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Righting Anachronistic Exclusions: The Ethics of Blood Donation by MSM

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Abstract

Recently, the FDA announced that it would soon lift the long-standing lifetime ban on blood donation by men who have sex with men (MSM). Re-examining blood donation by MSM, it is clear that there are several ethical goods that must be balanced. Through balancing the primary duty to safety with the imperatives to craft a policy that is formally equal, upholds the public's trust, and is non-discriminatory, an ethical blood donation deferral guideline may be advanced, both for MSM and the population at large.

Keywords

blood donation; MSM; blood donation policy; blood safety

Since 1983, the Food and Drug Administration (FDA) indefinitely deferred all men who have sex with men (MSM) even once since 1977 from serving as blood donors due to the increased risk of transfusion transmissible infections (Anderson, 2009; Food and Drug Administration, 2015). After years of controversy, the FDA announced in December of 2014 its intention to revise this lifetime ban in favor of a 12 month deferral (FDA Commissioner, 2015). It is not surprising that the response from stakeholder groups was mixed given the complex interplay of values at the nexus of health policy, ethics, social justice, and the law that informs this discussion (Dennis, 2015). This controversy was again brought to the forefront after the MSM community was unable to donate blood following a mass shooting in Orlando targeting the LGBT community (Arora et al, 2015).

It is clear that when analyzing current or future deferment policies on blood donation by MSM or any other subpopulation, at least four discrete but interrelated ethical goals must be considered. Most important is the primary goal of the FDA and the expectation of society at large of a safe blood supply. Second, deferment policies surrounding blood donation should be formally equal or fair. Third, an ethical blood deferment policy should account for societal obligations such as to uphold trust and ensure ongoing research to better inform policies. Finally, policies should strive to be non-discriminatory and acknowledge the role of public policy in contributing to societal stigmas (McNeil, 2016).

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The paramount ethical consideration is the safety of the blood supply. There is no clear right to donate, whereas recipients of blood transfusions do have a right to a safe blood supply in keeping with the ethical principles of beneficence and non-maleficence (Kesby & Sothorn, 2014). Since absolute safety cannot be guaranteed, deferments and bans should be comparable across donor groups in order to proportionally achieve the desired level of protection. Furthermore, while screening questionnaires continue to form the mainstay of the donor safety strategies, advances in blood testing such as nucleic acid amplification testing (NAT) effectively shortens the window period between exposure and testing positive for HIV to 11 days and has helped reduce the risk of transmission dramatically (Anderson, 2009). It is hypothesized, based on mathematical models, that the new 12-month deferral will result in release of one additional HIV-infected unit of blood every 11 years. As such, this ratio is much smaller than the 1:1.67 already accepted ratio applicable to an HIV-infected unit of platelets from a shared pool of donors (Vamvakas, 2009). However, given the unknown impact of quarantine release errors, compromised compliance with new guidelines, emerging transfusion transmissible infections, as well as donations during the NAT window period, it is unclear what the final safety impact of the new policy will be. All told however, any future risk is likely to be minimal and monitored by the FDA's national blood surveillance system (FDA Commissioner, 2015).

The second ethical issue that must be considered regarding bans on blood donation by any sub-population is that of formal equality – treating like cases similarly and unlike cases differently. In the era of NAT in which donated blood can be tested directly, it is less important how a person acquired the virus since after the NAT window period, each unit of blood carries the same, detectable risk (American Medical Association 2011). It is an ecological fallacy to assume that all MSM are equally high-risk and that all non-MSM are equally lower-risk (Kesby & Sothorn, 2014; Cascio & Yomtovian, 2013). The MSM population (much like any other segment of society) is not homogenous. Blanket policies that treat the MSM as such unfairly prohibit those MSM that are low-risk from donating blood. Some have argued that those in monogamous relationships, MSM who always wear condoms, and those on pre-exposure prophylaxis (PrEP) have a much lower transmission rate of HIV than the general MSM population – or other groups that are currently allowed to donate – and thus should be allowed to donate (Arora et al, 2015). Therefore, questionnaires that screen for specific high-risk behaviors are more appropriate than those featuring broad questions regarding membership in a heterogeneous group which do little to inform a medically and ethically appropriate risk stratification process. Ideally, these questionnaires would assess the likelihood that a person has acquired HIV during the NAT window period – the central consideration in terms of safety – regardless of mechanism of doing so.

In addition to the ethical imperatives that blood donation policies be safe and formally equal, there exist additional ethical considerations from a societal standpoint including the duty to maintain the public's trust in the blood supply. There is also a duty to update guidelines based on science and thus, the ethical imperative to conduct research to inform evidence-based practice in order to maximize safety (Wilson et al, 2014). Furthermore, society is ethically obligated to maintain an adequate blood supply. In our current framework of voluntary, non-remunerated blood donation, a maximally safe blood supply can only be achieved if a sufficient number of individuals partake in the donor pool (Bonig et al, 2012).

One report estimated that the current 12-month deferral will result in an additional 53,269 donors or an additional 89,716 pints of blood donated each year (Naomi & Gates, 2014). Thus, the public health ethical ramifications of the new deferral should be further studied, though the public comment period and the continued availability of the blood supply will help to guide this process.

Finally, blood donation deferral policies should be evaluated in terms of their discriminatory intent, effect, and expression (Fox, 2010). As previously discussed, while it is appropriate to be concerned regarding increased medical risks due to infection, it is inappropriate and discriminatory to be selectively precautionary in the context of one subpopulation while simultaneously having shorter deferrals for other high-risk populations. Furthermore, removing social obstacles such as discrimination can be seen as a net ethical good for society. A policy that is not evidence-based, consistent, and fair reinforces negative stereotypes and aggravates the stigma associated with MSM (American Medical Association, 2011).

Alternative strategies such as individualized risk assessment (such as done in South Africa and Italy), improved compliance, increased donor education, and a two-step donation process that includes the retesting of donors after the 11-day NAT window should all be considered (Arora et al, 2015; Suligoi et al, 2013; Heyns, 2006; Offergeld et al, 2014). These alternative strategies, some of which are utilized in other countries, would not require MSM in monogamous low-risk relationships to maintain abstinence for one year prior to donating blood. Instead, such strategies would appropriately defer members of society exhibiting true high-risk behaviors. As new evidence accumulates regarding the impact of the 12-month policy on the actual and perceived safety and availability of the blood supply, it is crucial to revisit the deferral discussion and to potentially revise as necessary. For example, while Great Britain and Australia also have 12-month deferrals, France recently removed its ban on gay men from serving as donors last year (Arora et al, 2015). Through balancing the primary duty to safety with the imperatives to craft a policy that is formally equal, upholds the public's trust, and is non-discriminatory, an ethical blood donation deferral guideline may be advanced, both for MSM and the population at large.

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