



Position Statement: Individual Risk Assessment

January 27, 2023

The Association for the Advancement of Blood and Biotherapies (AABB) commends the Food and Drug Administration (FDA) for its draft guidance recommending that blood donor eligibility be based on an individual's behavior and risks, regardless of gender or sexual orientation. Under the draft guidance, the current time-based blood donor deferral for men who have sex with men (MSM) would be eliminated.

For years, AABB has led efforts to champion the adoption of inclusive, science-based eligibility processes that support the safety and availability of the blood supply. The draft guidance from FDA meets these standards.

We applaud FDA for basing the recommendations in the draft guidance on the currently available evidence, including the ADVANCE (Assessing Donor Variability and New Concepts in Eligibility) study, which evaluated individual risk assessment strategies, surveillance information from the Transfusion-Transmissible Infections Monitoring System, data regarding the performance characteristics of nucleic acid testing, and the experiences of other countries, including the United Kingdom and Canada.

AABB works to continuously advance the importance of ensuring that blood donor deferral policies do not unnecessarily exclude individuals who are able to donate blood safely. FDA's draft guidance is a significant step towards the country's adoption of an individual risk-based approach to blood donor eligibility. We encourage FDA to finalize the draft guidance expeditiously following the public comment period and we look forward to submitting to FDA the new donor screening tools that incorporate individual risk assessment as soon as possible.