

## Talking Points: FDA Changes to Blood Donor Deferral Criteria

*Announced by FDA April 2020; Implemented by MVRBC July 2020*

U.S. Food and Drug Administration recognizes the need to maintain an adequate blood supply during the COVID-19 pandemic. To that end, FDA has reviewed the latest scientific data for some current policies regarding the eligibility of certain donors. FDA's latest donor eligibility guidance was issued in April 2020, during the COVID-19 pandemic, and will be reviewed by FDA based on feedback received from blood providers.

- These are commonsense changes based on data that should last beyond the pandemic and be made permanent.
- The FDA's actions which will allow for the re-entry of thousands of individuals to the donor pool who were previously deferred, include the following:
  - change from 12 months to a three month deferral for individuals at higher risk for HIV, including men who have sex with men (MSM), individuals who have used non-prescription injectable drugs, individuals who receive a blood transfusion, accidental contact with another individual's blood such as through a needle stick, receiving a tattoo, ear or body piercing not from a state regulated establishment, history of syphilis or gonorrhea, or sex with someone in these categories;
  - removal of the deferral criteria for geographical risk of vCJD for U.S. military bases in Europe excluding time spent in the UK from 1980-1996 (cumulative three months), and France or Ireland from 1980-2001 (cumulative five years);
  - reduced deferral time for travel by individuals who have never lived in a malarial endemic area but who traveled to such an area from 12 months to three months.
- Our Blood Center has worked to implement the changes FDA announced in April 2020. This process takes time as blood centers work diligently to modify their protocols and computer systems which must be done in a controlled manner in accordance with good manufacturing practices. The changes to deferral criteria are now in effect for MVRBC / CICBC / CBSI.

### **Additional Key Messages for COVID-19 Pandemic:**

- The COVID-19 pandemic has presented an unprecedented challenge to blood providers across the country. A large portion of all blood drives through August and September have been canceled, thus blood centers will have an ongoing need for individuals to continue to donate throughout the pandemic and the summer months.
- Blood centers across the country are taking extra measures to ensure both donors and staff are safe and healthy, including social distancing measures and increased infection control procedures, slowing operations in donor waiting rooms and availability of donation chairs.
- All donors are screened to ensure they are healthy and feeling well. Individuals should not donate blood if they are feeling ill. Each donor also goes through a mini-physical that includes a temperature check as well as a visual check on the donor's well-being (coughing, nose draining, hard time breathing, etc.).
- To assist blood centers with social distancing measures, individuals are strongly encouraged to make appointments which will be needed on a continual basis over the next several weeks and months to replenish the nation's blood supply through the summer ensuring blood is available for patients in need and beyond.
- Blood donation is not a mass gathering or social event and is a designated essential service that individuals can and should leave their homes for, even during shelter in place measures. Individuals

who are healthy and eligible to donate are encouraged to schedule an appointment to do so in order to maintain an available blood supply.

- Based on other respiratory illnesses including similar coronaviruses, there is no known risk of transmission of COVID-19 through the blood donation process or from blood transfusions.
- There is no intrinsic risk to the safety of the blood supply, but there is risk to the availability of blood for patients in need because of an increase in canceled donation appointments and blood drives.