CRS INSIGHT

Zika Poses New Challenges for Blood Centers

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Introduction

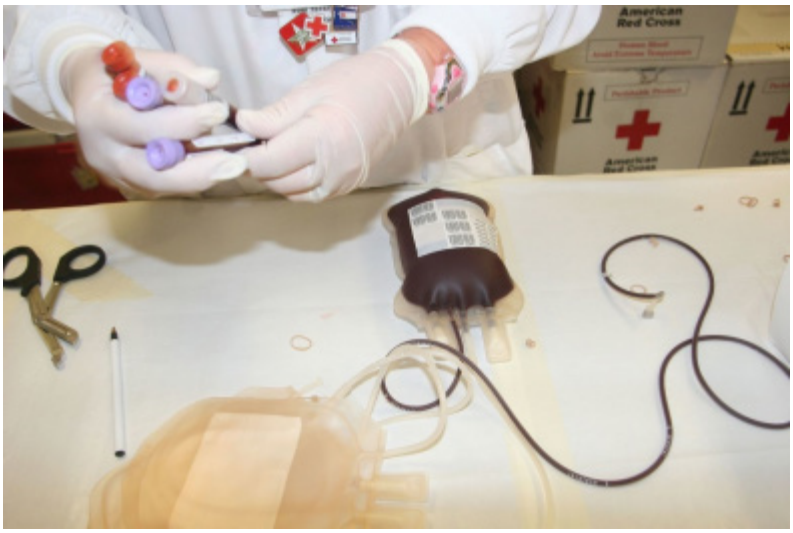
On July 27, the Food and Drug Administration (FDA) advised blood centers in Miami-Dade and Broward counties in Florida to stop collecting blood until they could test each donated unit for Zika virus (ZIKV). OneBlood, which operates blood centers throughout most of the state, had already decided, after consulting with the Florida Department of Health (FDOH), to suspend collections in south Florida.

Two days later, FDOH announced the first cases of local (i.e., mosquito-borne) ZIKV transmission in the continental United States, originating in Miami-Dade county. Also, OneBlood announced that it would immediately begin testing of all blood units collected throughout its service area using an investigational test that FDA cleared for use earlier this year.

These are the latest in a series of steps to prevent the spread of ZIKV in the blood supply. In February, FDA released a set of donor screening and deferral recommendations, which U.S. blood banks implemented. FDA also advised suspending blood collections in areas where ZIKV was being spread by mosquitoes until testing could be implemented.

The Zika-related donor deferrals have exacerbated an already tight U.S. blood supply this summer. Last month, the nation's blood bankers issued a joint appeal for blood donors to sustain inventories across the country.

Figure 1. An American Red Cross Worker Prepares Donated Blood for Testing



Source: U.S. Department of Defense, 2006.

Evolution of the Zika Threat

The Zika virus, first recognized in Uganda in 1947, is thought to have emerged in the Western Hemisphere early in 2015. Although most cases of ZIKV infection are mild, prenatal infection can cause severe birth defects, including microcephaly. ZIKV is transmitted among humans by the bite of an infected mosquito, by sexual contact, from mother to fetus, and through contaminated blood transfusion. ZIKV has spread from South America into Central America and the Caribbean. Puerto Rico has been hard hit, with more than 5,600 confirmed infections to date.

On July 29, FDOH reported four cases of mosquito-borne transmission of ZIKV originating from one neighborhood in Miami, the first such cases in the continental United States. An additional 11 cases from the same neighborhood were identified over the next few days. Six of these people had no symptoms of illness.

The Centers for Disease Control and Prevention (CDC) has issued public health guidance to stem further spread in this area, included an unprecedented recommendation that pregnant women avoid travel to the affected neighborhood. Local officials have expanded mosquito control efforts, but the effectiveness of these efforts is in question.

Response of FDA and the Blood Banks

On February 16, 2016, FDA issued donor education, screening, and deferral recommendations for immediate implementation to reduce the risk of transmitting ZIKV by blood transfusion. The agency had concluded that transfusion-transmitted ZIKV was likely, based on possible cases in Brazil and other evidence. Transmission of ZIKV by transfusion was subsequently confirmed.

FDA provided two sets of recommendations. One was for U.S. blood centers in *areas without local transmission*, which at the time included the entire continental United States. For those centers, FDA advised deferring—for four weeks—potential donors who (1) reported traveling to an area with active ZIKV transmission, (2) engaged in behaviors (including sexual contact) that may have exposed them to ZIKV, or (3) reported symptoms suggestive of ZIKV infection.

In *areas with local transmission*, which at the time included only Puerto Rico, FDA was more prescriptive. It recommended suspending blood collections until a ZIKV test was available and, in the meantime, procuring blood products from areas without local transmission. In early March, the Department of Health and Human Services announced that it would coordinate and pay for shipments of blood products to Puerto Rico from blood centers in the continental United States.

On March 30, FDA announced the availability of a test for ZIKV in donated blood under an Investigational New Drug

(IND) application, the first of two such tests. Blood centers in Puerto Rico quickly resumed collections and began sending samples to a testing facility in Florida that had implemented the investigational ZIKV test.

OneBlood is one of several blood banks that have recently implemented ZIKV testing under the IND protocol. To date, it is the only one testing blood collected in the continental United States where local mosquito-borne ZIKV transmission has been confirmed. The other blood banks have implemented ZIKV testing as a precaution. FDA will use data from the IND protocols to evaluate the tests for licensure. (The IND test used for donated blood is different from ZIKV tests used to diagnose illness in patients. Currently, there are no FDA-approved ZIKV diagnostic tests, but FDA has granted emergency use authorizations—EUAs—for several tests under development.)

The affected Miami-Dade neighborhood may be the first of a number of "hot spots" of local ZIKV transmission expected this summer and fall on the U.S. mainland. This incident suggests that universal unit testing may be needed to adequately protect the blood supply in some areas before local transmission of ZIKV is detected.

However, during the summer, with donors on vacation and colleges out of session, blood centers often struggle to maintain adequate inventories. The ZIKV donor deferral is just one of several factors making the summer of 2016 even more challenging for blood centers than usual.

In May, blood centers raised the minimum hemoglobin level required for males to donate, one of a series of changes in a recent FDA rule that updated and revised existing blood banking regulations. An initial survey of blood banks indicated that this has caused a 2.4% loss of male donors. In June, FDA announced the recall of multiple lots of blood products with unacceptably high white blood cell counts due to a faulty filtering device. White blood cells typically are filtered out to reduce the risk of an adverse reaction caused by the transfusion recipient's own immune response to the foreign cells.