as well as people living with HIV.
- 3) Maintaining a safe, robust national blood supply is of the utmost importance to support routine and emergency medical care and as a component of preparedness for emergency response. Assessing eligibility based on individual risk will safely expand the pool of eligible blood donors.

### Recommendations:

- **Update the blood donor screening recommendations to focus on behavioral risk, not gender identity or sexual orientation.**
- **Follow the latest biomedical science to screen blood donations for blood-borne pathogens.**

## BACKGROUND

Beginning in 1983, FDA required blood donation deferral policies for MSM. These policies have changed over the years, starting with a lifetime ban and evolving to the current policy that requires a 3-month period of sexual abstinence.<sup>iii</sup> Although there are protective behaviors that minimize HIV/AIDS risk for all sexually active people, these mitigation factors are not currently considered when individuals are assessed to donate blood. As the current policy focuses exclusively on sexual orientation, it is discriminatory and promotes stigma towards MSM.

Initial precautions were put into place when little was known about HIV. Since then, our collective ability to detect HIV and prevent transmission has drastically improved. Assessing blood donors based on individual behavioral risk—rather than categorical restrictions on MSM—would provide a deferral justification rooted in science.

## RECOMMENDATIONS/EVIDENCE-BASE

ASTHO recommends updating FDA policy to align with the latest science, safely increase the number of eligible blood donors to help ensure a robust national blood supply, and reduce stigma associated with identity-based deferral policies.

1. **Update Blood Donor Guidance to be Based on Behavioral Risk, Not Gender or Sexual Orientation.** Current evidence does not support deferring donation eligibility for MSM and women who have sex with MSM as an effective mechanism for reducing risk of HIV transmission. The deferral policy had previously been updated from a lifetime ban to a 12-month deferral. Analysis of this policy change shows no statistically significant increase in HIV incidence or transmission risk, suggesting further deferral reduction is unlikely to increase risk to the blood supply.<sup>iii,iv</sup> Additionally, a three-month deferral does not match the current window period for HIV test detection of virus, which can be as short as 10 days.<sup>v</sup> In the past two decades, there has only been one case of transfusion acquired HIV, and the blood donor was not reported to have any HIV risk factors.<sup>vi</sup>

High-risk sexual behaviors are not exclusive to MSM, which speaks to the need for an individual behavior-based risk assessment. Behavioral risk stratification would allow a more comprehensive assessment of individual risk, better maintain the safety of the nation’s blood supply, and remove

the stigma associated with evaluating risk based on identity. Under the current policy, MSM at lower risk for HIV infection—such as those in a monogamous relationship and practicing safer sex—would be excluded from blood donation, whereas a heterosexual person at higher risk for HIV-infection (e.g., someone having unprotected sex with multiple partners) would be permitted to donate blood. To address this discordance, blood donors in countries such as Spain and Italy are asked if their sexual partner is new, casual, or if the donor has multiple partners.<sup>vii</sup> Applying such an assessment would appropriately categorize MSM in a monogamous relationship as “low risk.”<sup>viii</sup> Research supports a behavioral risk-based stratification approach, which may consider sexual activity and knowledge of partner status.<sup>ix</sup>

## 2) Follow the Latest Biomedical Science to Screen Blood Donations for Blood-borne Pathogens.

### APPROVAL DATES:

Infectious Disease Policy Committee Approval: November 7, 2022

Board of Directors Approval: December 4, 2022

Policy Expires: December 31, 2025

*ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.*

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<sup>i</sup> McAdam C, Parker L. “An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm.” *DePaul J Health Care L.* 2014. Available at:

<https://via.library.depaul.edu/cgi/viewcontent.cgi?article=1006&context=jhcl>. Accessed 9-2-2022.

<sup>ii</sup> FDA. “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.” Available at: <https://www.fda.gov/media/92490/download>. Accessed 9-2-2022.

<sup>iii</sup> Grebe E, Busch MP, Notari EP, Bruhn R, Quiner C, et al. “HIV Incidence in US First-Time Blood Donors and Transfusion Risk with a 12-Month Deferral For Men who Have Sex with Men.” *Blood.* 2020. 136(11):1359-1367. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7483431/>. Accessed 9-2-2022.

<sup>iv</sup> FDA. “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.” Available at: <https://www.fda.gov/media/92490/download>. Accessed 9-2-2022.

<sup>v</sup> CDC. “HIV: Types of Tests.” Available at : <https://www.cdc.gov/hiv/basics/hiv-testing/test-types.html>. Accessed 9-2-2022.

<sup>vi</sup> CDC. “HIV Transmission Through Transfusion - - - Missouri and Colorado, 2008.” Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5941a3.htm#fig1>. Accessed 11-1-2022.

<sup>vii</sup> Goldman M. “International Perspectives on Blood Donor Eligibility, Men who have Sex with Men (MSM).” BPAC Meeting Maryland, March 2019. Available at: <https://www.fda.gov/media/128428/download>. Accessed 9-2-2022

<sup>viii</sup> Karamitros G, Kitsos K, Karamitrou I. “The Ban on Blood Donation on Men who Have Sex with Men: Time to Rethink and Reassess an Outdated Policy.” Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5554671/>. Accessed 9-2-2022.

<sup>ix</sup> Park C, Gellman C, O’Brien M, Eidelberg A, Subudhi I, et. Al. “Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have Sex With Men.” *Am J Public Health.* 2021. 111(2):247-252. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7811078/>. Accessed 9-2-2022.