

IMPLEMENTATION OF Individual Donor Assessment

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How Individual Donor Assessment Was Informed by Research

In the United States, all blood donations are tested for known transfusion-transmitted infectious agents that pose a risk to patient safety. Screening of all potential donors using the Donor History Questionnaire (DHQ) is also critical for patient safety. This pre-donation screening helps to further safeguard the blood supply against recently acquired infections by asking donors about recent behaviors that could potentially have exposed them to an infection that may not be detected by testing or for which testing is not currently available.

The “window period” is the time after an infection is acquired but before it can be reliably detected by testing and is a limitation of currently available tests. Asking about behaviors in the past three months allows blood collectors to adequately cover the “window periods” for hepatitis B and C and HIV testing.

Individual Donor Assessment

In January 2023, the U.S. Food and Drug Administration proposed new recommendations for gender-inclusive, sexual behavior-based screening questions for all blood donors. With this change, the DHQ used to screen blood donors will no longer include questions specific to men who have sex with men (MSM).

Instead, the new criteria will ask all donors, regardless of gender or sexual orientation, if they’ve had a new or multiple sexual partners in the past three months. If a donor answers yes to having had a new or multiple sexual partners, they would be asked if they’ve had anal sex with any of these partners. Donors who report having had a new sexual partner, or more than one sexual partner in the past three months and anal sex in the past three months, will be required to wait three months from the date they most recently had anal sex to donate. If they have not, and meet all other eligibility criteria, they will be able to donate. This change means that more sexually active gay, bisexual and other MSM will be eligible to donate blood.

To inform this decision, FDA considered data from the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study, data from the transfusion transmitted infections monitoring system (TTIMS), and data from research conducted in countries that previously adopted individual donor assessment to determine blood donor eligibility.

The ADVANCE Study

Much of the research that informed the decision to recommend individual donor assessment came from the ADVANCE study, a landmark pilot research collaboration between Vitalant, OneBlood, and the American Red Cross designed to evaluate alternatives to the FDA's 3-month blood donor deferral policy for MSM. It was the first step in determining whether individual donor assessment could be used to effectively evaluate donor risk to support eligibility and deferral decisions at blood centers while maintaining the safety of the blood supply.

The ADVANCE study examined a number of HIV risk factors, such as anal sex and rates of HIV infection among MSM study participants. In addition, the ADVANCE study determined the rates of Pre-exposure Prophylaxis (PrEP) and Post-exposure Prophylaxis (PEP) use among MSM study participants. Study findings have not yet been released publicly, but FDA has reviewed the data and determined it supported a transition to individual donor assessment.

Transfusion-Transmitted Infections Monitoring System

TTIMS is a blood donation safety monitoring program established in 2014. The TTIMS project includes characterization of transfusion-transmissible infection (TTI) marker risks in at least half of the U.S. blood supply with monitoring of temporal, geographic and demographic trends. TTIMS also provides a framework for evaluating the effect of a new intervention (such as implementation of a new deferral policy) on TTI risks and blood donor risk factors.

TTIMS data demonstrated that there was no increase in HIV positivity in the blood supply following a previous expansion of donor eligibility in 2015,¹ and FDA will continue to use TTIMS after this change to monitor and maintain the safety of the blood supply.

Research and Data from Outside of the United States

FDA's decision to recommend an individual donor assessment approach to donor screening and eligibility relied in part on surveillance, epidemiology and risk assessments conducted in the United Kingdom and Canada, which adopted gender-neutral donor eligibility process in 2021 and 2022, respectively. The U.K.'s [FAIR Report](#) and Canadian Blood Services' [Research Resources](#) describe the scope and results of these studies in detail.²⁻⁵ To date, the United Kingdom and Canada have not reported safety concerns following the implementation of individual donor assessment. The FDA's proposed donor screening and deferral recommendations are similar to those used in the U.K. and Canada but are adapted for use in the United States.

*This information will be updated after FDA publishes additional information about the research data supporting the agency's decision to recommend individual donor assessment.

Key references

1. Custer B, Stramer SL, Glynn S, Williams AE, Transfusion-transmissible infection monitoring system: a tool to monitor changes in blood safety, *Transfusion* 2016, 56:1499- 1502.
2. Caffrey N, Goldman M, Lewin A, Grégoire Y, Yi Q-L, O'Brien S, Removing the men who have sex with men blood donation deferral: Informing the risk models using Canadian public health surveillance data, *Transfusion Clinique et Biologique*, 2022, 29:198-204.
3. O'Brien SF, Goldman M, Robillard P, et al., Donor screening question alternatives to men who have sex with men time deferral: Potential impact on donor deferral and discomfort, *Transfusion* 2021, 61:94-101.
4. Goldman M, Caffrey N, O'Brien SF, Screening for high-risk sexual behavior in Canada, *Transfusion* 2022, 62:2419-2422. 34. Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). Donor Selection Criteria Report. July 2017. <https://www.gov.uk/government/publications/blood-tissue-and-cell-donor-selectioncriteria-report-2017>.
5. FAIR. Can donor selection policy move from a population-based donor selection policy to one based on a more individualized risk assessment? Conclusions from the For the Assessment of Individualized Risk (FAIR) group; 2020.

AABB partnered with Canadian Blood Services in the development of these materials.

Additional information and resources on individual donor assessment is available at aabb.org/ida.