Assessment of the Safety of Donated Blood Products after Reduction of the Deferral for Men who have Sex with Men Blood Donors from Twelve Months to Three Months

In November 2017, Great Britain reduced their deferral for blood donation by men who have sex with men (MSM) from one year to a three month deferral after their last at-risk sexual encounter ((Sturrock & Mucklow, 2018). Ten months after this policy change, the article "What is the Evidence for the Change in Blood Donation Deferral Period for High-Risk Groups and Does it go Far Enough?" was published in the Royal College of Physicians Clinical Medical Journal in August of 2018. This article addresses the historical context for variation in blood donation guidelines, the social ramifications of these rules, the statistical prevalence of transfusion transmissible infections (TTI) in the population of MSM compared to the general population, and different models for how the policy change may impact the rates of TTI in the blood donation pool. This article is exceptionally relevant given the United States' transition from a twelve month to a three month deferral for MSM blood donors in May of 2020. This policy change poses an interesting discussion including if this increases the risk of TTI with blood transfusion and whether this adequately addresses an unjust rule eliminating MSM as blood donors.

Deferrals for blood donors were established to ensure the safety and efficacy of transfused blood products. There are three types of deferrals: temporary, indefinite, and permanent. Temporary deferral refers to a deferral for a defined time, often due to a recent vaccination or a medication. This type of deferral can be very important to ensuring that blood products obtained from the donor will be maximally effective; such as in a case where a donor comes to donate platelets, but they have recently taken aspirin, clopidogrel, or another anti-platelet medication. They will be deferred from donating platelets until the platelets affected by that medication have cleared from their system because any unit taken from them with that medication in effect would not provide the intended therapeutic impact if administered to a

patient. Permanent deferrals remain in place for the duration of a donor's lifetime and are often associated with a disease state; in example a confirmed HIV infection. Finally, indefinite deferral is temporary, pending termination of the event that caused the deferral. This category includes local outbreaks of potentially transmissible infection or a concerning testing of a previously donated product.

MSM was initially established as a permanent deferral in 1982 by the FDA during the height of the AIDS epidemic (BBGuy Essentials 080CE, 2020). Since there was mystery surrounding the transmission of this disease and it was commonly seen in homosexual males, this lead to the initial exclusion of MSM from donating blood. However, even after the transmission of the HIV virus was better understood, this permanent deferral from blood donation for MSM remained in place until 2015, when this transitioned to a twelve month deferral after the last at-risk sexual contact. There has been one more relevant policy change in the United States since the 2015 transition, and as of May 2017, MSM are deferred from donating blood for three months after their last at-risk sexual encounter. However, despite these policy changes, the discussion remains to assess whether blood products from MSM pose an increased risk for TTI.

There is a concern that HIV and other TTI are of higher prevalence in the MSM population, thus making them a higher risk group for donating blood. The prevalence of HIV in the general population of the UK in 2016 was 1.6 per 1000 people, and 57.8 per 1000 people in MSM (Sturrock & Mucklow, 2018). Comparatively, a report by the CDC tracking HIV trends in the United States from 2014-2018 found the HIV prevalence to be 3.7 per 1000 people, and approximately half of those cases were in MSM (Estimated HIV Incidence and Prevalence, 2019; U.S. Census Bureau QuickFacts: United States, n.d.). A HIV screen is performed on every

donated unit, and the hope is that all HIV-infected units are detected in this screen and removed from the donor population. However, the complicating factor is that there is a window period between when an individual is infected with HIV and when the virus can be detected in the blood. The window period for detecting HIV with nucleic acid testing (NAT), which detects the viral genome in the sample, is only five days (Sturrock & Mucklow, 2018). NAT is more expensive than serological tests and is commonly used as a confirmatory test after repeat-positive serological testing via two different validated serological tests. The window period for serological tests if 15 days (Sturrock & Mucklow, 2018). Therefore, the combination of these improved testing methods and stringent deferral policies aims to reduce the potential for HIV-infected blood products to enter the donation pool. The current recommendation is to have a deferral twice the length of the window period (Sturrock & Mucklow, 2018) to increase the likelihood that all potentially HIV-infected blood products are caught prior to release to the donor pool. This supports that even a three month deferral may be longer than necessary to maintain a safe donation pool. A reflective study following the deferral shift in the UK found that in the transition from a twelve month to a three month deferral, the risk of donation of an HIV-positive unit increased 0.18-0.67 per million products donated, this was deemed to fall under the threshold of less than one per one million units. Additionally, it is notable that there have been no instances of HIV transmission in plasma products in the United States since the late 1990s (Improved Deferral Periods for Blood Donors, 2019). This policy shift in the UK provides a thoroughly studied model of measured and minimal risk to support similar policy changes in the United States.

An additional consideration when designing blood donor deferral policies is the level of expected compliance and honest reporting on screening questionnaires. Individuals often choose

to donate blood products because it makes them feel good to help others, which may cause a donor to underestimate the importance of the screening questions and proceed to donate (Sturrock & Mucklow, 2018). This supports the reduction of the deferral for MSM because a shorter, but well-enforced deferral period may be more successful at reducing the number of potentially HIV-infected blood products entering the donation pool. Furthermore, the blanket deferral affecting all MSM does not consider social factors that may reduce the riskiness of MSM encounters, such as long-term, monogamous sexual partnerships. Finally, MSM composes a significant portion of the population which is excluded from regularly donating blood. Although there are increasing medical interventions that may serve as an alternative to blood product administration, there is still a pressing need to increase blood products in the transfusion pool. This blood product shortage was exacerbated by the challenges of the SARS-COVID-19 pandemic decreasing blood drives and regular blood donations.

The policy change in 2017 in the UK to reduce the deferral from blood donation for MSM from twelve months to three months serves as model for similar policy changes in the United States given that the effects on the safety of the donor pool were thoroughly studied. Since this reduction of deferral, there has been no significant increase in the donation of HIV-infected blood products in the UK. Close monitoring of TTI rates in donated blood products is important to ensure the continued safety of the transfusion pool. This policy change seems like a step in the right direction to increase the number of safe blood products available for transfusion.

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