The Bioethics of Blood Donation by Men who have Sex with Men

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Introduction

When donating blood in the United States, a short screening process allows for a quick estimation of risk level for transfusion transmittable infections (TTIs) such as human immunodeficiency virus (HIV)(Center for Disease Control, 2019b). For men who have sex with men (MSM), this screening process places them in a high-risk category. This means that these men cannot donate within 12 months of their last sexual encounter with a man. Some have called this policy discriminatory and homophobic. Policies with possible homophobic undertones need to be identified and addressed, as government suggested policies should progress with their nation; that said, public health is a complicated issue and governmental policy needs to be examined ethically.

During the acquired immunodeficiency syndrome (AIDS) epidemic in the United States, the Food and Drug Administration (FDA) banned MSM from donating blood in an effort to further prevent the spread of disease. In 2015, the ban was lifted and replaced by a deferral period of 12 months, requiring that MSM not donate within 12 months of their last sexual encounter with a man (Center for Biologics Evaluation and Research, 2019). This research will address the ethicality of this policy and others from a bioethics standpoint. The ethics of public health policy need to be carefully considered, so that we as a country can keep citizens safe and minimize suffering.

I will address three possible policies in this research and compare their ethicality using the fundamental principles of bioethics. The current 12-month deferral period, an outright ban, and a ‘no action’ policy are the major policies that have been proposed by the FDA. In order to understand the ethicality of these policies, more background is necessary.

Background

Currently, all donated blood is tested by the Center for Disease Control (CDC) before it is able to be transfused. This testing performed by the CDC is based on regulations FDA and the Center for Biologics and Research, two organizations that monitor and review the blood supply and blood donation centers (Center for Disease Control, 2019a; Leveton et al., 1995). This research will focus on the FDA's 12-month deferral policy, as it is the current recommendation for blood donation centers.

Before 2015, the FDA recommended that all male blood donors that reported homosexual contact be indefinitely deferred (essentially banned) from giving blood. This policy was incredibly controversial, as many argued it was discriminatory and others believed it was necessary. In 2015, the FDA revised recommendations and advised the current 12-month deferral policy for MSM (Center for Biologics Evaluation and Research, 2019). This is the current policy in place today.

One of the major reasons this change was possible was an enormous stride in testing. Testing blood donations for HIV antibodies began in 1985. These tests worked 6 to 12 weeks after infection and were very sensitive. However, this was at the cost of many false positives and the additional testing was added (Alexander, 2016). Eventually, in 2009, nucleic acid testing (NAT) was approved and recommended by the FDA for use in all blood testing for transfusions (Hans & Marwaha, 2014). This testing is able to detect HIV within 3 days of infection and is also highly sensitive. However, no testing is accurate 100% of the time and it is important to note that 1 positive in 2,135,000 donations is 'missed' by NAT testing (Dodd et al., 2002). This change

allowed the FDA to identify high-risk individuals without banning them entirely. However, this policy is still a point of contention.

Arguments In Favor of the Deferral Period

Major proponents of this deferral period include the FDA, CDC, and many politicians. Their main argument in defense of the policy is that it protects those receiving blood. Additional reasoning by the FDA especially cites the efficacy of the policy. This is informed by a higher incidence of HIV and other TTIs in MSM (Sturrock & Mucklow, 2018). If the FDA were to advise against deferrals entirely, there would be a potential four-fold increase in HIV transmissions from blood transfusions (Center for Biologics Evaluation and Research, 2019).

Arguments Against the Deferral Period

There are those that disagree with the policy and fight for the removal of the deferral period. Among these groups are LGBTQ+ advocates and some politicians. Their main point of focus is the rights of the blood donors (*Ban the Ban*, 2018). These activists use previous cases to argue for removal of the policy on the basis of civil rights, discussed further in the context of the ban on donations from Haitian immigrants in the 1980s (Valbrun, 1990). Other arguments include the problems associated with narrowing of an already limited blood supply, the privacy of the donors, and an ensuing lack of trust between MSM and doctors. Some LGBT groups argue that this lack of trust contributes to the spread of HIV by discouraging MSM from seeing doctors(*Ban the Ban*, 2018).

Bioethics

In this research, I will explore three potential blood donation policies as they relate to a major framework of bioethics, the ethical matrix: respect for autonomy, non-maleficence, beneficence, and justice. This means that policies regarding medical procedures should not force

the patient into the procedure, but also should consider that patients (or donors) make their own choices regarding what they share with medical professionals. Secondly, medical practitioners should aim to do no harm (non-maleficence). Procedures and policies should be implemented with the intention to benefit the patients (beneficence). Finally, these same policies should not infringe on citizens' rights or break any laws.

Overall, this matrix takes into consideration the actors involved with and affected by the policy; mainly LGBTQ+ groups and MSM, government agencies, and those requiring blood transfusions. Each of these stakeholders is invested in these policies all for different reasons. LGBTQ+ groups and MSM want to ensure that there is no discrimination against MSM. Government agencies, specifically the FDA, are invested as they are designing and implementing the policy and it is important that they take the other stakeholders' views into account. Finally, patients that need blood transfusions would advocate for their safety in terms of the blood supply.

It is important to note that this is not the only way to analyze these policies and their ethicality; many different frameworks for bioethics and ethics in general can be applied in this manner, further explored in the discussion section (Arora, 2017; Mepham, 2005).

This topic presents a fundamentally ethical dilemma, with basic arguments that the public health is paramount or that civil liberties are of the utmost importance to the American people. A thorough examination of the arguments and interests of these groups, observational studies performed in other countries such as Australia and the UK with similar or alternative policies, and legal precedents for the civil liberties related to this issue, based in the framework of the ethical matrix should provide a comprehensive overview of the topic to inform the question of its ethicality.

Methods

I will analyze three policies proposed by the FDA in their 2015 Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. These three include: the current 12-month deferral period, where MSM cannot donate within 12 months of their last sexual encounter with a male; the previous indefinite deferral (or ban) where self-reported MSM are not eligible to donate; and a 'no action' policy, where any MSM can donate, regardless of when they last had sex. While these are the policies this research will focus on, the FDA did suggest multiple other policies. These included things like pre-testing donors and having them return for a second appointment or individual risk assessment by trained professionals (Center for Biologics Evaluation and Research, 2019). These options require more resources and are considered less feasible.

In order to thoroughly examine these policies, many different aspects of their implementation need to be reviewed. Purely statistical analyses of NAT, observational studies of these policies in other countries, and a legal precedent involving Haitian immigrants in the 1980s are the main sources I will be drawing on for this research. In addition, newspaper articles to represent the public opinion, LGBTQ+ activist articles and blogs, and doctors' opinions on the subject will further inform this research.

One of the criticisms of this bioethical matrix is the argument that each of these cells can be weighted differently and this weight can facilitate decision making in different directions (Mepham, 2005). For example, one bioethicist might consider the beneficence of those requiring blood transfusions the most pressing issue and another might find justice for blood donors to be

of the utmost importance. In order to properly address this issue, I will first analyze and 'complete' each cell of the matrix for each policy, then analyze them from the perspectives of the main actors and their major concerns. For example, from the perspective of the FDA the cell of the most importance would be justice for all other actors, as they are a government agency (explained further in the discussion section). For the LGBTQ activists, the analysis would rely heavily on the justice for the LGBTQ community. Then, in the discussion, I will compare the 'results' of each group being taken into consideration.

Data

As mentioned, all of the blood used in transfusion is tested, regardless of the donor's survey answers. Multiple tests (all approved by the FDA) are used to prevent the spread of transfusion transmittable infections (TTIs). One of these assays, NAT, can detect HIV within 3 days. With NAT, the risk of HIV infection through transfusion is 1 positive unit per 1,934,230 donations (Zou et al., 2010). Before NAT was introduced in the United States in 2009, HIV could go undetected for up to 6 months (Hilts & Times, 1990).

As testing has evolved, so have the policies surrounding it. Like the U.S., a number of countries have made the switch from an outright ban to a defined, time-based deferral period (some 1 year, though some instituted 5-year deferrals). Australia changed from an indefinite deferral policy to a one-year deferral and experienced no statistical change in HIV infections from the blood supply, as evidenced by a 5-year period after the change with no detectable decrease in blood safety from the 5 years prior to the new policy (Seed et al., 2010). However, aside from a few observational studies, there is very little information about HIV infection and

blood donors. More studies need to be conducted, over longer periods of time to accurately represent this system (Buck et al., 2015).

A similar ban on Haitian and sub-Saharan immigrants donating blood was a result of the widespread fear in 1990 of the AIDS epidemics, during which the incidence of HIV in Haitian immigrants was thought to be higher. This policy, while merely a suggestion by the FDA, was followed by most major blood banks and deemed racist, illogical, and discriminatory by Haitian groups and even physicians (Lambert, 1990). It was replaced later that year with self-reported questions to determine if a potential donor had engaged in 'high risk behavior' in the previous six months, as those with AIDS may not test positive six months after contracting the virus (Hilts & Times, 1990; "U.S. to Lift Haitian Blood Donor Ban," 1990).

Many issues surrounding this policy are tied to the fact that the survey is self-reported. A study found that it was common for everyone, including but not limited to MSM, to answer the questions not as they were literally asked, but as if they were asked 'Is your blood safe?'. This presents many issues, most importantly: a donor may think their blood is safe and answer in a way that would allow them to donate even though they had participated in high risk behaviors(Center for Biologics Evaluation and Research, 2019).

Analysis

I will be analyzing each of the three major policies proposed by the FDA in terms of the four categories of the bioethics matrix. Figure 1 provides an overview of each policy listing major points that will be considered. In Figure 2, I will highlight the most important aspect of the matrix for each of the stakeholders.

Policy	Overview
12-month Deferral	- Introduced in 2015 - Studies (Australia/Italy) show it is as safe as a ban - Self-reported
Outright Ban	- FDA recommended until 2015 - Labelled discriminatory - Self-reported -Similar ban on Haitian immigrants was changed
No Action	- Difficult to study/no evidence - Possible four-fold increase in HIV transmission through transfusion - Would increase blood supply

Figure 1: Table with a brief overview of the major points of each policy.

Autonomy

Autonomy, in terms of this bioethical matrix, is used to ensure that patients only undergo procedures to which they have consented. In this particular case, the autonomy (self-governance) of the donors also needs to be taken into consideration. Major issues are the privacy of MSM and their self-reporting. Not specific to any policy, but important to note, is that those receiving these transfusions have no influence over the blood they receive and their safety is dependent on the testing and regulation by the FDA and similar bodies.

In terms of the FDA's current 12-month deferral policy, autonomy relates to issue of self-reporting. Knowledge of 'high risk' sexual behavior by the American Red Cross is reliant on the donors filling out a questionnaire. This self-reporting of behavior means this information is

unreliable and donors may or may not be truthful when filling out these questionnaires (as mentioned earlier). In a similar vein, donors may not want to answer this question, as it is a personal matter. This, of course, is their choice but they will not be able to donate blood.

Similarly, a full ban on MSM donating would rely on self-reporting. This, of course, would present the same problems as the current policy. Additionally, it might be less likely for MSM to self-report sexual activity if it would prevent them from donating blood entirely(*Ban the Ban*, 2018). Generally, this policy would rely more heavily than the current policy on self-reporting and could come with additional problems.

The third suggested policy, one of no action, would not rely on self-reporting at all. Since donation in this case would not be dependent on sexual behaviors of MSM, these men would most likely not have to report these behaviors. It has been suggested that this might even increase the 'self- policing' part of the donation process and higher risk individuals may avoid donating if there is no screening process (Karamitros et al., 2017). There is no available concrete evidence to support this claim.

Non-maleficence

Ideally, any medical policy or procedure would not bring harm to the patient or others. This is accounted for in the non-maleficence section of the matrix, in which false negatives, false positives, trust in doctors, and legality are the major factors for the stakeholders.

The current FDA policy is in place in an attempt to limit the amount of TTIs passed to those requiring blood transfusions. Some LGBTQ+ activist groups also argue that because this policy turns MSM away from giving blood, it could deter MSM from visiting doctors in regards to TTIs. This could potentially further the spread of TTIs in the MSM community (*Ban the Ban*, 2018).

A full ban on MSM donating blood would bring up issues of discrimination. While the current policy still allows MSM to donate and remains in the gray area of civil liberties, a flat-out ban would most likely be considered a discriminatory rule (Sturrock & Mucklow, 2018). The legality will be discussed more at length later in terms of justice. However, this policy would prevent TTIs from any MSM and their partners, assuming they are truthful. Again, this brings up the issue of self-reporting. Overall, the policy is not one that avoids maleficence.

The major problem with this policy in terms of non-maleficence would be the prevention of the spread of TTIs. There have been a few studies related to the strength of testing, but none that definitively show a no action policy is as safe as the current policy (Blankschaen, 2018). In fact, an FDA study estimated that without the suggested deferrals, there may be a four-fold increase in HIV transmission through transfusions (Center for Biologics Evaluation and Research, 2019). However, a no action policy would alleviate the issue of MSM trusting their doctors, as they most likely would not be asked to divulge that information when donating and would experience no negative impact at that time related to their sexual behavior. This policy also would definitely not infringe on the civil rights of MSM.

Beneficence

The main question of beneficence: is this policy protecting those that need blood. This is the concern of the governmental agencies enforcing these policies, and those receiving blood. Also issues that need to be addressed are whether or not there is enough blood.

As mentioned, this 12-month deferral policy is intended to mitigate the amount of TTIs transmitted through blood transfusions. Blood from donors that engage in high risk sexual behavior, as MSM are classified, is kept from the blood supply because these high- risk

behaviors have a higher rate of TTIs (*HIV and Gay and Bisexual Men | HIV by Group | HIV/AIDS | CDC*, 2020).

The full ban policy is intended to entirely prevent the spread of TTIs from the high risk population through transfusion. While studies are difficult to perform, some have shown that this policy is no more effective at preventing the spread of TTIs than a no action policy (Seed et al., 2010). Again, more blood is always needed and this would limit the pool of potential donors even further than the 12-month deferral policy.

The American Red Cross frequently has a shortage of blood, and opening the donor pool as a no action policy would might alleviate that shortage (American Red Cross, 2019). A no action policy may not be sufficient to ensure the safety of the blood supply. While a number of other countries (Italy, Australia, and Canada included) have switched to a deferral period and have been observed, there is little to no research on any deferral period of less than a year (Center for Biologics Evaluation and Research, 2019). While it is possible that there may be no change in blood supply safety, there is no evidence to support this way of thinking.

Justice

Civil liberties and the right to safe treatment are the major legal concerns related to this issue. An ideal policy would not infringe on the rights of any citizen, but each policy has its drawbacks in terms of rights.

The deferral policy currently in place is intended to keep the blood supply safe for those that require transfusions, but is considered discriminatory and unreasonable by many LGBTQ+ groups (*Ban the Ban*, 2018). While there are limited studies about the efficacy of this policy in preventing the spread of TTIs, the FDA's stance is one of 'better safe than sorry'; if this policy were to prevent any spread of TTIs from transmission, the FDA would most likely advise blood

donation centers to follow it. However, MSM and LGBTQ+ activist groups argue that this policy is discriminatory and prejudiced, painting the entire MSM community with a broad brush. The FDA's defense would be that MSM (monogamous or not) do have a higher incidence of HIV (Prejean et al., 2011).

The previous policy of an outright ban in the US has since been revised by the FDA. A major concern with the policy was that it was thought to be discriminatory. With the previously mentioned data on the FDA's move to change a similar policy relating to Haitian immigrants, this was especially true. This ban is still considered the safest policy by some, but studies in countries such as Australia and Italy that have moved from a ban to a deferral policy contradict this way of thinking(Seed et al., 2010; Suligoi et al., 2013). The FDA's position on this policy is that it was no safer than a deferral, hence the move to the current policy.

In the case of a no-action policy, the issue of justice revolves mainly around the safety of the blood supply. While all blood is tested before transfusions, HIV cannot be detected in the blood within 9 days of infection (Hans & Marwaha, 2014). Again, there is little to no research in this area, though many assume this would increase the number of HIV transmissions through transfusions since there is a higher incidence rate of HIV in MSM (Prejean et al., 2011; Zou et al., 2010). The FDA's conservative estimates cite a potential four-fold increase in HIV transmissions through transfusions(Center for Biologics Evaluation and Research, 2019).

Stakeholders	Autonomy	Non-maleficence	Beneficence	Justice
Those Receiving Blood Transfusions	No Choice	**False Negatives**	Enough Blood	Safe Care
Men who have Sex with Men	Privacy Self-reporting	Trust in Doctors False Positives	Help in Crises	**Civil Liberties -Precedence**
Government and Regulatory Policies (FDA, CDC)	Privacy Self-reporting	Legality False Negatives	Blood Supply	**Discrimination** **Providing Safe Blood**

Figure 2: Bioethics matrix with bolded cells to represent heavily weighted considerations.

Discussion

Figure 2 provides a summarized ethical matrix of the considerations necessary to decide on a policy. One of the major points of this system is that it is mainly organizational. This table does not indicate which policy should be in effect or even which policy each stakeholder may prefer. The next step in evaluating these policies using this method is to determine which of these four pillars is weighted most heavily for each stakeholder. While this in no way is meant to indicate that every person in each of these groups believes the same thing, it is helpful in this case to generalize and speak to what is best for the group as a whole because of membership to that group. Figure 3 summarizes the rest of the discussion section, with stakeholders' preferred policies.

Stakeholders	12-Month Deferral	Outright Ban	No Action
Those Receiving Blood Transfusions	-Safe as Ban -More blood than ban	-Thought to be safest	-Potentially unsafe
Men who have Sex with Men	-Compromise, still discriminatory	-Discriminatory	-Most just
Government and Regulatory Policies (FDA, CDC)	-Safe as Ban -More Blood -Compromise	-Safe -Discriminatory	-Potentially unsafe

Figure 3: Overview of individual policies and stakeholders' concerns. Preferred policies are shaded, policies to consider are bolded.

People receiving blood transfusions may individually care more about justice or beneficence, but as a generalized group in this scenario, the most important category of these four is non-maleficence. Blood transfusions are necessary for a good portion of the American public (Community Blood Center, 2007), and their personal safety comes first. Because there is the possibility that an outright ban policy may be the safest of the three policies, this may be the policy most suited for this group. However, given that there is some evidence that this policy is statistically no different safety-wise, it is possible there is room while still being as safe as possible for a 12-month deferral policy. This is based on the evidence from previously mentioned case studies in Australia and Italy (Seed et al., 2010; Suligoi et al., 2013). Assuming there is no difference between these two policies in safety, the weight shift second to beneficence. With the shortage of blood the American Red Cross frequently experiences, allowing more people to donate would be in this group's best interest.

The LGBTQ+ community and MSM first value that the policy is just. While the 12-month deferral policy was considered an adequate compromise in 2015, many argue that the world has continued to change to become more tolerant of homosexual relationships (Center for Biologics Evaluation and Research, 2019). Again, this method of analysis requires broad generalization of groups and not everyone in this group will be in agreement, but given that the LGBTQ+ community values (in this situation) justice, a no action policy most aligns with this group's viewpoint.

While the job of governmental agencies is to keep the blood supply safe, I would argue that beneficence is a close second to justice. The government as a whole has a job to uphold the law while ensuring the safety of the citizens. In this cell of Figure 2 (shaded), it is apparent that while the government has a duty to avoid implementing discriminatory policies, it is tasked with keeping the blood supply safe. Between these three policies, a governmental agency might see the 12-month deferral policy as a means of keeping the blood supply safe and coming to a compromise with a policy that is not as harshly discriminatory as other alternatives.

Conclusion

Worldwide, this is a contentious issue and it is important that the United States make an effort to fully understand how we as a nation weigh the ethical implications of a policy intended to protect citizens that may be discriminatory. This policy could set a precedent for other nations, and as a country, we should recognize the importance of not only protecting our citizens, but providing a safe and inclusive environment for all.

Based on this information and method of analysis, it seems that the current 12-month deferral policy may be an effective compromise at this point in time. That is not to say it is the

‘correct’ decision, or that this is the only possible method of analysis. Other ethical frameworks may indicate that the outright ban or no action policy is more acceptable, or even that there is another policy not discussed that would benefit the most people. There are many different ways to analyze this policy, and it is a complicated matter of public safety. There is no one right answer, though it is important that we as a nation weigh the ethical implications of policies governing the medical field.

In order to make the best decision regarding these policies, one needs to understand the ethical and societal implications, and be fully informed of the possible risks and benefits. In order to make these decisions, we must be well informed and able to analyze the policy from every angle.

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