"Tainted Blood or Tainted Policy? The MSM Regulations on Giving Blood: Is it Time to Modify the Ban?"

Kevin F. Green

Delaware Valley University

Americans woke up the morning of 01 October 2017 to horrific news; a lone gunman in Las Vegas had killed 58 people and injured over 500. The incident became the deadliest individual mass shooting committed by an individual in the United States. As the grim details began to emerge and a shocked nation was trying to understand, within hours residents of Las Vegas queued at blood centers to donate. Local area blood banks were overwhelmed with donations (Hauser, 2017). Although donations were needed it was not due to this shocking event. Nevada was experiencing a shortage of blood that just recently officials had categorized as "dangerously low." A message posted shortly before the shooting on the Las Vegas United Blood Services' website noted that donations had been declining for several weeks and that inventory levels had dwindled.

While some of the blood donated that day went to the victims, the majority was used to replenish an already low supply. There is a misconception in the United States that blood is most needed during disasters. This is not true. The daily need for blood and blood products for medical procedures continuously drains the existing supply. According to the American Blood Center's website seventy two percent of the daily need for blood comes from hospital-based surgeries, ICUs and general medicine. The need for blood is constant and with decreasing donations each year it has resulted in a critical shortage.

Unfortunately, our nation's shortage of blood continues to be affected by outdated and, arguably prejudicial restrictions on who can donate. Until recently gay men, more specifically men who have sex with men (MSM), have been ineligible to donate blood due to perceived risk of disease transmission. Since December 2015

donation is allowed only if MSM have had no sexual contact with another man in the past year as such contact is considered high-risk. However, there is no such prohibition for heterosexuals who engage in high-risk sexual activities. The problem is this categorical ban does not properly balance the need for additional donors and maintaining the safety of our blood supply. A more evenly applied screening of high-risk activities of all donors, regardless of sexual partner, is needed.

Part One - Background

In 1985 the Food and Drug Administration, needing to protect the blood supply, implemented a policy to exclude blood donors considered at high risk of contracting HIV. MSM were permanently deferred along with Haitians, commercial sex workers, and intravenous drug users. The United States was in the middle of a health care emergency and those groups represented the highest incident of HIV infection. Without a screening test for HIV there was public and scientific unity regarding the ban, especially in light of the exigent nature of the disease. However, what began as an emergency policy has remained an entrenched one.

The FDA has upheld their MSM policy based on data that gay and bisexual men continue to be, as a group, at highest risk of contracting HIV; concerned that even with testing there is a risk infected blood may make it into the blood supply. However, others at elevated risk of HIV are subject to significantly less restrictive deferral or no deferral at all. The maintenance of inconsistent deferral policies highlights the need for a clearer standard that focuses on behavior not sexual partner. If any high-risk activity could jeopardize the blood supply should not precautions be taken? Conversely, if there is

evidence that a MSM donor does not practice high-risk activities should they not be allowed to donate blood?

Part Two – Compounding the Need

Las Vegas is not alone in the need for a robust blood supply. As of July 2017, the American Red Cross (ARC) advertised it was facing a blood shortage when it issued an emergency call for eligible individuals to donate blood. There were 61,000 fewer donations than what was needed (American Red Cross, 2017).

Data from the National Health Survey shows that in 1973 there were 10.2 million US blood donors (Health Statistics, 1976). Today that number is around 6.8 million, according to the American Red Cross. They estimated that of the 38% who are eligible less than 10% actually donate. Each day 14,000 donors are needed to maintain the nation's blood supply (American Red Cross, 2017).

All donated blood undergoes extensive testing for syphilis, HIV, and hepatitis among others diseases. Introduction of nucleic acid amplification testing (RNA) modalities in 1999 greatly improved the sensitivity (proportion of positives that are correctly identified) and specificity (proportion of negatives that are correctly identified) of viral testing. Such testing has reduced the risk of HIV infection to approximately one in two million blood units (Stramer, 2004).

Current generation RNA tests can detect HIV antibodies within seven to 14 days (window period) of infection as it identifies the specific pathogen rather than the antibodies. Older HIV tests used to identify antibodies, such as enzyme immunoassay and Western blot, have a window period of three months. Concern is that testing in a window period would provide negative or indeterminate results (Quest, 2017 / Clinical

Laboratory, 2011). RNA testing has reduced incidents of infection to one in two million blood units (Stramer, 2004). Despite higher infection rates among MSM, improved testing mitigates the risk of HIV transmission.

With the need for increased blood donations and robust screening techniques why is the FDA continuing to categorically defer MSM, a significant population willing to donate?

Part 3 – Governmental Policy Obstacles

The FDA remains steadfast in maintaining a ban on MSM donations. Changes were considered in 2001 and 2006 yet it was not until December of 2015 that the original exclusion policy was replaced. New regulation means that men can only donate if they have not had sexual contact with another man in the past twelve months. Along with citing a significant level of HIV in the MSM population the FDA cited this deferral was in line with other countries' policies (CBER, 2015). Under current screening guidelines the term 'sex' is defined by the respondent with no opportunity to make a distinction between high risk (unprotected anal sex) or low risk (i.e. frontage, oral sex) activities. Heterosexual respondents (other than those who acknowledge intravenous drug use or contact with sex worker) who engage in high risk activities would not be excluded.

Studies vary, but it is generally accepted that there are 10 million men (8.5%) in the US that have had at least one male sexual partner. It is estimated that if the MSM ban were lifted an additional 360,600 men would likely donate, a 4% increase. If MSM who have not had sexual contact with another man in the past twelve months were

permitted, 185,800 additional men would likely to donate, a 2% increase (Miyashita, 2014).

Although higher than other groups, HIV infection rates are on the decrease among MSM. The CDC reported in 2015 (the last complete year of data) that gay and bisexual men accounted for 67% of the total new diagnoses; down from 78% (CDC, 2017). Conversely the percentage of heterosexual transmission is increasing.

However, this statistic is not representative of the MSM donor pool, as the FDA points out. The prevalence of HIV infection in blood donors who reported that they were MSM was determined to be 0.25%, much lower than the estimated 11-12% HIV prevalence in the MSM population. This indicates that considerable self-selection likely took place in individuals who donate (CBER, 2015).

In a study conducted in 2015 by Sheon S. Hughes, Qualitative interview findings from the blood donation rules opinion study, MSM who donate recognize the higher incidence of HIV in their population but considered themselves low-risk and with an altruistic goal of 'saving lives' (Hughes, 2015). Predominant reasons for donation, based on a 2013 United Kingdom study, were categorizing oneself as low risk (Slowther, 2013). Gay and bisexual men are more likely to test for HIV specifically or as part of their routine medical care. Self-screening may not be adequately reflected in the FDA's review of the data. Recently a study showed that only 8.9% of MSM would qualify to donate though 90.6% would donate. More interestingly 26.7% admitted to donating despite the prohibition giving rise to the true effectiveness of the current screening methodologies (Liszewski, 2017).

However, even in light of the above the FDA is not immune to the public's perception. MSM deferral policies often involve government and external consultations to address the public's perception and trust (Wilson, 2014). After 30 years many still consider HIV a 'gay disease' perpetuating stigma around transmission (Yarber, 2013). In 2012 a proposed federal pilot study to assess the effect of a policy change met rebuke from public comments to the Federal Register. Comments were largely from conservative groups related to concern over changing social norms rather than soundness of the research. No such federal studies have been conducted since.

There are less restrictive alternatives; reducing the deferral period, pretesting all potential donors and implementing risk-based questionnaires.

The speed of obtaining RNA results supports a reduced deferral period. MSM donations would increase with any any deferral period that is shortened. However, the challenges of re-engaging deferred donnors remain. More research is needed regarding deferred donor follow up. Any categorical deferral of MSM does not address at risk activities in other growing donor populations.

Rapid testing has revolutionized HIV screening efforts. The bioLytical INSTI™ test can detect HIV in 60 seconds (INSTI Package Insert, 2014) and the OraSure HIV testing kit in 20 minutes (OraQuick® Package Insert, 2004). However, testing has costs and operational considerations such as results counseling which makes this not a viable option. The FDA stated that pretesting would be logistically challenging and likely viewed as discriminatory with resource constraints difficult to implement (CBER, 2015).

Part Four – A Better Solution

The FDA should move to a risk-based screening system. After assessing the donor's personal sexual practices, a deferral is given only for those with an identified high risk. For all others, the deferral should be eliminated. This policy would allow donors, without respect to sexual partner, at low or no risk of HIV to donate blood. The FDA has stated that individual risk assessment would be extremely difficult to validate and implement in our current donor system due to resource constraints (CBER, 2015).

However, this policy would be facilitated by the fact that there are validated assessment tools already being utilized. The current FDA blood donor questionnaire has questions to identify potential risk. In order to differentiate between low and medium risk MSM donors, the individual risk assessment questions could refocus on recent sexual history questions (CBER, 2016). The CDC released the PrEP (HIV prophylaxis) guidance in 2014 with a risk index tool to quickly determine which MSM are at high risk of acquiring HIV (CDC, 2014). This approach can identify individuals, rather than categories, who may present a risk to the blood supply. The American Association of Blood Banks (AABB), America's Blood Centers, and the American Red Cross have advocated for the adoption of similarly comprehensive approaches (AABB, 2014). The FDA should give more consideration to developing risk based assessment and look to integrate existing tools. The increase in donations should offset any resource constraints.

The FDA's resistance to change has centered largely on its view that sufficient data does not yet exist to support a less restrictive approach. More data is needed; however, less restrictive policies have existed elsewhere prior to the policy change and should be closely reviewed. Nearly 20 industrialized countries have a less restrictive or

no ban policy. Italy, Spain, Argentina, Mexico, Poland and Russia, do not defer MSM. In 2016 the United Kingdom reduced their MSM deferral to three months. After a year long governmental review of the policy, the National Health Service supported the change.

Dr. Moira Carter, of the Scottish National Blood Transfusion Service stated "[i]t's very frustrating for gay men who are monogamous, even in long-term relationships, who are married and have children, to not be able to give blood. What is not acceptable is to make the deferral period longer than the risk period and to do so would be discriminatory."

Italy adopted in 2008 a model utilizing risk behavior screening questions and blood testing for all donors regardless of sexual partner. Individuals who are flagged by screening, not by lifestyle, are deferred. They have not experienced an increase in infected donations since implementing this policy (GHMC, 2010).

While Italian results are encouraging there are related issues that still need to be addressed. Objective training standards and implementation guidelines are needed. Other potential issues include: privacy concerns; eliciting truthful responses; time efficiency; and the potential of such questions to discourage individuals from donating.

Since the initial categorical ban of MSM was put in place more than 30 years ago advances in the testing and processing of donated blood, changes in the epidemiology of sexually transmitted infections and improved scientific knowledge have shown it needs to be reversed. What remains in place is a what some consider a prejudicial attitude towards MSM. The deferral from blood donation of MSM, whether for a fixed period or permanently, will continue to be a keenly debated issue with competing views

being expressed on both sides of the argument. However, any policy change should be guided by the latest available scientific evidence and not archaic and prejudicial views. Risk based screening would be more effective than a categorical deferral ban by increasing overall donation rates and reducing risk of transmitting HIV. A blood donor system that is based on screening for high-risk sexual behaviors not sexual partner is needed. The current 12-month ban excludes a large number of MSM who could donate and prevents what should be the agency's goal: to safely increase the nation's donor pool.

References

American Association of Blood Banks. (2014, November). *Joint statement on ACBTSA recommendation to change MSM deferral policy*. American Association of Blood Banks. Retrieved October 15, 2017, from http://www.aabb.org/advocacy/statements/Pages/statement141114.aspx

American Red Cross. (2017, July 5). Emergency need for blood donations as red cross experience critical blood shortage. *American Red Cross*. Retrieved October 15, 2017, from http://www.redcross.org/news/press-release/Emergency-need-for-blood-donations-as-Red-Cross-experiences-critical-blood-shortage

bioLytical Laboratories, Inc., Package Insert. (2014). *INSTI™ HIV-1/2 Antibody Test Kit*. Retrieved from https://www.fda.gov/downloads/Biolog...remarketApprovalsPMAs/UCM235249.pdf

Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, U.S. Department of Health and Human Services. (2015). *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*. Retrieved from https://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm

Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, U.S. Department of Health and Human Services. (2016, May). *Implementation of acceptable full-length and abbreviated donor history questionnaires and accompanying materials for use in screening donors of blood and blood components*. Retrieved from https://google2.fda.gov/search?q=implementation+of+acceptable+full+length+and+abbreviated+donor+history+questionnaires&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&requiredfields=-archive%3AYes&output=xml_no_dtd&getfields=*

Centers for Disease Control and Prevention, U.S. Public Health Service, U.S. Department of Health and Human Services. (2014). *Preexposure prophylaxis for the prevention of HIV infection in the united states – 2014 A Clinical Practice Guideline*. Retrieved from https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

Centers for Disease Control and Prevention, U.S. Public Health Service, U.S. Department of Health and Human Services. (2017, September 27). HIV and AIDS diagnoses. *Center for Disease Control and Prevention*. Retrieved October 15, 2017, from https://www.cdc.gov/hiv/group/msm/index.html

Clinical and Laboratory Standards Institute. (2011, June). *M53-A Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection*. Retrieved from https://clsi.org/media/1442/m53a_sample.pdf

Gay Men's Health Crisis. (2010). *A drive for change reforming U.S. blood donation policies*. Retrieved from http://www.gmhc.org/files/editor/file/a_blood_ban_report2010.pdf

Hauser, C. (2017, October 2). Blood donation lines for Las Vegas shooting victims stretch for blocks. The New York Times. Retrieved from https://www.nytimes.com/2017/10/02/us/donate-blood-las-vegas.html

Hughes, S., Sheon, N., Siedle-Khan, B., Custer, B., & NHLBI Recipient Epidemiology and Donor, Evaluation Study. (2015). Saving Lives, maintaining safety, and science-based policy: Qualitative interview findings from the blood donation rules opinion study (blood DROPS). *Transfusion*, 55(12), 2835.

Liszewski, W., Terndrup, C., Jackson, N.R., Helland, S., & Lavin, B.C. (2017). The beliefs and willingness of men who have sex with men to comply with a one-year blood donation deferral policy: a cross-sectional study. *Transfusion*, 57(9), 2234.

Miyashita, A., & Gates, G. J. (2014, September). *Update: Effects of Lifting Blood Donation Bans on Men Who Have Sex with Men*. Retrieved from *https://williamsinstitute.law.ucla.edu/wp-content/uploads/Blood-Ban-update-Jan-2015.pdf*

National Center of Health Statistic, U.S. Department of Health Education and Welfare, Health Resources Administration. (1976). *Blood Donor Characteristics and Types of Blood Donations United States – 1973.* Retrieved from https://www.cdc.gov/nchs/data/series/sr_10/sr10_106.pdf

OraSure Technologies, Inc., Package Insert. (2004, July). *OraQuick® Advance Rapid HIV-1/2 Antibody Test*. Retrieved from https://www.fda.gov/downloads/BiologicsBloodVaccines/ucm091917.pdf

Quest Diagnostic Laboratory Guidelines. (2013, July). HIV-1 RNA, Qualitative TMA. *Quest Diagnostic Laboratory Guidelines*. Retrieved October 15, 2017, from http://www.questdiagnostics.com/testcenter/testguide.action?dc=TS_HIV-1_RNA_Qual_TMA

Slowther, A., Watkins, N.A., & Kelly, D. (2013, Jun). Evidence-Based Policy and Practice Leads to Changes in the Criteria for MSM to Donate Blood. *Transfusion Medicine and Hemotherapy*, 40(3): 155–158. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3725011/

Stramer, S. L., Glynn, S. A., Kleinman, S. H., Strong, D. M., Caglioti, S., Wright, D. J.,…Busch, M. P. (2004). Detection of HIV-1 and HCV infections among

antibody-negative blood donors by nucleic acid-amplification testing. *The New England Journal of Medicine*, 351(8), 2004,760-768. doi:10,1056/NEJMoa040085

Walker, Peter. (2017, May 06). Government set to make it easier for gay men to give blood. The Independent. Retrieved from http://www.independent.co.uk/news/health/gay-blood-donation-sex-aids-three-months-year-a7721606.html

Wilson, K., Atkinson, K., & Keelan, J. (2014) Three decades of MSM donor deferral policies. what have we learned? *International Journal of Infectious Diseases*, 18, 1-3.

Yarber, W., Sayad, B., & Strong, B. (2015). *Human sexuality: Diversity in contemporary america, 8th edition*. New York, NY: McGraw-Hill Education