



Ban the Ban: A scientific and cultural analysis of the FDA's ban on blood donations from men who have sex with men

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Abstract

In recent years, the Lesbian Gay Bisexual Transsexual Queer (LGBTQ) community has experienced a number of triumphs. From the end of the military's "Don't Ask, Don't Tell" policy to the repeal of the Defense of Marriage Act, the political and social landscape in the United States is becoming more inclusive of homosexuality.¹ While there still remain many discriminatory practices, a particularly egregious one is the U.S. Food and Drug Administration's (FDA) ban on blood donations by men who have sex with men. In addition to being societally regressive, this policy frustrates efforts to overcome the nation's blood shortage. In May 2015, the FDA released a draft guidance document suggesting a shift from the existing lifetime ban to a twelve-month deferral period. While this is a progressive step in the right direction, the new regulation would require donors to remain celibate for twelve months prior to donation, which maintains the categorical association between gay sex, risky sex, and HIV. This updated policy is as discriminatory as the lifetime ban and will not significantly increase the number of eligible donors. A shift away from a categorical and unnecessary ban towards a systematic and scientifically based series of tests and screenings that focus on indicators of risky sex would grow America's pool of blood donors without increasing the risk of transfusion-related transmission of HIV. Support within the academic community and populations unaffected by the ban would be effective strategies to challenge and ultimately demand the ban's complete removal.

Origins of a discriminatory policy

The FDA implemented its lifetime ban policy in 1983 as a response to the HIV/AIDS epidemic. During a time of crisis, it was intended to exclude populations considered to be at high risk: men who have sex with men (MSM), women who have sex with MSM, and transgender people who were categorized as MSM. What began as an emergency measure became an entrenched policy, despite advances in HIV prevention and detection and an increased awareness of HIV risks within these target populations.

Today, the policy covers MSM and transsexuals who have had sex with a man since 1977, as well as any women who have had sex with MSM since then. This includes individuals in committed and monogamous relationships, those who always use condoms, and those who have practiced abstinence for decades; the ban applies regardless of HIV-negative test results. The FDA's policy is categorical and directly discriminates on the basis of sexual orientation.²

Under the eligibility requirements for blood donations, the MSM ban is based on "Lifestyle and Life Event" criteria. There are a number of other FDA

justifications for ineligibility, such as travel to certain countries during an outbreak of an infectious disease, receiving an animal organ transplant, or contracting hepatitis. The only other lifestyle ban-for-life is intravenous, non-prescription drug use.³ MSM who practice safe sex in consensual and monogamous relationships are considered as high risk for HIV transmission as intravenous drug users, while heterosexual donors who engage in un-protected sex with multiple partners are not. Currently, a straight man who has sex with a prostitute is only deferred for twelve months, while a gay man who engages in healthy, monogamous sex is banned for life.⁴ Under the FDA's proposed policy change, MSM who remain celibate for twelve months may be eligible to donate. Although a step in the right direction, this proposal is still based in bias and ideology, conflating gay and risky sex, rather than focusing exclusively on transmission risk factors: men in monogamous same-sex relationships who test HIV-negative are unnecessarily barred from donating by the FDA's current methods.

Numbers behind the ban

The latest surveillance data from the US Centers for Disease Control indicate that the majority of new HIV infections occur in MSM. In 2010, MSM accounted for 78% of new infections among American men, and 63% overall.⁵

Still, significant advancements have been made in HIV testing since its advent in 1985. Third and fourth generation tests can detect HIV antibodies within three to four weeks of infection, compared with older HIV tests for which the window period was as great as three months.^{6,7} RNA tests now detect the virus directly rather than through antibodies, further narrowing the window period to less than ten days.⁸ These improved testing capabilities can mitigate the risk of viral transmission despite high infection rates among MSM, as every single blood donation is currently screened for HIV. MSM who have been

recently tested can more confidently claim an HIV-negative status, which poses no donor risk.



Artwork by Steven Li

In its appeal to donors, the American Red Cross, which supplies approximately 40% of the nation's blood, stresses that "an urgent need for blood and platelets" exists, especially since it received 80,000 fewer donations than expected during the summer of 2014.^{9,10} While 38% of the population is eligible to donate blood, only 10% does.¹¹ There is a clear need to increase the donor pool. In a 2010 study conducted by the Williams Institute at UCLA School of Law, the number of banned donors was calculated to be 2,603,004.¹² Were the ban lifted, it would result in an estimated 130,150 additional donors and 219,200 additional pints of blood.¹³

Due to the number of potential donors that are unjustly turned away, the existence of adequate screening protocols, and the desire for increased donations within the medical community, the current restrictions are unconscionable.¹⁴ Given the importance of blood donations and the ability to more effectively screen and test for HIV infections, a serious question should be posed to the FDA and the scientific community: is it necessary to categorically ban MSM from donating blood?

This is a civil rights and public health issue

In addition to a medical or scientific perspective, the FDA's MSM policy can be viewed through a civil rights lens: this is a highly discriminatory policy that exacerbates the stigmas associated with homosexuality. In the 1980s, the FDA banned all Haitian-Americans who had arrived in the country after 1977 from donating blood. The agency's rationale was similar to that of the MSM ban: Haiti had a high rate of HIV infections and the United States government hoped to protect the blood supply. The ban was met with huge opposition and was eventually removed in 1990.¹⁵

The FDA agreed to a heightened testing protocol whereby Haitian-American donors would be tested prior to donating, asked modified screening questions, and afterwards have their blood donation tested in the usual manner. One of the ban's opposition leaders, Dr. Alix Mathieu, remarked that, "this disease is not one of races or nationalities...it is one of risky behavior."¹⁶ This logic equally applies to MSM. The Supreme Court of the United States has increasingly used equal protection grounds to impose a higher level of scrutiny on laws that subject LGBTQ people to discrimination.¹⁷ The FDA has not been able to demonstrate that the ban is rational, necessary, or proportionate given the existence of less discriminatory approaches.

Currently, blood drives leave MSM with two options: do not donate (as they currently are instructed), or donate and lie about their sexual history (which undermines the notion of "coming out"). Both options are problematic and promote unhealthy medical practices. To enforce a culture in which willing individuals may not donate plasma, platelets, or other blood products ultimately harms the patients that blood centers and healthcare providers exist to serve. To incentivize individuals to lie about their sexual behavior for the purposes of donating threatens the great progress that LGBTQ movements have made in recent years. It sends a message to gay men that they are still "other" and that at least some part of them is unwelcome. As marriage equality continues to be constitutionally upheld across the United States, it is archaic that gay men and those with whom they have had sexual intercourse may not participate in the simple but powerful act of donating blood.¹⁸

The current state of the FDA ban

Although the FDA Advisory Committee on Blood Safety and Availability reaffirmed the lifetime ban in its December 2013 meeting, the MSM policy went under review again in December 2014.¹⁹ The committee debated a reduction from a lifetime ban to a one-year deferral for men who have had sex with men within twelve months of attempting to donate, although it ultimately voted against the shift.

In response to the advisory committee's decision, 80 members of congress sent a letter to the Department of Health and Human Services (HHS), of which the FDA is an agency, criticizing a categorical approach and urging the department to adopt a risk-based policy. The letter concludes by calling on HHS to implement an improved policy by the end of 2014.²⁰

By the end of 2014, the FDA announced it would change its MSM policy to a one-year deferral for men who have had sexual intercourse with other men within the past twelve months. AABB (formerly the

American Association of Blood Banks), America's Blood Centers, and the American Red Cross jointly supported such a shift, noting that the lifetime ban is medically and scientifically unwarranted.²¹

In May 2015, the FDA released a draft guidance document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products." The document elaborates on the agency's 2014 commitment but does little to overcome its historic treatment of gay sex as inherently risky sex. In the document, the FDA proposes improved Donor History Questionnaire questions to screen out ineligible donors. The list begins with donors who have tested HIV-positive, who have engaged in commercial sex, and who have engaged in non-prescription injection drug use; all of these categories would be banned for life. A male donor who has had sex with another man within twelve months appears at the end of the list, just after donors who have been treated for syphilis or gonorrhea and those who have received a tattoo or piercing from an unlicensed shop; all of these categories, including MSM, would receive a twelve month deferral under the proposed policy.²²

The guidance document notes that the male donors who report that they are MSM have a lower prevalence of HIV infection than the general MSM population (.25% as opposed to 11-12%); the FDA concedes this suggests "considerable" self-selection by MSM individuals who choose to donate.²³ Despite this evidence that the high rate of HIV among the general MSM population does not necessarily translate to a high rate of HIV among MSM donors, the FDA's twelve-month deferral does not allow for such self-selection, instead continuing the categorical association between gay sex and risky sex.

While some groups claim the proposed shift as a victory or a step in the right direction, any progress that it represents is superficial. The one-year proposal is unnecessarily long given that most effective testing

can be performed within four weeks. More importantly, it does nothing to correct the underlying stigma and misguided beliefs about gay sex that the current ban maintains. This shift excludes an entire population of men who could donate and advance what should be the agency's goal: to safely increase the nation's donor pool.

Under the proposed reform, a man who has frequent, protected, and monogamous sex, and who is regularly tested, would still be ineligible to donate. The new policy would require twelve months of complete sexual abstinence in order to donate, which suggests that any gay sex is risky sex. It fails to screen individual MSM donors for any behavior that may make them high risk for HIV, opting instead for the same categorical ban.

The draft guidance document allows for 60 days of public comments, after which the FDA will develop and release final rules on the matter.

Alternatives to the ban

In lieu of a permanent and categorical ban or the proposed deferral, the FDA should shift to an "Assess and Test" screening system. After assessing the donor's personal sexual practices, a deferral may be given only for those in whom a risk of infection has been identified, such as individuals who have engaged in frequent, unprotected sex with multiple partners since their prior HIV test. For this risky group, a short period of abstinence may be appropriate to allow for reliable test results. For donors who are not high risk, the deferral should be eliminated altogether.

This model can be applied to both homosexual and heterosexual donors and would not consider monogamous or safe sex to be risky, mirroring the current protocol for straight donors.

As has been the standard since 1985, all blood is tested for HIV after donation, so these initial screening

questions serve as only the first step in an Assess and Test approach.²⁴ Under current testing protocol, the risk of transfusion-transmission of HIV is one in two million.²⁵

The United States is not alone in its treatment of MSM. South Africa uses a six-month deferral period, while the UK, Australia, and Sweden defer for twelve months. Canada and New Zealand defer MSM for five years.²⁶ As with the FDA's stipulations, these policies require celibacy during the deferral period, maintaining illusory associations between HIV and gay sex, rather than between HIV and risky sex. Italy, however, has adopted an Assess and Test model that uses "risk behavior" screening questions and blood testing, which it applies to all donors, regardless of sexual orientation.²⁷ It defers individuals who are flagged by screening, not by lifestyle. Italy has not experienced an increase in infected donations since implementing this policy.²⁸

This approach can identify individuals, rather than categories, who may present a risk to the blood supply. AABB, America's Blood Centers, and the American Red Cross have advocated for the adoption of similarly comprehensive approaches.²⁹ Unlike the ban on MSM donors or the new deferral, the Assess and Test approach uses rational and scientifically based deferral periods, applied fairly, to maximize the donor pool and minimize risk.³⁰

Support is essential to ending the ban

There must be greater awareness among the unaffected population in order to end this discriminatory policy. To achieve this end, blood donation organizers should adopt the following practices:

1. Explain the FDA policies in any marketing material that advertises an upcoming blood drive;

2. Dedicate a page on their website to educate visitors about the policies; Inform each blood donor of the FDA policies at the time of donation;
3. Direct donors and the general public to the Change.org³¹ petition to repeal the policies and to call on their elected officials to demand improved policies by the FDA;
4. Educate their board of directors, or equivalent governing bodies, about the FDA policies; and
5. In each of the above actions, advocate that simply shifting to a categorical deferral policy does little to address the ban's discriminatory underpinnings.

Generating greater public support and drawing attention to the FDA's inadequate justification of its policies are meaningful actions.

Institutions of higher education across America are another important battleground for this issue. For many students, college is an opportunity for personal and sexual exploration and identification. This can be especially true for young, gay men who were not raised in accepting environments or who are in the process of coming out. To simultaneously receive overt messages from the FDA that a homosexual lifestyle is somehow perverse can create serious emotional and psychological confusion. On the other hand, campuses are centers of political and social activism where discriminatory practices, once acknowledged, can be addressed. Organized protests against such policies can provide reassurance for those affected. Protests against the treatment of sexual violence on college campuses, for example, have both made national headlines and received presidential attention. Current awareness-raising activities against the ban include distribution of information at blood drives and the organization of drives where ally surrogates can donate in the place of banned individuals.

Opposition to the FDA's MSM policy should not be interpreted as opposition to blood donation itself,

which is vital and should be encouraged. It is important, however, to demonstrate that donations are being made in spite of these policies, and that more donors would participate if all policies barring MSM donations were lifted.

Colleges and universities house the next generation of American leaders and can play a strong role in shaping their social perspectives. Campuses are specific, controllable environments in which a strong,

deliberate movement against the FDA policies could take root. Universities are also home to that nation's leading medical researchers, whose expert voices carry greater with the FDA and policymakers in general. Increased awareness of and organization around the FDA's policy would yield immediate positive health effects for affected populations in the form of social equity and support, as well as long-term benefits to society at large by increasing the donor pool and access to blood for those who need it.

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Conflicts of Interest

This author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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