

The ethical implications of the lifetime blood donation ban policy on homosexual and bisexual men: Exploration in the context of professional doctorate

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The United States (U.S.) Federal Drug Administration (FDA) mandated since the mid 1980s, that all blood donors be screened beforehand through a series of questionnaires. As a result of those strict guidelines, homosexual men, also called men who have sex with men (MSM), are permanently deferred from donating blood once they admit to engaging in sexual behavior even once since the year 1977. The Nucleic Acid Testing (NAT) technology is helping reduce the risk of having a contaminated blood product to 1 in every 2.3 million units. Prohibiting all MSM donors from donating blood is excluding numerous healthy candidates from this altruistic act and has numerous negative ethical implications especially in the area of justice, respect of human dignity, and utility among others. This paper aims at exploring the lifetime blood donation deferral on homosexual and bisexual men from ethical perspectives.

Keywords: deferral, blood donation, homosexual males, ethical principles, utilitarian, justice.

The Human Immunodeficiency Virus (HIV) became epidemic by the late 1980s, where up to 800,000 individuals were infected with this virus in the United States, (U.S.) (Moss, 1989). The majority of the infected individuals were homosexual men which explains the reason this virus is linked to this group. As a result of this historical event, the Food and Drug Administration (FDA) indefinitely banned homosexual and bisexual men from donating blood, while at the same time deferred other high-risk groups from donating blood for a set period of time (12 months) (FDA, 2010). Consequently, this policy created a great controversy especially since this ban varies among the developed countries. The U.S., France, and United Kingdom (UK) indefinitely ban homosexual men from donating blood, whilst Australia and Japan impose a one year deferral period, and Spain and Italy refrain from imposing any restriction to this risk group

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(*Constitutionality of gay blood donor*, 2009). This ban creates many ethical implications, which will be described in this paper.

Policy ban: introduction and historical background

In the 1980s, 10,000 Hemophiliacs contracted AIDS, which was fatal to the majority of the HIV-infected Hemophiliacs (Caplan, 2010). HIV was then discovered to be transmitted through the blood system. Consequently, the FDA mandated that all blood products undergo screening processes to check for HIV and other viruses before the blood product is transfused (Neill, 2010). In 1983, the FDA instituted the policy that indefinitely banned men who had sex with men (MSM) from donating blood, which was officially implemented in the year 1985 (FDA, 2010; Martucci, 2010). In fact, among the questions that all male blood donors are required to answer is the following: 'have you had sex with another male even once since 1977?' (Caplan, 2010: 1). A positive answer to this question prompts an indefinite deferral from blood donation regardless of the sexual history.

Since the policy implementation, the Blood Products Advisory Committee (BPAC) reconvened twice in the year 1997 and 2000. BPAC recommended maintaining such guidelines while acknowledging the fact that such policy excludes many healthy individuals who could be ideal candidates for blood donation (Martucci, 2010). The advisory committee to the Department of Health and Human Services (DHHS) convened on June 11, 2010, where the majority (9-6) ruled against lifting the lifetime ban on homosexual and bisexual men from donating blood. However, the FDA made an astonishing statement where they acknowledged that this policy could be permitting high risk donors and banning low risk individuals from donating blood (Quigley, 2010). Among other professional organizations, the house of delegates of the American Medical Association suggested in their 2008 annual meeting, that the MSM lifetime deferral be changed into five-year deferral, given that those individuals 'present no greater risk than the general population' (AMA, 2008: 1). Finally, jointly the American Association of Blood Banks (AABB), American Red Cross (ARC) and the America's Blood Center (ABC) requested that the FDA amend the lifetime deferral policy, given that this policy is 'medically and scientifically

unwarranted' (AABB, 2010:1). Evidently, this policy creates much debate among the diverse professional organizations.

Ethical argument

Since its implementation 25 years ago, the lifetime deferral ban on MSM donors has not been amended in light of the various technological and scientific advances. This author argues against maintaining this policy relying on various research and scientific advances accomplished in this field of study.

Technological advances

Since the discovery of the Human Immunodeficiency Virus, a few blood screening methods such as Enzyme-Linked Immunosorbent Assay (ELISA) and western blot were adopted. These tools possess very high sensitivity and specificity measures (greater than 95%) (*Fact sheets on HIV/AIDS for nurses*, 2002). The screening tools contributed to a safe, non-contaminated blood supply, through detecting the various viral antibodies among the blood products donated. However, these tools failed to detect the antibodies during the window period, which is the period that stems from the time the virus enters the vascular system to the time the antibodies are released. This may take up to few months. Then, Nucleic Acid Testing (NAT), established in the late 1990s, was again found to be highly sensitive in detecting the RNA portion of the virus, that regular antibody screening methods failed to detect (Mine, 2003). In fact, the risk of NAT making an error in detecting HIV-1 would be one in ten million (As cited in, Caplan, 2010). The advantage of this technology relies in its shortening of the window period to few days instead of weeks (Martucci, 2010). Having such advanced technology renders the risk of releasing an infected unit of blood, or transfusing a contaminated unit as very minimal. In a relatively recent presentation in Germany, sponsored by the World Health Organization (WHO), the assessed Residual Risk of releasing an HIV contaminated blood is less than one in 3 million products (Lower, 2006). Similarly, during the 2006 FDA workshop, the residual risk of transfusion contamination was discussed. FDA experts stated that the residual risk is 'so low that they cannot be measured directly, hence we rely on models to estimate...' (Epstein, 2006: 13). These

technological advances did not exist when HIV and AIDS became epidemic in the United States during the early 1980s, which would justify the MSM policy at that time. Therefore, given how low and unquantifiable the residual risk is for an HIV contaminated blood product to get transfused warrants lifting this lifetime deferral ban.

High risk groups

Prisoners, paid blood donors, prostitutes, intravenous drug users (IDU), and homosexual men are among the high-risk groups routinely screened before blood donations (Williams, 2006). Ironically, the deferral period for blood donation varies among the different high-risk groups. During the interview process, donors who report to having had sex with an IDU, prostitute, hemophiliac, or with an individual who tested positive for HIV are deferred from blood donation for a period of 12 months. Female donors who admit to having sex with an MSM are deferred for the same period of time. On the other hand, donors who ever report using needles for non-prescribed drugs or steroids are indefinitely deferred from blood donation. Similarly, male donors who report to having had sex with another man even once since 1977 are indefinitely deferred from blood donation (Williams, 2006). The last statement automatically places any man who had sex with another man in the high-risk category regardless of their sexual behavioral history. This is a discriminatory statement and ethically unjustified, that links the sexuality of a certain group (homosexual and bisexual men) to diseases such as AIDS.

HIV Prevalence among MSMs: Comparison to Other Groups

The Center for Disease Control and Prevention (CDC) reported that approximately half or 48% of the one million HIV infected Americans are men who had sex with another man. MSM represent four per cent of the American male population and are 44 times more likely to develop HIV infection than other males (*HIV and AIDS among gay*, 2010). Comparatively, other racial and ethnic groups were reported to have an overburdening rate of HIV infection. In 2006, 45% of the new HIV infections reported in all 50 states and Washington DC are accounted to African Americans. In 2007, African Americans accounted for 46% of the HIV infected individuals (CDC, 2010). The CDC reported, during the 25th anniversary of the HIV/AIDS

discovery, on the many advances accomplished in this field, especially in terms of screening, prevention and treatment. They reported, however, on the 'remaining challenges' which represent the groups that are still overburdened with the virus. Men who have sex with men, blacks and more specifically heterosexual black women are among the groups that carry the highest prevalence of HIV infections. For the period between 2001 and 2004, 51% of the HIV infections were accounted for by blacks, of which 54% or 23,820 individuals are heterosexual black women (Fenton, 2006).

The CDC report described above shows that MSM is not the only group that has a high prevalence of HIV infections. Rather, African Americans in general and heterosexual black women specifically represent another group that continuously challenges the American community with its burdening prevalence of HIV infections. Thus far, there exists no policy that indefinitely bans this ethnic group from donating blood, although the prevalence of HIV infection is almost identical in both groups. This represents a discrepancy that has not been addressed by the government agencies and deserves a thorough discussion.

In reviewing the literature, two historical events related to blood donation ban are selected. Homosexual men were not the only group that was banned from donating blood. African Americans, during the World War II were banned from this altruistic act. This ban was later 'relaxed' where African-American blood was segregated from "White blood." Haitians, who emigrated since the year 1977, were another group that was excluded from donating blood due to the AIDS epidemic. However, the FDA in the year 1990 banned all Haitians, regardless of emigration time, from donating blood. This ignited a great deal of anger among Haitians, who held immense demonstrations that forced the FDA to finally lift the ban (Lambert, 1990; Martucci, 2010). It is clear that lifting the ban on the diverse ethnic groups, contributed in strengthening the link between sexuality and AIDS, rather than ethnicity (Martucci, 2010). This reinforces the need to examine this policy from ethical perspectives, especially since an indefinite ban is not scientifically and medical justified.

Policy discussion: opponents versus supporters

The lifetime deferral ban on blood donation from men who have sex with men created a great controversy among the various professional organizations in general. This section presents the supporting and opposing viewpoints, using few studies conducted that defended or opposed such views.

Policy proponents

The policy that indefinitely defers homosexual men from donating blood is urged by policymakers to remain unchanged, due to the higher rate of HIV contamination associated with this group. The risk of acquiring unknown pathogens from an MSM activity is another reason that is advocated against lifting this ban (Epstein, 2006; Phillips, 2008; Skinner, 2010).

The FDA's main priority is to secure a safe blood supply. In their 2006 workshop, the FDA representatives stated that one of the layers to ensure a safe blood supply is appropriate 'screening and deferral based on risk factors' (Epstein, 2006: 11). FDA experts believe that putting deferral criteria in place will eliminate many high-risk donors, where the latter contributes in increasing the risk of contaminating the blood supply (Epstein, 2006).

In reality, the deferral policy in place does not necessarily eliminate all MSM from donating blood. This is evident in the study that was conducted on 25,000 donors, where an anonymous survey was used and weighted analyses of data were conducted. Out of 25,168 male respondents who donated blood, 1.2% admitted MSM activity since 1977 (Sanchez, 2005).

The main reason the FDA insists on keeping this policy is related to the high prevalence rate of acquiring HIV infections among the MSM population. MSM are 60 times more likely to have the virus compared to the general population. Among blood donors, MSM is the group that has the highest prevalence of HIV. The FDA states that the current and advanced technology fails to completely eliminate the risk of transfusing a contaminated blood, even though the risk of transfusing a contaminated unit is less than one in one million units. The FDA maintains the

belief that the 'nearly eliminated' risk of having a contaminated blood product is mainly due to the procedures followed to screen individuals at risk. Finally, the commitment towards ensuring a blood supply, free of any contamination makes the FDA reluctant to change such policy (FDA, 2010).

Mark Skinner, president of the World Federation of Hemophilia, argues against lifting the lifetime ban. He states that there is no scientific evidence that supports changing this policy. He posits that safety of blood products is essential, and allowing MSM to donate blood would increase the risk of blood supply contamination, especially since MSM are 44 times more likely to be infected with HIV than heterosexual males. Another important fact he lists in his argument relates to the possibility of high risk behaviors among homosexual men generating 'unknown' pathogens. He admits, however, that this policy is discriminatory but 'justifiable' as it serves to protect the safety of all Americans (Skinner, 2010).

Policy opponents

The opponents of this policy base their arguments on scientific ground related to the technological advances achieved in screening blood products (Epstein, 2006; *Fact sheets on HIV/AIDS for nurses*, 2002; Martucci, 2010; Mine, 2003). Some discuss the issues of double standard associated with this policy (Neil, 2010).

Double standard is an issue often mentioned when discussing the lifetime ban on homosexual men. As mentioned previously, the deferral period varies among the risk groups. Heterosexual men, who could engage for years in high-risk behaviors, such as unprotected sex with prostitutes, are deferred from blood donation for a period of 12 months (Neil, 2010).

A quantitative probabilistic technique was performed, in order to calculate the risk and benefit of allowing homosexual/bisexual men from donating blood once they refrain from MSM activity for 1 year (MSM1) and 5 years (MSM5). MSM5 and MSM1 add to the overall nation blood supply a total of 14,730 and 75, 190 units respectively. Among the added donors, an estimated

322 MSM5 HIV infected individuals and 1645 MSM1 HIV infected ones would be donating blood. The risk of transfusing an infected blood unit is predicted to be 0.03 (95% CI) for the MSM5 and 0.18% for MSM1. In other words, the risk of transfusing an infected unit of blood, while adding MSM1 and MSM5, would be one unit every 45 years to a maximum of one unit every 20 years (Anderson et al., 2009).

Ethical arguments

The lifetime deferral ban from blood donation has numerous ethical implications. Closely examining this policy reveals violation of the ethical principle of justice. In addition, this author argues toward amending the ban relying on the utilitarian theory.

Utilitarian theory

Changing the lifetime ban on homosexual men could be supported by the utilitarian theory. This ethical principle describes an act that serves to 'produce the maximal balance of positive value over disvalue' or 'do the greatest good for the greatest number' (Beauchamp, 2009: 337). By adding the 14,000 and 75,000 units of blood (while maintaining a very low to minimal contamination risk of less than 0.5%), would significantly add to the greatest good (Anderson, et al., 2009).

There exists a need to increase the blood supply secondary to known blood shortages in the U.S. and worldwide. In 2006, the number of surgery days postponed became wider (1-16 days) compared to the year 2001 and 2004. In addition, a total of 412 surgeries were postponed as a result of blood shortages (Whitaker, 2007). The blood shortage is severe worldwide. To maintain an adequate blood supply, 1-3 % of the donor population must be accounted. According to the 2007 World Health Organization (WHO) report, less than 1% of the population was blood donors in 80 out of 172 countries studied (*Improving blood safety*, 2007).

A recent study performed in the University of California Los Angeles (UCLA), which aimed at estimating the number of blood units that will be added to the nation's blood supply in the case

that this ban is lifted. Using data retrieved from the General Social Survey (GSS) between the year 2000 and 2008, it is estimated that approximately 2.5 million individuals would be eligible to donate. Out of the 2.5 million eligible individuals, it is estimated that 130,000 will donate resulting in a total of 219,000 blood units added to the nation's blood supply (Goldberg, 2010).

The minimal or near negligible residual risk that the advanced blood screening methods are generating combined with the substantial number of blood products that would be added to the overall blood supply justify lifting the imposed lifetime deferral ban.

Ethical principle: justice

The ethical principle of justice calls that 'equals must be treated equally and unequals must be treated unequally' (Edwards, 2006: 59). Men who have sex with men are considered among the high risk groups and are completely excluded from donating blood. However, MSM is considered high-risk when those individuals engage in high-risk behaviors such as having multiple sexual partners. How is this just when any bisexual or homosexual man is excluded regardless of his risk behavior? Like heterosexuals, homosexual men could be engaged in a monogamous relationship and pose no greater risk of contamination than any other blood donation. The ethical principle of justice is violated in this policy because the deferral time varies among the high risk groups. A homosexual man who does not pose a threat on contaminating a blood supply is excluded according to this policy from donating blood. On the other hand, a heterosexual man who has engaged for years in high-risk behaviors will be deferred for 12 months from blood donation. In this case, the latter poses a greater risk than the former donor. Finally, developed countries vary in their approach toward the deferral period based on risk. This policy does not follow the ethical principle of justice simply because homosexual and bisexual men are not treated equally among the different developed nations.

Conclusion

Giving blood is an altruistic act that is mainly performed to serve good reasons. There exists a great need for blood donations that aim to treat individuals with chronic diseases such as

Hemophilia. During the September 11 events, half a million blood pints were donated, that saved numerous lives (*56 facts about blood and blood donation*, 2008). However, this same event increased the awareness of the gay community toward this lifetime deferral policy. Clearly, this created a great deal of disappointment among the gay community. This ban could have been justified during the early 1980s in the light of all the fatalities generated from the HIV infected blood transfusions. The advanced screening technology that secures a very minimal to negligible risk of contaminated blood transfusions validates amending this policy into a defined deferral period, which is homogenous with other high-risk group deferral policies. Finally, changing the lifetime ban, supported by the utilitarian theory, should allow healthy individuals to donate, contribute into a substantial increase in blood donations, while keeping the risk at a minimum.

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