

BLOOD SAFETY AND ZIKA

Ensuring safe and available blood requires coordination

The Centers for Disease Control and Prevention (CDC), the US Food and Drug Administration (FDA), and the National Institutes of Health (NIH) work together to monitor the safety of the US blood supply. While the American Red Cross is the largest supplier of blood in the United States, accounting for about 40% of collections, there are other blood suppliers as well. Coordination between blood centers is crucial to ensure blood is safe and available.

Share how your jurisdiction will define “area of local transmission” for Zika virus

- Blood collection centers need to know where there is local transmission of Zika virus so they can make sure they are compliant with FDA Blood Donor Deferral Guidance (<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm>).
- Blood centers collecting in areas with local transmission of Zika virus have to import blood if it is not screened using laboratory testing (not yet FDA approved) or subjected to pathogen reduction (only approved for platelets and plasma).
- What is the appropriate geographic subdivision in reporting information from, and defining, an area of local transmission? For example, will reporting be accomplished at the zip code level or at the county or some other administrative level?
- Will identification of an area with local transmission where FDA Blood Donor Guidance needs to be applied be determined according to the case characteristics?
 - Single case
 - Multiple linked cases
 - Multiple unlinked cases
- Will identification be based on factors other than geographic region?

Identify a point person and engage in planning and communication with partners

- Identify points of contact for Zika and blood safety at the health department for blood centers in your jurisdiction.
- Individual blood centers will decide if they will screen the blood they collect for Zika virus, once the test is available. When an area has identified local Zika virus transmission, health departments need to ask blood centers if they are screening blood for Zika virus or if they plan to outsource to replace donations in that area.
- Consider multiple forms of communication, such as
 - Active, where state public health departments notify blood centers in real time about any new and relevant matters.
 - Passive, where the blood centers will monitor a website or other resource that you update periodically or on a regular schedule.
- How will you approach the investigation of suspected transmission of Zika virus by blood transfusion and how will you collaborate with blood centers?

Understanding FDA guidance for blood safety

You can find the full FDA recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika on FDA’s website:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM486360.pdf>

For questions and answers about the FDA recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika, please visit

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM490435.pdf>

| Area | Type of transmission | FDA Guidance |
|---|---|---|
| <p>Areas without active Transmission of Zika virus</p> | <p>Travel-related Risk</p> | <p>Defer donation for 4 weeks after symptoms consistent with Zika for a:</p> <ul style="list-style-type: none"> ○ Donor with a history of Zika virus infection ○ Donor who reports symptoms consistent with Zika within 2 weeks of leaving an area with active transmission of Zika virus ○ Donor who had sexual contact with a man who has been diagnosed with Zika or traveled to or lived in an area with active transmission of Zika virus in the past 3 months ○ Donor who has lived in or traveled to an area with active transmission of Zika virus |
| <p>Areas with Active Transmission of Zika virus</p> | <p>Local Zika Risk</p> <p>Visit http://www.cdc.gov/zika/geo/index.html to identify areas with active transmission of Zika virus.</p> <p>If local transmission is reported in your state, contact your state and local health departments to determine areas with active transmission of Zika virus.</p> | <p>Obtain Whole Blood and blood components for transfusion from areas of the United States with no active transmission of Zika virus to fulfill orders.</p> <p>You may:</p> <ul style="list-style-type: none"> ○ Collect and prepare platelets and plasma locally if you implement pathogen reduction technology using an FDA-approved pathogen reduction device as specified in the Instructions for Use of the device. ○ When available, collect blood components locally and test blood donations with an FDA-licensed blood donor screening test for Zika virus*. ○ Only use locally collected blood components if blood components from an area without active transmission or pathogen-reduced blood components are not available and the prescribing physician identifies an urgent need for transfusion that outweighs the risk. <p>*An FDA-licensed blood donor screening test is not currently available for Zika virus</p> |

Further background on CDC’s role in blood safety is available at <http://www.cdc.gov/bloodsafety/>

Investigation toolkit: <http://www.cdc.gov/bloodsafety/tools/investigation-toolkit.html>