AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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Leslie Kux, JD
Associate Commissioner for Policy
U.S. Food and Drug Administration
White Oak Building 32, Room 4232
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments

Dear Associate Commissioner Kux:

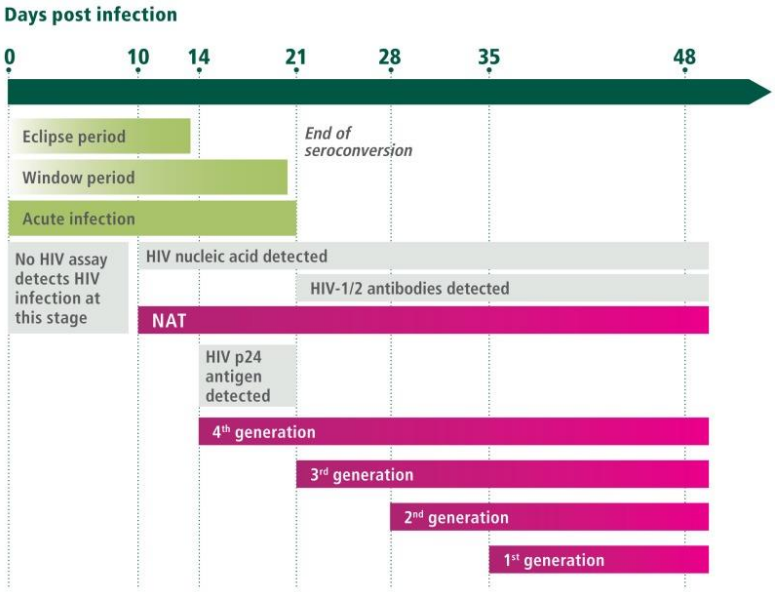
On behalf of the physician and medical student members of the American Medical Association (AMA), I commend the Food and Drug Administration (FDA) for opening a public docket for comment on the FDA's blood donor deferral recommendations for reducing the risk of human immunodeficiency virus (HIV) transmission. Ensuring the safety of the nation's blood supply and the welfare of patients who receive blood products is of the utmost importance. Advances in HIV screening technology, however, allow for a re-evaluation of current policy. The AMA urges the FDA to support the use of rational, scientifically-based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their individual risk, and supports research into Individual Risk Assessment (IRA) criteria for blood donation.

Current blood deferral policies violate the ethical principle of formal equality, i.e., the notion that like cases should be treated alike and different cases treated differently. In part, they do not reflect the contemporary realities of HIV/Acquired Immune Deficiency Syndrome (AIDS), but rather the state of knowledge in the early years of the epidemic, before the disease was well characterized epidemiologically and, importantly, before the advent of the highly sensitive and specific methods now used to test all units of donated blood.[i]

HIV Testing Technology

Reduction in the risk of HIV transmission from blood transfusion has been attributed to the use of donor educational materials, specific deferral questions, and significant advances in HIV donor testing (e.g., HIV antibody assays, p24 antigen assays, and nucleic acid tests (NAT)).[ii] Minipool NAT testing was introduced in 1999 reducing the detection window for HIV to 11 days. From 1999-2008, of the 66 million blood donations tested there were 32 positive HIV NATs, with an incidence of 1 in 2,060,000.[iii]

Figure 1: Detecting HIV-infection with various formats and generations of in vitro diagnostics over the natural history of infection[iv]



By comparison, the window period between infection and detection for hepatitis C (HCV) is approximately four weeks, and most tests are more accurate at six to nine weeks; the shortest window period between infection and detection for syphilis is one to two weeks, with detection more likely after six weeks. When donated blood can be tested directly, risk behaviors are not relevant—each infected donor poses the same detectable risk outside the "window period" for transmission of the given disease.[v] Current American Association of Blood Banks (AABB) policy mandates screening of all donated units by nucleic acid testing, which can identify infected units within 11 days of transmission of HIV.[vi]

Individual Risk-Based Deferral

The FDA's 2015 guidance that changed U.S. policy from a lifetime blood donor deferral period for men who have had sex with men (MSM) to a one-year deferral period marks an important step forward in blood policy, and was supported by the AMA. However, the current deferral process still relies on categories rather than assessing an individual's risk for HIV infection and potential transmission through blood donation. With advances in testing technology, the AMA supports deferral periods that are fairly and consistently applied to donors according to their individual risk.[vii] The 2015 FDA recommendations excluded individual risk-based options at that time for several reasons: [viii]

- Difficulty with pretesting logistics (e.g., using trained medical professionals would be beyond current blood donor system resources);
- Initial available epidemiologic data did not support the concept that MSM who report mutual monogamy with a partner or who report routine use of safe sex practices are at low risk for HIV; the rate of partner infidelity in ostensibly monogamous heterosexual couples and same-sex male couples is estimated to be about 25 percent, and condom use is associated with a 1 to 2 percent failure rate per episode of anal intercourse; [ix,x]

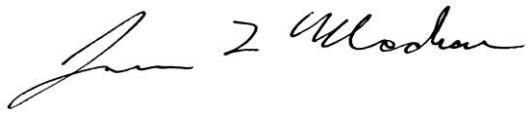
- The prevalence of HIV infection is significantly higher in MSM with multiple male partners compared with individuals who have only multiple opposite sex partners.

The prevalence of HIV infection in male blood donors who reported that they were MSM is 0.25 percent, significantly lower than the estimated HIV prevalence 11-12 percent in the general MSM population.[xi] A proposed method of "assessing and testing" could more accurately identify individuals at risk of HIV infection and potential transmission rather than relying on blanket categories.[xii] Using an "assess and test" method, an individual assessed to be high-risk, such as individuals who have engaged in frequent, unprotected sex with multiple partners since their prior HIV test, could have a short deferral period of abstinence to allow for reliable test results. For donors who are not high risk, the deferral could be eliminated altogether. This model could be applied to any donor regardless of sexual orientation or sexual practice/behavior and would not consider monogamous or safe sex to be risky, mirroring the current protocol for heterosexual/straight donors.

Ensuring the safety of the blood supply is of paramount importance. The AMA welcomes the opportunity to engage with the FDA in the agency's ongoing efforts to achieve that goal through a comprehensive approach that takes advantage of emerging technologies and embodies the core principles of strong ethical policy for public health.

Thank you for considering our comments. If you have any questions, please contact Shannon Curtis, Assistant Director, Federal Affairs, at shannon.curtis@ama-assn.org or at (202) 789-8510.

Sincerely,



James L. Madara, MD

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[vii] AMA, Blood Donor Deferral Criteria Revisions, Resolution 008-I-16, adopted at the AMA 2016 Interim Meeting.
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