Individual Risk-Based Assessment for Blood Donation in the United States—Is It Time?

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See also Park et al., p. 247.

The COVID-19 pandemic has focused attention on two issues that have been of ongoing discussion and public health concern in the United States: continued declines in blood product utilization coupled with even larger declines in blood donation collection. These issues have resulted in a tenuous situation of a product with limited supply and limited shelf life. The pandemic has highlighted the effort required to maintain an already delicate balance of blood collection and supply and exacerbated the ramifications of such a limited supply by causing an additional, immediate, and significant reduction in the number of voluntary blood donations across the United States because planned blood drives following shelter-in-place orders were canceled.

In April 2020, the US Food and Drug Administration (FDA) issued recommendations that included a reduction of the then deferral period for men who have sex with men (MSM) from 12 months to 3 months from last sexual contact with a man.[1] These changes were long in the making and were issued following a dramatic decrease in blood product availability following the COVID-19–related significant and abrupt drop in blood donation. Although the reduction in the MSM deferral period was not the only change made to donor deferral criteria, reductions in time-associated deferrals for travel-associated malaria, Creutzfeldt–Jakob disease, and variant Creutzfeldt–Jakob disease would not be expected to have similar import; removing the MSM time-based deferral is estimated to provide upward of a half million donations per year. Yet, following the issuance of this recommendation, a response to the call for blood donors who have recovered from COVID-19 (convalescent plasma) still resulted in some MSM being turned away from donation. Changes to the blood collection and testing infrastructure must be made timely and adopted uniformly to ensure that the safety of blood recipients remains the priority, while balancing the residual risk of any donated blood product with the availability of those products.

In "Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have Sex With Men," Park et al. (p. 247) present their argument for eliminating time-based deferral and implementing risk-based deferral for blood donation in the United States to strengthen the resilience of the public health reliance on the voluntary blood donation system. The authors present the rationale that the reduction to three months deferral rather than elimination of the deferral entirely ignores scientifically rigorous studies indicating that the blood screening assays currently in use have a documented HIV-positive detection period of, most conservatively, 7 to 10 days, thereby reducing the risk of transfusion-transmitted HIV infection to the transfusion recipient to significantly less than that of more common, noninfectious disease complications from transfusion, such as those caused by circulatory overload.[2–5]

The authors' platform includes immediately implementing a universal, self-reported, risk-based deferral questionnaire that affords the opportunity for blood collection organizations to bring in new and subsequently return blood donors, alleviating some of the stress on the collection side by increasing the eligible blood donor population. Blood donation deferral should be based on individual risk assessment, regardless of gender identity or sexual orientation. Park et al. highlight that conflicting blood donation guidelines remain in place, as currently the donor health questionnaire permits a donor to self-identify gender and asks for their knowledge of sexual partner habits. They point to studies demonstrating donor lack of understanding of the donor health questionnaire, admission of not fully reading questions before answering them, and concealing behavior to donate blood, regardless of risk level.

Where individual risk-based blood donor deferral programs have been established, studies have shown no increase in HIV incidence in blood donations. The authors put forward these studies as documented evidence of the effectiveness of the individual risk-based assessment.

However, to be effective, the risk-based assessment must be written in language that is not confusing to a donor and must be branched according to risk stratification to avoid undue donor time burden at the collection point. Perhaps donors at higher risk could be counseled and deferred for a specified period and low-risk donors would proceed to donation, but whatever the process would ultimately be, the donor health questionnaire in the United States is designed to be self-administered, with a few additional probing questions for travel outside the United States and medication use, and there are potential issues with stigma and failure to disclose behaviors when donors are questioned face-to-face regarding behaviors.

How then can the donor health questionnaire and the subsequent interview process be streamlined so they lead to better disclosure and reduced risk for the transfusion recipient? The risk-based questionnaire with a branching design for risk stratification definitely has merit, and in fact a study sponsored by the FDA that has been designed to collect information to support the development of such a questionnaire is being piloted,[6] but continued monitoring, rapid review of results, and open public discourse that includes all stakeholders is key. The authors present a rational argument that deserves thoughtful consideration and continued discussion. AJPH

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CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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