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Health Emergency Preparedness Task Force | Alert

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FDA Issues Guidance for Blood Banks to Reduce Risk for Collection of Zika Infected Blood

On Feb. 16, 2016, the Food and Drug Administration issued guidance for blood banks with recommendations for donor screening, donor deferral, and product management to reduce the risk of transmission of the Zika virus through transfusion. The FDA issued this guidance because the risk of transmission of Zika by blood transfusion is considered likely.

The FDA's recommendations vary as a function of geography.

Areas of the United States without Active Transmission of Zika

The FDA recommends that blood banks update their donor educational material to include the risk factors for signs and symptoms of Zika infection so that donors can self-defer. Donors who exhibit signs and symptoms of Zika infection within two weeks of departure from an area with active transmission of Zika should self-defer for four weeks after the resolution of symptoms. Donor history questionnaires should also be updated to assess prospective donors' history of residence or travel to areas with active transmission of Zika in the past four weeks.

Donors with a history of Zika symptoms, or those who had sexual contact with a man who has been diagnosed with Zika or who traveled to or resided in an area with active Zika infection in the three months prior to the sexual contact, should be deferred from donating for four weeks. The FDA's recommendation calls for these procedures to be implemented as soon as feasible, but no later than four weeks from the issuance of this guidance.

Areas of the United States with Active Transmission of Zika

In areas of the United States with active Zika-transmission, *e.g.*, Puerto Rico, the FDA recommends that blood banks obtain blood from areas of the country without active virus transmission. Alternatively, blood banks may collect and

prepare platelets and plasma locally if they implement pathogen reduction technology for platelets and plasma using an FDA-approved pathogen reduction device, or if locally collected blood is screened for Zika with a FDA-licensed blood donor screening test. It is important to note that there is presently no FDA-licensed test to screen blood donations for either the Zika virus or antibodies associated with the virus. The FDA noted it may permit the use of an investigational donor screening test under an investigational new drug (IND) application or investigational pathogen reduction under an investigational device exemption (IDE) in situations where approved technologies are unavailable.

Areas with active Zika should update their donor history questionnaire to conform to the one used in uninfected areas but should also collect information on the donor's sexual contact for those who had contact in the last four weeks with a man who has been diagnosed with Zika or has shown symptoms suggestive of Zika in the last three months.

According to the FDA, blood banks should also take careful steps to manage post-donation information, product management, and product disposition and labeling to ensure that in case donated blood or blood components is identified after collection as being obtained from a donor who should have been deferred, the collection can be quickly quarantined and destroyed. These recommendations should be implemented immediately for intrauterine transfusions, transfusion in pregnant women, or transfusion in other at-risk recipients. For all others, the recommendations should be implemented within two weeks, but no later than two weeks from the issuance of the guidance.

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