Blood Drives United

Summary on MSM Blood Donation Policy – 11/3/13

Blood Drives United (BDU), the University of Michigan organization working to increase awareness of the need for blood donation, firmly believes that the Food and Drug Administration’s (FDA) policy banning men who have sex with men (MSM) from donating blood is in need of a change. Current blood donation policies prevent a number of low-risk individuals from donating blood while allowing a number of higher-risk individuals to donate.

A particular question in the health history questionnaire that all donors complete permanently defers any potential male donor who has had sexual contact with another male since 1977. While the intention is to identify risky behavior, the reality is that the question is discriminatory and inadequate. The MSM population has been linked to higher prevalence of certain diseases; however, the current questionnaire fails to address the underlying risky behaviors, including unprotected sex and having multiple sexual partners, which are modes of transmission of these diseases. This proposed change seeks to allow the inclusion of newly eligible, safe donor populations while at the same time reinforcing the safety of the blood supply via the alteration of the question to, “Have you had unprotected sexual contact with a new sexual partner in the past 12 weeks?” An affirmative answer would result in a scientifically reasoned twelve week deferral, based on the window period where an HIV-afflicted individual can transmit HIV without testing positive for the virus. However, this deferral could be extended to a maximum of one year for consistency with other behaviorally-based deferral periods. This proposed question eliminates any discrimination against sexual orientation, while strengthening restrictions on risky behaviors that presently go overlooked.

With the advent of existing, improved biological testing alongside the implementation of rationally-based questions, policy change can help save lives, secure the safety of the blood supply, and create greater equality amongst donors. Regardless of sexual orientation, an individual should be allowed to donate blood if they otherwise pass all of the FDA’s eligibility requirements, including but not limited to a disease-free status.
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Statement on MSM Blood Donation Policy – 11/3/13

Appeals from blood collection agencies to reverse nationwide blood supply shortages have brought increasing attention to the existing bans on certain individuals that prevents them from donating blood in the United States. The Food and Drug Administration (FDA), which oversees blood donation regulations in the United States, currently imposes a lifetime deferral from donating blood on men who have had sexual contact with other men (MSM) since 1977. ¹ This policy has recently received media attention due to the efforts of a mayor in Campbell, California. Mayor Evan Low identifies as a gay male and is thus ineligible to donate blood, but has decided to help sponsor blood drives as a public health measure while also promoting a change to the FDA’s policy.² The FDA’s advisory committee has acknowledged that the current screening policy is "suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations."³

In June 2012, a group of U.S. Congressmen, including Representative Mike Quigley and Senator John Kerry, authored a letter to the Department of Health and Human Services (HHS) that pressed them to take action to reconsider the ban, naming the perpetuation of bias against the LGBT community and the security of the nation’s blood supply.⁴ A question posed to male donors is, “From 1977 to present, have you had sexual contact with another male, even once?”⁵ An affirmative answer results in a permanent lifetime deferral. HHS convened a body of experts, the Advisory Committee on Blood Safety and Availability (ACBSA), which reviewed the ban

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⁴ [“Full Length Donor History Questionnaire.”](https://www.aabb.org/resources/donation/questionnaires/Documents/dhq/v1-3/Full-LengthDonorHistoryQuestionnairev1.3.pdf)
⁵ [BloodDrivesUnited@umich.edu](mailto:BloodDrivesUnited@umich.edu)
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and recommended that it be kept in place due to inadequate scientific data supporting change.\(^6\) However, the ACBSA also concluded that the ban was “suboptimal,” recommending that further evaluation and feasibility studies be completed.\(^6\)

The American Red Cross (ARC), American Association of Blood Banks (AABB), and America’s Blood Centers (ABC) have reviewed the policy in light of new scientific evidence and concluded that the lifetime deferral of MSM is “medically and scientifically unwarranted.”\(^7\) They support a change of the current policy that would reduce the deferral period to one year, harmonizing with the deferral period for other high-risk sexual behaviors. The American Medical Association has additionally opposed the lifetime ban on blood donation, concluding that existing data and models support a change to a reduced deferral policy.\(^8\) The official policy of the American Red Cross is stated as follows:

“The FDA is responsible for determining donor eligibility requirements and the Red Cross is required to follow their decisions. However, the Red Cross does support the use of rational, scientifically-based deferral periods that are applied fairly and consistently among donors who engage in similar risk activities. We will continue to work through the AABB to press for donor deferral policies that are fair and consistent and based on scientific evidence, while still protecting patients from potential harm.”\(^9\)

Blood Drives United (BDU), a student organization at the University of Michigan responsible for planning and executing blood drives on campus through the American Red Cross, endeavors to evoke a change in the present blood donation policy.


\(^9\) [http://www.redcrossblood.org/donating-blood/eligibility-requirements/eligibility-criteria-topic#stds](http://www.redcrossblood.org/donating-blood/eligibility-requirements/eligibility-criteria-topic#stds)

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BDU proposes to implement a change in the pre-donation questionnaire that replaces the current question concerning potential risky behavior with, “**Have you had unprotected sexual contact with a new sexual partner in the past 12 weeks?**” An affirmative answer would result in a scientifically reasoned twelve week deferral, based on the HIV window period where an HIV-afflicted individual can transmit the disease without testing positive for the virus. However, this deferral could be extended to a maximum of one year for consistency with other behaviorally-based deferral periods. This change is intended to secure the safety of the blood supply by identifying risky behavior in all populations.

Blood testing for blood borne pathogens has and continues to improve, reducing the risk of disease contraction via blood transfusion. For bloodborne pathogens, relevant testing includes West Nile Virus, syphilis, human immunodeficiency virus (HIV), and the bloodborne hepatitis B and C viruses (HBV and HCV).\(^1\),\(^10\),\(^11\),\(^12\) A window period exists immediately after infection and lasts in individuals with normal immune responses 2 to 12 weeks for HIV, up to 8 weeks for HCV, and 10 weeks for HBV.\(^13\),\(^14\),\(^15\) Due to the increased effectiveness of testing, the risk of contracting HIV from a transfused unit of blood has been reduced to about one case per 2 million transfusions in the United States, almost exclusively from so called "window period" donations.\(^16\) This rate will likely continue to drop with the implementation of new diagnostic tests, such as nucleic acid testing, which are more sensitive than current antibody tests and are

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\(^1\) [http://www.redcrossblood.org/donating-blood/donation-faqs](http://www.redcrossblood.org/donating-blood/donation-faqs)
\(^10\) [http://hivtest.gov/faq.aspx#exposure](http://hivtest.gov/faq.aspx#exposure)
\(^12\) [http://hivtest.cdc.gov/faq.aspx#exposure](http://hivtest.cdc.gov/faq.aspx#exposure)
\(^14\) Chu CM, Liaw YF, Pao CC, Huang MJ. The etiology of acute hepatitis superimposed upon previously unrecognized asymptomatic HBsAg carriers. (1989) Hepatology. 9:452.
\(^15\) [http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm](http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm)
\(^16\) [BloodDrivesUnited@umich.edu](mailto:BloodDrivesUnited@umich.edu)
able to identify the presence of pathogens in lesser amounts of time following exposure.\textsuperscript{17,18} Nucleic acid testing has been reported to be capable of shortening the undetectable window period to 9 days for HIV, 7.4 days for HCV, and 30-38 days for HBV, each of which is within a one year deferral period.\textsuperscript{19} Despite the increased effectiveness of blood testing for blood borne pathogens, the window period risk remains. The purpose of the time frame suggested in the proposed question is to reduce the possibility of false negative test results to a greater extent than is presently addressed in the pre-health screening. If the dates of the behavior under consideration occur outside of the defined window period length, then transfusion transmission risk is greatly reduced due to the increased likelihood of detection.

Up-front screening through the health history questionnaire is thought to eliminate approximately 90 percent of unsuitable donors.\textsuperscript{20} The current questionnaire includes a number of questions relating to donor behavior, including questions dealing with behavior such as intravenous needle use, sexual contact involving money exchange, and travel outside of the United States and Canada.\textsuperscript{21} In this situation, a heterosexual individual, for example, who has multiple sexual partners and does not practice safe sex could be allowed to donate blood despite an increased risk for disease transmission.

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No donor eligibility questions have been shown to reliably identify a subset of MSM (e.g., based on monogamy or safe sexual practices) who do not still have a substantially increased rate of HIV infection compared to the general population or currently accepted blood donors. In the future, improved questionnaires may
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\textsuperscript{17} http://hivtest.cdc.gov/faq.aspx#exposure  
\textsuperscript{20} http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/  
There are presently no questions that address a number of risky behaviors including unprotected sexual contact and sexual contact with new partners, a concern that was raised during the ACBSA’s deliberations on changing the policy. This proposed change would take this into account.

The FDA’s policy on MSM is based on the documented increased risk of certain transfusion-transmissible infections, including HIV and hepatitis, associated with male-to-male sexual contact. The FDA states that the deferral policy “is not based on any judgment concerning the donor's sexual orientation.” According to statistics gathered by the FDA, men who have had sex with men since 1977 have an HIV prevalence 60 times higher than the general population. Even taking into account that 75% of HIV infected men who have sex with men already know they are HIV positive and would be unlikely to donate blood, the HIV prevalence in potential donors with a history of male to male sexual contact is 200 times higher than first time blood donors and 2000 times higher than repeat blood donors. According to the 2010 version of the Centers for Disease Control HIV Surveillance Report, 28,782 out of 46,913 (61.35%) new HIV infections diagnosed in 2010 were determined to have resulted from male-to-male sexual contact. The current policy is not an arbitrary one, as it seems to reflect a correlation between sexual orientation and a higher risk of transmission of certain diseases. However, this is not the case because the underlying risky behaviors, not sexual orientation, are the primary mode of transmission of HIV.

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22 [http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm](http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm)
24 [http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm](http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm)
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“Blood services commonly argue that exclusion of MSM relates to a behaviour rather than orientation. This might technically be correct but undeniably MSM is an important component of the lifestyle of gay men and hence exclusion will likely be considered indirect discrimination.”

Regardless of sexual orientation, an individual should be allowed to donate blood if they otherwise pass all of the FDA’s eligibility requirements, including but not limited to a disease-free status.

An increasing number of countries have modified their restrictions on MSM donation. The Chinese Ministry of Health lifted a ban on lesbian blood donation that also allowed celibate gay men to donate, Canada has adopted a five-year deferral following sexual contact, and the United Kingdom, Sweden, Japan, and Australia have adopted one-year deferrals following sexual contact to align with deferrals for other risky behaviors.

Blood donors can and should be assessed as individuals, especially in the context of this proposed policy change. Using a constructed model and situations with equal compliance participation, a study in the United Kingdom found that a shorter deferral period resulted in only marginally greater (0.228 cases/million donations vs. 0.227 cases/million donations) HIV transmission risks than using a lifetime exclusion period for MSM. Additionally, the Italian government changed its donor eligibility criteria from a permanent MSM deferral to individual risk assessments of all donors and has found that there was no statistically significant increase in the proportion of HIV-seropositive MSM.

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27 http://www.chinadaily.com.cn/china/2013-07/01/content_16700941.htm
31 Suligoi et al. “Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy.” Blood Transfusion. 2013 Jul;11(3):441-8
A 2010 study by the Williams Institute at the University of California-Los Angeles estimated that if gay men who had not had sexual contact for the past 12 months were allowed to donate blood, more than 53,000 additional men would likely make more than 89,000 blood donations annually. That number may seem small, but blood banks say it could help enormously, especially now, when blood supply shortages are common. This proposed change seeks to supplement the number of eligible donors and reinforce the safety of the blood supply. A fundamental issue of the current policy is orientation, while the real focus should be on sexual behavior. The goals of this petition are to generate the potential to save a greater number of lives, secure the safety of the blood supply, and create equality amongst donors. The discrimination against the MSM population during the blood donation process is a social injustice that can be addressed in safe, effective ways.

You can contact the authors of this petition, Sara Fritz, Chelsea Fournier, Betsy Gast, Samantha Rea, Kevin Weiss, at blooddrivesunited@umich.edu if you have any comments, questions, or suggestions.

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