

An Evaluation of Policy Restrictions on LGBTQ Blood Donations

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ABSTRACT

This research project evaluates the blood donation restrictions in place for men who identify as LGBTQ. LGBTQ men cannot donate blood for three months after their last sexual encounter. With the severe shortage of blood resulting from the drop in donations during the COVID-19 pandemic, the male LGBTQ community represents a sizable population of potential donors that can help alleviate the scarcity of blood. Research has shown that a deferral period for the group as a whole is no longer necessary if LGBTQ donors are assessed for individual risk factors. The U.K. has eliminated policies that restrict LGBTQ donors by introducing individual risk assessments for all donors. The three-month deferral period in the U.S. does more harm than good by placing difficult restrictions on an entire population and it is discriminatory. In this paper, I argue that the current policy in place for LGBTQ donors is no longer necessary and that the U.S. should adopt individual risk assessment procedures like the U.K. has done.

INTRODUCTION

Restrictions in Place

Under the U.S. Food and Drug Administration's (FDA) revised blood donation guidelines, men who have sex with men (MSM) are unable to donate blood until three months after their last sexual encounter ("Revised Recommendations," 2020). This means that all MSM *must abstain* from having any sexual intercourse for at least three months prior to the date of blood donation. The restriction is designed to reduce the risk of transmitting any bloodborne disease through the blood donation.

According to the Centers for Disease Control and Prevention (CDC), "if a person has a negative HIV result and has not had any possible exposure during the past three months, they [the donor] can be confident that they do not have HIV" (Arquilla & Morales-Brown, 2021). Infections and diseases can pass through screenings undetected, and so the three-month deferral is in place to allow for adequate time for any infections to develop, and thus better detection in blood screenings before the blood is processed and stored away.

Who Oversees Those Restrictions?

The Center of Biologics Evaluation and Research (CBER) within the FDA "regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act" (FDA.gov). CBER oversees all blood components which includes transfusions, plasma, platelets, and all blood products. CBER oversees the blood donation restriction policy because it involves the products of blood and the use of it for transfusions. The American Red Cross which operates under the FDA follows the policies and procedures established by the FDA when obtaining blood donations.

Purpose of Research

The purpose of this research is to evaluate the existing policy for LGBTQ blood donations and to reevaluate existing research to determine if the policy in place is necessary. Restrictions on MSM donations were, at most, understandable when they were implemented. HIV/AIDS back in the 1980s was barely known. Scientists and doctors were still trying to figure out the disease and how it progressed through the human body and if there was any way to cure the disease. The medical technology back then was also subpar to what we have today. Medical testing and screening are not the same as it was back then. With the advancement in technology, blood testing and screening has become advanced enough that bloodborne diseases are easily detected.

All donated blood goes through the same screening process before it is stored away in blood banks. Because of the technology that exists today, the restriction in place for MSM is no longer necessary. Since all blood is screened, the policy is moot. The only thing restrictive policies do now is restrict possible donors from donating lifesaving

blood. Blood banks are only allowed to keep donations that test negative. Any blood that goes through initial testing and is detected for any bloodborne disease is removed and discarded. The donor of the blood that has tested positive for any disease will be notified within a few weeks of initial donation (thebody.com). The FDA keeps a detailed record of all donors who can and cannot donate blood. This record is to check if donors have any record of blood donations or any possible history with disease (FDA.gov). These records, however, do not guarantee that past donors can donate again.

So, since all blood is tested, no matter how many times you have donated before, or any diseases you have had in the past, all blood is still routinely screened. So, why does this policy restriction for LGBTQ donors still exist? All it does is restrict suitable donors. The goal of this research is to evaluate existing policies, the history of restrictions on LGBTQ donors, and assess the current state of the science. The research supports the argument that screening donors on the basis of individual factors, such as whether MSM are in monogamous relationships or not, is safe and a way to end policies that restrict blood donations from individuals based on who they are.

POLICY EVALUATION

Who is Included in the Restriction?

The policy that the FDA has implemented regarding LGBTQ blood donations is a 3-month deferral period from the last occurrence of sexual intercourse. This deferral period includes gay and bisexual men, and women who have had sex with bisexual men. The FDA has a Donor History Questionnaire (DHQ) to help assess donor risks. The following questions come directly from the FDA's website in a document from April 2020 (revised August 2020) titled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Product":

- A. A history ever of a positive test for HIV,
- B. A History in the past 3 months of exchanging sex for money or drugs,
- C. A history in the past 3 months of non-prescription injection drug use,
- D. A history in the past 3 months of sex with any of the following individuals: a person with a history of a positive test for HIV, a person with a history in the past 3 months of exchanging sex for money or drugs, or a person with a history in the past 3 months of non-prescription injection drug use,
- E. A history in the past 3 months of receiving a transfusion of Whole Blood or blood components such as packed red blood cells, platelets, or plasma,
- F. A history in the past 3 months of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes,
- G. A history in the past 3 months of a tattoo, ear or body piercing,
- H. A history in the past 3 months of syphilis or gonorrhea, or treatment for syphilis or gonorrhea,
- I. For male donors: a history in the past 3 months of sex with another man,
- J. For female donors: a history in the past 3 months of sex with a man who has had sex with another man in the past 3 months.

For each possible donor, these assessments are done to ensure the lowest chance of possible transmission of bloodborne diseases and pathogens. If a donor is considered high risk, the Donor Deferral section in the same FDA document lists the criteria for medical professionals to follow if a donor is to be deferred. The newly revised guidelines lowered deferrals for MSM from 12 to 3 months. The full list of deferrals is as followed:

1. Defer indefinitely an individual who has ever had a positive test for HIV.
2. Defer for 3 months from the most recent event, an individual who has exchanged sex for money or drugs.
3. Defer for 3 months from the most recent event, an individual who has engaged in non-prescription injection drug use.
4. Defer for 3 months from the most recent sexual contact, an individual who has had sex with a person who has ever had a positive test for HIV.
5. Defer for 3 months from the most recent sexual contact, an individual who has had sex with an individual who has exchanged sex for money or drugs in the past 3 months. If the individual has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.

6. Defer for 3 months from the most recent sexual contact, an individual who has had sex with an individual who has engaged in non-prescription injection drug use in the past 3 months. If the individual has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.
7. Defer for 3 months from the most recent allogeneic transfusion, any individual who has a history of receiving an allogeneic transfusion of Whole Blood or blood components.
8. Defer for 3 months from the most recent exposure, any individual who has a history of contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or mucous membranes.
9. Defer for 3 months from the most recent tattoo, ear or body piercing, an individual who has a history of tattoo, ear or body piercing. However, individuals who have undergone tattooing within 3 months of donation are eligible to donate without deferral if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink. Individuals who have undergone ear or body piercing within 3 months of donation are eligible to donate without deferral if the piercing was done using single use equipment.
10. Defer for 3 months after completion of treatment, an individual with a history of syphilis or gonorrhea, or an individual with a history of diagnosis or treatment for syphilis or gonorrhea in the past 3 months.
11. *Defer for 3 months from the most recent sexual contact, a man who has had sex with another man during the past 3 months.*
12. *Defer for 3 months from the most recent sexual contact, a female who has had sex during the past 3 months with a man who has had sex with another man in the past 3 months.*

Creation of Restriction on MSM

By the 1980s, the Human Immunodeficiency Virus (HIV) was spreading throughout the United States and the rest of the world. HIV caused Acquired Immunodeficiency Syndrome (AIDS) and the world would soon be in the grips of the AIDS Epidemic. According to the CDC, HIV “weakens a person’s immune system by destroying important cells that fight disease and infection” (CDC.gov). This disease is deadly because of how it attacks our bodies system and destroys our CD4+T cells. These cells are responsible for regulating “effective immune response to pathogens” (Luckheeram et al., 2014). Without the CD4+T cells and a working immune system, the human body is more susceptible to illness and disease and the body will be unable to defend against said illnesses which can lead to death. HIV/AIDS attacks these organs which can lead to multiple symptoms of chronic illness, weakness, fever, and can lead to death. The disease has no known cure and can be easily transmitted to other individuals through unprotected sex.

MSM were more likely to contract the disease because men were more prone to unprotected anal intercourse with multiple partners. According to James Myhre, an American journalist and HIV educator and Dr. Dennis Sifris, an HIV medical specialist and the Chief Medical Officer of LifeSense Disease Management, “The risk of HIV through unprotect anal intercourse is seen to be extremely high, as much [as] 18 times greater than vaginal intercourse” (Myhre & Sifris, 2020). MSM were more likely to have unprotected sex with multiple partners. Thinking of not just the person you are having sex with, but everybody that person has had sex with, it is like a chain link, the more people one person has sex with, the more likely to spread the disease.

During the AIDS epidemic, the fear was cross-contaminating other patients with blood that is infected with the AIDS virus. If one MSM donor is HIV positive and donated blood more than once, then that one donor could infect multiple individuals who can then spread the disease as well and not even know they are infected. If the recipients of the HIV positive donor donate blood as well, then the disease spreads even more through other recipients. This was the fear of how fast the disease could spread. So, to prevent this, in 1977 MSM were banned from giving any blood donations at all (Shaw, 2020). This restriction targeted gay and bisexual men. The policy would later include women who have had sex with bisexual men to restrict them of donating blood. This was targeting women as well because if they had sex with men who have had sex with other men, they could be possible carriers of the disease.

Policy Changes that have Occurred

The original creation of this policy was in 1977 at the start of the AIDS epidemic. The policy has gone through changes over the years. The original policy restricted gay and bisexual men and women who have had sex with bisexual men from ever giving blood donations. The policy was a lifetime ban and there was no way around it. If you ever answered yes to MSM, you could never donate blood.

In 2015, the FDA reevaluated the policy and changed the policy from a lifetime ban to a deferral of 12 months which required MSM applicants to abstain from having sex for a period of 12 months from their last sexual encounter (Straube, 2020). This policy was a wonder at the time because it did give gay and bisexual men the opportunity to donate blood. However, the policy was still extremely restrictive because of the expectation that gay and bisexual men would have to abstain from sex for a full year if they wanted to donate blood.

In 2020, the COVID-19 pandemic occurred, and this was a devastation on the nation’s blood bank supply. Blood donors were unable to donate blood because people were required to isolate and to practice social distancing. Blood drives were cancelled due to the pandemic. These events created a national emergency because blood supplies were extremely scarce. The American Red Cross was making urgent calls to request “blood and blood component donations in the wake of a nationwide shortage” (Kopp & Raman, 2020). People still needed blood transfusion and because people could not donate this created a crisis for The American Red Cross.

The FDA evaluated the restrictions in place on MSM and concluded that the restrictions could be modified. It eased deferral periods from the original 12 months to 3 months. The FDA stated that this would make it easier for LGBTQ donors to achieve the deferral period and would allow more potential donors to participate in blood drives and help relieve the nationwide shortage.

New Technology

Technology has come a long way since the 1980s when researchers were trying to understand HIV/AIDS. In 1984, researchers “finally identified the cause[s] of AIDS-the HIV virus- and the FDA licensed the first commercial blood test for HIV in 1985” (history.com, 2017). Nowadays, blood testing and screening can identify numerous specimens which include “red cell antibodies, Hepatitis B, Hepatitis C, HIV, HTLV, Syphilis, and CMV” (“Discrimination, n.d.). In the 1980s, the scope of what could be discovered through testing was limited.

With the advancement of universal testing and blood screening, bloodborne diseases are easier to detect which allow for better protection when determining safe blood to use. Since all blood is screened when initially donated and goes through all the same tests, the need for the restrictions of LGBTQ became moot. Why restrict an entire community of possible donors when every blood donation goes through the same processes of testing and screening before storage? It would make more sense to remove the restriction because it would open a wider pool of applicants for future donations. Because of how far testing has come and because of all the antibodies screened through initial testing, the chances of processing and transfusing HIV positive blood from *all* donors are very low (Gobrial & Lui, 2021).

Saving More Lives

If the LGBTQ community could donate blood without any restrictions, more lives could be saved. Table 1 shows the estimated number of MSM potential donors. 8.5% of men reported having sex with at least one same-sex partner since the age of 18, 4.1% of men reported having sex with at least one same-sex partner in the last 5 years, and 3.8% of men reported having sex with at least one same-sex partner in the last 12 months (Gates and Miyashita, 2014).

Report at least one male sex partner:	% of Men	# of Men ^{svi}
Since Age 18	8.5%	10,033,500
In Last 5 Years	4.1%	4,839,700
In Last 12 Months	3.8%	4,485,600

Table 1. Estimate of the MSM population in the United States (Gates and Miyashita, 2014).

Because of the shortages in blood banks, it has become a national concern that blood supply could be running at an all-time low. Members of the LGBTQ community are still turned away due to the policies in place which sees all LGBTQ male donors as potential risk factors rather than evaluating each individual’s potential risk factors. If LGBTQ could donate blood based on their own individual risk factors, then there would be more donors which means more blood in the banks.

Some individuals have rare blood typing which makes it “difficult or even impossible to get a blood transfusion or organ transplant” (Villines, 2019). This makes rare blood type individuals at high risk for fatality because of the

lack of blood supply for their rare blood types. This, however, can be combatted by allowing MSM to donate blood. Because an entire demographic of donors is put through restrictions, they are less likely to donate blood which reduces the chances of obtaining rare blood type donations. If the restrictions were removed, this would introduce an entire population of new donors which will increase the likelihood of obtaining a donor with a rare blood type.

A blood transfusion is a common medical procedure. It is used in the ER for patients in accidents, used for people who have diseases like anemia which require regular transfusions, as well as for many other surgical procedures. These new donors can help with minimizing the shortage already occurring. Ayako Miyashita, Director of the Los Angeles HIV Law and Policy Project and Gary Gates, the former Research Director, completed an analysis on the effects on blood supply if MSM blood restrictions are removed. Miyashita and Gates' analysis found that if the restrictions were to be removed, that it could increase the "total annual blood supply by 2%-4%, adding from 345,400 to 615,300 pints of blood each year" (Gates & Miyashita, 2014).

If the LGBTQ community could donate blood without any restrictions from the FDA, an estimated 360,000+ could donate blood (see Table 2). According to Gates and Miyashita (2014), "The American Red Cross suggests that each blood donation has the potential to be used in life-saving procedures on three individuals." By using the statistics from The American Red Crosse, MSM donors could potentially provide life-saving blood for over a million patients.

	# Eligible to Donate	# Likely to Donate	# of Pints Donated
Lifting of Blood Donation Ban	4,200,500	360,600	615,300
Twelve-Month Deferral	2,164,100	185,800	317,000
Five-Year Deferral	2,003,300	172,000	293,400

Table 2. Estimate of number of men who may donate blood (Gates and Miyashita, 2014).

DISCUSSION

Discrimination

This restriction that targets specifically LGBTQ men can be classified as discrimination. According to the Merriam-Webster dictionary, discrimination can be defined as "prejudiced or prejudicial outlook, action, or treatment" or "the act, practice, or an instance of discriminating categorically rather than individually" (merriam-webster.com). The act of discriminating categorically rather than individually speaks volume of the categorical deferral of MSM donors for 3 months. Instead of considering each MSM donor on the basis of individual risk factors, the entire LGBTQ male population is forced to follow strict regulations that prevent them from enjoying the formalities of life. People enjoy having sex, and to require that an entire population abstain from participating in something as great as sex is discrimination. You cannot force a population to restrict their lifestyles to include them as donors.

The argument can be made that "if you don't want to abstain from having sex, then just don't donate." How about LGBTQ fundamental rights? The fundamental rights (or better known as natural rights), to live life free from discrimination. LGBTQ individuals just want to be treated the same as everyone else, have equal opportunities in life, and participate in everyday activities without prejudice. Donating blood is a common experience for people to have, and to restrict a whole community would be to restrict them from participating in an act of generosity, a basic life experience.

Does this violate the 14th Amendment's Equal Protection Clause? Sexual orientation has been a controversial topic when it comes to the Equal Protection Clause. To protect a group based on their sexual orientation is hard to classify. However, the LGBTQ community has faced scrutiny through the years because of their sexual orientation

and has been targeted by other groups, for example, religious organizations. Some religious practices reject the ideals of LGBTQ because they object to their lifestyle. For example, some religions reject LGBTQ couples when requesting marriage. LGBTQ are denied basic rights of freedom of religion where they sometimes cannot pick a religion because of their sexual orientation or who they can or cannot marry. Professor of Law Brian Fitzpatrick and Distinguished Professor of Law and Director of the Center for Civil Rights at the University of North Carolina School of Law Theodore Shaw have discussed the struggles that LGBTQ have faced when it comes to the Equal Protection Clause. According to Fitzpatrick and Shaw “in its recent same-sex marriage opinion, *Obergefell v. Hodges* 2015, the Court suggested that discrimination against gays and lesbians can violate the Equal Protection Clause (Fitzpatrick & Shaw, 2020).

The Equal Protection Clause allows for equality and protection under the law for LGBTQ. Donating blood should not be different for anyone because of their sexual orientation. This is why we should ask whether the 14th Amendment is being violated if a certain group is treated differently for who they are under government policies. The federal government is not allowed to discriminate against any group due to the 14th Amendment, yet MSM cannot donate blood like everyone else because they are restricted as a result of their sexuality. Attorney Angela Giampolo of Giampolo Law stated, “Blood donations have plummeted due to social distancing practice, blood drive cancellations, and general questions surrounding the safety and practicality of donating blood during the pandemic” (Giampolo, 2020). Even with the crisis of COVID-19 causing a blood shortage crisis, LGBTQ still must follow a three-month deferral from sex.

These examples can be debated on whether they apply. Scholars and attorneys have been arguing this topic for years. But it is worth mentioning, can an organization like the FDA truly put restrictions in place when they actively target a specific group based on who they are? Some agree with the idea because it’s a safety measure. To restrict the entire population of MSM is considered the safest approach. However, targeting an entire group because they are living their lives normally is discrimination, and if the FDA evaluated each LGBTQ donor with an individualized risk evaluation, then the LGBTQ community would have more opportunities to donate blood.

What has Become of the Policy Today?

The current policy in place is the deferral for 3 months from the most recent sexual contact for MSM. Since its initial creation, going from a lifetime ban, to 12 months abstaining from sex, to 3 months abstaining from sex is a huge improvement, yet it still restricts MSM from donating blood because of unrealistic standards set in place. Three months from abstaining from sex is unrealistic for individuals who are already willingly donating blood but must follow strict scrutiny to do so based on who they are rather than on their actions, such as many of the other reasons the FDA recommends deferrals for prospective blood donors.

The American Red Cross has stated that it “recognizes the hurt this policy has caused to many in the LGBTQ+ community and believes blood donation eligibility should not be determined by methods that are based upon sexual orientation” (redcrossblood.org). Even though the American Red Cross recognizes that it is hurtful to put restrictions on a specific group, it is bound by the FDA’s existing guidelines and policies.

New Medication

Since 1977, when this policy restriction was initially created, there was no medication available to help combat HIV/AIDS. The disease was still relatively new and was a huge danger because there was no medicine known at the time that could help prevent contracting the virus. Back then, if you contracted HIV/AIDS, it was essentially a death sentence for a patient. Not only did people not want to be around infected individuals, there was no medication that could properly manage the disease.

Today, we have come a long way since the 1970s. We have medications to help manage pain and sickness for patients who have contracted the disease. We even have medications that help prevent contracting the diseases. For instance, Pre-Exposure Prophylaxis, or better known as PrEP, is a prescription medication that when taken as prescribed, is highly effective for preventing HIV in individuals. PrEP has been known to reduce the risk of contracting HIV from sex by 99% compared to someone not on PrEP (CDC, 2020).

Preventative medications will make it easier for LGBTQ donors to not contract the diseases and allow for more possible donors. The policy was put in place initially to reduce the risk of spreading HIV/AIDS. With medications that help combat the possibilities of contracting the disease, the policy can change so that it better serves donors who take initiative in protecting their health, as one potential measure of individual risk.

Other Nations Changing Their Policies

The United Kingdom has finally allowed LGBTQ members to donate blood without any restrictions or requirements to abstain from sex. The U.K. had a similar policy to what is in the U.S. with a yearlong ban on abstaining from sex. LGBTQ men who wanted to donate blood had to wait a full year after having sex.

Now with the policy eradicated from the U.K., all men, including MSM, can donate blood on the basis of meeting individual screening protocols. There are still restrictions in place but are more realistic compared to previous initiatives taken. The new protocol in place states that MSM who have had one monogamous partner for more than three months can donate blood. This is regardless of either the donor's or their partner's gender and the kind of sex they have.

However, there are still restrictions in place. Any donor who has sex with anyone besides their monogamous partner, someone who has sex with multiple partners, or someone who has a new monogamous partner must have abstained from anal sex for the past three months. This is important since HIV/AIDS is easier to contract and through anal sex.

The National Health Service (NHS) is a government-funded medical service which allows anyone who lives in the U.K. to receive medical care and services without being asked to pay for said services ("What is the NHS?," 2017). These services can include doctor visits and surgery, getting treatments in a hospital from a doctor or nurse, the visiting and services of a midwife, and even urgent care and ambulance rides for life-threatening injuries.

The NHS Blood and Transport program requires that each potential donor must be fully assessed for potential risks which they do through a donor check list questionnaire (Milton, 2020). Questions can ask donors if they have had new partners in the last three months or if they are on any medications such as PrEP. These assessments help better understand risk factors that donors bring when they donate blood. This can also help medical professionals better understand who is a high-risk donor is and who is not. Blood donations can then be better handled based on the risk values of each donor.

With countries like the U.K. making further strides towards equality for the LGBTQ community, maybe the U.S. can follow suit? Something that the U.S. can do is evaluate the practices that the U.K. is using with their LGBTQ donors and see if it is possible to duplicate these practices here in the U.S. The U.S. can do what the U.K. did and change the policy once more to what the U.K. has with only restricting MSM donors who have had more than one sexual partner in the last three months and see if it is viable to implement here in the U.S. If it is, then we can replicate the U.K.'s procedures for LGBTQ blood donors. If not, maybe we can re-evaluate the U.K. procedures and figure out an alternative approach that is also based on individual rather than group traits.

What Comes next?

Sixteen Democratic senators are pushing for legislation called the Science in Blood Donation Act of 2020 that would require the FDA to revise the restrictions put in place for LGBTQ blood donations (Demings, 2020). The legislation would require the FDA to revise the guidelines and deferral procedures for donors by evaluating each donor in an "individual risk-based analysis" rather than treating the entire LGBTQ population as a potential risk factor (Vella, 2020). The severe shortage seen currently in our blood banks might be a push in this direction. Gay rights advocates continue to push in this direction as well.

Dr. Jeff Kirchner, chief medical officer for the American Academy of HIV Medicine and a practicing HIV specialist has stated that "Everybody's blood is screen for these transmissible infectious diseases, regardless of who the donor is... patients who are on therapy and have undetectable viral loads can't transmit their virus" (Morrison & Schnell, 2020). Now would be the time to evaluate the LGBTQ policy because of the desperate need for donors. Dr. Jerome Adams, former vice admiral in the U.S. Public Health Service Commissioned Corps and licensed anesthesiologist called the FDA decision for reevaluation "tremendous" because of how much blood donations have fallen, and that this reevaluation would be a solution for hospitals facing "critical shortages" of donations (Ebbs, 2020).

The FDA is funding a study that is looking into the three largest blood centers in the U.S. The research "is intended to conclude whether donor deferral can be based on individual risk assessments rather than blanket rules" (Morrison, 2020). The FDA hopes to conclude their findings by the end of 2021.

To conclude, I think the main roadblock for change to the restrictions on MSM blood donations is generating enough support for it. Although the FDA is doing research that might support the policy change, there could still be political resistance. At present, I think the best course of action is to follow the evidence from the FDA's current study and treat the U.K. as a "laboratory experiment." If a non-discriminatory approach works for the U.K., why wouldn't we want to replicate it here?

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