

# IMPLEMENTATION OF Individual Donor Assessment

## Timeline for Implementation of Individual Donor Assessments: Talking Points and FAQs for Blood Collection Facilities

Blood collection facilities may receive inquiries from donors or from the media about new eligibility criteria while the blood community works to implement the recommendations in FDA's final guidance. AABB believes that during this interim time period, it is important that the blood community be transparent and proactive with communications. AABB has developed these talking points and FAQs to help blood center staff answer questions, to support accurate proactive communications, and clarify any misunderstandings about the timeline for implementation.

### Background on the final guidance timeline:

- On May 11, 2023, FDA released its final guidance requiring an individual donor assessment (IDA) approach for donor screening process and new gender-inclusive questions for all individuals to determine blood donor eligibility.
- On the same day, FDA formally recognized the new version of the donor history questionnaire (DHQ), which is a critical tool for implementing the new donor screening criteria.
- Blood collection facilities throughout the United States are now permitted to begin the months-long process to carefully implement the new IDA eligibility criteria. Blood collection facilities are looking forward to welcoming new and returning donors as soon as the extensive work is completed and are working diligently to do so.
- Depending on the individual blood collection facility, this process is expected to take between two and six months. This process includes:
  - Developing new policies and procedures to align with new FDA requirements, including full review and sign off by medical director.
  - Updating the FDA-regulated Blood Establishment Computer System with all changes required by FDA, including completion of FDA-required testing and validation of performance to ensure blood safety.

- Developing new donor screening materials required for IDA, including extensive updates to electronic donor screening software.
- Completion of comprehensive staff training to educate all teams on new policies and the development of new SOP documents.
- Performing and documenting all staff competency assessments to support blood safety.
- Completion of additional training donor-facing staff on new screening questions and protocols, since they will have an important role in answering questions from donors and the public.

**Did you know?** Donor screening computer systems and blood safety computer systems must be approved by FDA as medical devices. Changes to blood donor center computer systems require detailed and precise steps and quality control measures to meet all FDA requirements because they help ensure the safety of both patients and donors.

## **FDA finalized the guidance, so why can't I donate today?**

- Implementing the new donor screening criteria has many steps that take time to correctly implement. For example, all blood collectors must update their computer programs and protocols, train staff appropriately, and confirm processes will be performed as required to ensure the continued safety of the blood collection process for donors and patients.
- Blood collection facilities throughout the United States look forward to welcoming new donors when the transition to the new IDA-based screening criteria is completed.
- Every blood collection facility in the United States is working diligently to get these updates in place as quickly as possible, while ensuring the quality of the new processes, and must continue to collect and prepare blood to meet the needs of patients on a daily basis

## **I saw another center is already utilizing the updated IDA screening questions. Why aren't you?**

Each blood center is a bit unique in their resource and processes for making these significant changes. However, we all share the same commitment of making these changes as quickly as possible.

*TIP: Reference your center's talking points specific to your implementation timeline.*

## **Are you stalling because you don't want my donation?**

- We are grateful to donors and prospective donors of all ages and backgrounds who understand the importance of life-saving blood donations and welcome them to our centers.
- Every blood center is committed to making the transition to the new screening protocols as quickly as possible, while maintaining the highest quality of safety for each donor and the patients who will receive their donated blood.

- The blood community remains committed to continuing to address systemic barriers, further modify practices and policies, and to welcoming a diverse donor base that more fully and equitably reflects and serves the U.S. population.
- The blood community is committed to diversity, equity, inclusion and access (DEIA), not only because it is the right thing to do, but because as a science- and evidence-based group, the values embedded in our DEIA efforts will help us achieve our vision to help every patient, match every need and serve every patient.

## Isn't all blood tested anyway? Why are screening questions necessary?

- Yes, every donation is tested for a wide array of infections that could potentially be transmitted through blood transfusion. But even with the tremendous improvements in donor testing technology, no test is perfect, and there are some infections for which there is not yet a reliable test available.
- One reason we have such a safe blood supply is the layering of a donor screening questionnaire with donation testing and other blood safety steps. Testing methods that are used to test every blood donation have a limitation called the “window period.” The window period is the time between when a donor has acquired a new infection that could be transmitted to a patient by blood transfusion, and the time a donor test can reliably detect the infection. If a donor has recently acquired an HIV or hepatitis infection, current testing methods may not pick it up for a short time following infection.
- The Donor History Questionnaire is critical in helping identify people who may have had a recent exposure to a new infection of concern, such as HIV or hepatitis B and C.

## Is the blood supply going to be safe after these changes?

- The blood community always works tirelessly to protect the safety of patients and donors and is united in its commitment to maintain the safety and availability of the nation’s blood supply during this transition process and at all times.
- This donor criteria change will not compromise the safety or adequacy of US blood supply.
- Every blood collection facility in the United States has a profound responsibility to the patients we serve. Safety is paramount in everything we do.
- The new criteria will continue to defer those who may have recently acquired an HIV infection. Other criteria already in place identify additional risk factors for acquiring HIV, and these will continue to be applied consistently for all donations. The evidence gathered through multiple research and infectious diseases monitoring initiatives, from other countries that have already implemented IDA, by the FDA and our accreditor — AABB — support making this change.

## Some people who previously have been eligible to donate are not eligible under the new criteria. Why is that?

The new guidelines focus on assessing each blood donor individually. Out of an abundance of caution, some people may be asked to defer their donation based on criteria that indicate there could be an increased risk for a newly acquired infection that would not be detected by currently available testing methods.

## Are you discriminating against those who are taking PrEP? (for use if pressed)

- Pre-exposure prophylaxis (PrEP) is a highly effective medication regimen used for HIV prevention during sexual contact but do not cure HIV.
- FDA reminds us that these medications “do not fully eliminate the virus from the body, and donated blood from individuals infected with HIV using PrEP can potentially still transmit HIV to a patient.”
- In people taking PrEP or post-exposure prophylaxis (PEP), the low levels of HIV show the medication is working but those low levels of HIV may not be detectable by the HIVtest. We rely on accurate HIV testing as part of our multi-layered approach to blood safety.
- FDA describes it this way - “the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals.”
- There needs to be more research on how PrEP and PEP medications affect HIV testing. At this time, individuals who take PrEP or PEP are unable to donate for 3 months from most recent use of oral PrEP and 2-years from most recent use of injectable PrEP.
- This impact on donor testing is an issue impacting blood operators worldwide. Tests used to detect HIV and other viruses are manufactured by other companies, not our blood center. The advanced testing technology for blood safety is very effective.
- The US blood collector community supports ongoing studies assessing the impact of PrEP on donor testing.

## I want more information on this process.

- Donors and members of the public and media are encouraged to visit AABB’s public-facing information on this issue at [www.aabb.org/IDAimplementation](http://www.aabb.org/IDAimplementation)

# Responding to Upset or Angry Donors

Donors may get upset for various reasons. They may be frustrated at the slow pace of change and angry that they have been unable to donate previously, they may feel uncomfortable or offended by the individual donor assessment screening questions or they may get angry upon being deferred. In all cases, the model for responding is Thank, Acknowledge, Inform.

| THANK  | ACKNOWLEDGE  | INFORM  |
|--|--|---|
| <ul style="list-style-type: none"> <li>• Thank you for voicing your concerns/questions/frustrations.</li> <li>• We appreciate all feedback to help us improve what we're doing.</li> <li>• We really appreciate your patience with this process.</li> <li>• Thank you so much for coming in today. We really appreciate it.</li> </ul> | <ul style="list-style-type: none"> <li>• I understand that you are very upset/frustrated/angry. That's totally understandable.</li> <li>• I'm sorry that this experience has been so difficult/painful/frustrating for you.</li> <li>• I can understand why you are upset, and I am sorry you feel this way.</li> <li>• I know this questionnaire is long and asks lots of sensitive questions. I'm sorry about that.</li> <li>• It's completely natural to feel uncomfortable/nervous/etc.</li> <li>• We truly understand that being turned away from donating blood can leave any donor with a sense of frustration and disappointment.</li> <li>• We recognize that eligibility criteria for men who have sex with men and transgender and nonbinary donors is a particularly sensitive issue affecting many who have experienced longstanding marginalization and stigma.</li> </ul> | <ul style="list-style-type: none"> <li>• The blood community is working diligently toward greater inclusivity for donors while maintaining a safe and adequate supply of blood products for the patients we serve.</li> <li>• We are continuing to take steps to modify our practices and policies and cultivate a donor base and workforce that more fully and equitably reflects our diverse population.</li> <li>• We do have policies in place to prevent HIV transmission. We are confident in our policies that are evidence informed and their ability to ensure a safe blood supply.</li> </ul> |

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](http://aabb.org/ida).

