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Important Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding Zika Virus Transmission Risk in the World

The Centers for Disease Control and Prevention (CDC) has changed information on its Blood and Tissue Safety webpage used to communicate epidemiological information about Zika virus (ZIKV) to the blood and tissue collection community. CDC had previously identified areas with active transmission risk in other countries by using travel notice start and end dates; however, identification of risk areas involving other countries and territories will now be provided using a world map of areas with risk of Zika. Areas of active ZIKV transmission risk in the United States will continue to be defined at the county level within a state, including risk start and end dates, as listed on the CDC webpage for Blood and Tissue Safety.

The CDC reports that, based on laboratory analyses and mathematical modeling, a conservative yet plausible estimate for introduction of ZIKV and substantive risk of exposure in North America, South America, Central America, and the Caribbean is January 1, 2014 (1,2,3). Furthermore, scientific evidence confirms ZIKV presence in some African and Asian countries for decades, in some cases dating back to the 1950's (4,5,6).Therefore, the possibility of mosquito-borne ZIKV transmission to travelers may have started before the travel notice dates originally posted on the Blood and Tissue Safety webpage.

Based on the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research's Guidance for Industry titled *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products* (March 2016), residence in or travel to an area with active ZIKV transmission, as identified by CDC, and sex with a male known to reside in or travel to an area with active ZIKV transmission, are considered ZIKV risk factors for the purpose of determining eligibility of living donors of HCT/Ps. Donors of HCT/Ps should continue to be screened as recommended in FDA's March 2016 Guidance.

Regarding references to use when screening HCT/P donors:

- First access the CDC webpage for Blood and Tissue Safety.
- To evaluate domestic travel, the "Areas of Active Zika Virus Transmission Risk in the Continental United States" is listed first and continues to be defined at the county level within a state. For the purpose of screening HCT/P donors, do not use other CDC webpages or maps for evaluating travel within the United States.
- For evaluating travel to areas outside of the continental United States, as of the date of this announcement, you should use the new links to a world map and to a table of "Areas with Interrupted Transmission." Residence in or travel to a country or territory identified on the world map page is considered a risk factor for ZIKV as described in FDA's current guidance for HCT/P donors. The table of "Areas with Interrupted Transmission" should be used, when applicable.
    - As a resource for donor eligibility determinations made before today's announcement, the previous travel notice table with dates has been posted on FDA's website but only remains available for historical purposes.
- The CDC webpage for Blood and Tissue Safety should be monitored frequently for any updates.

Considerations for HCT/Ps Recovered Prior to Posting of this Announcement

HCT/Ps recovered prior to posting this announcement (i.e., prior to the change to CDC's Blood and Tissue Safety webpage) should have been screened for travel to other countries and territories using the table of Travel Notice Posting Dates which has now been archived for historical purposes. However,

HCT/P establishments may want to consider this new information regarding potential risk related to travel outside of the continental United States, as well as the new information regarding the estimate for introduction of ZIKV, and evaluate whether this affects your practices. Prior to potential use, establishments may also wish to take into consideration the type of HCT/P and the risk factors for potential ZIKV infection in recipients.

FDA is providing establishments with this notification of potential risk to HCT/P safety out of an abundance of caution and in the interest of providing patients and practitioners with information to make informed choices, such as decisions regarding use of cryopreserved semen for reproductive purposes. At this time, the potential risk to previously recovered HCT/Ps, including semen, is believed to be small enough that no formal regulatory action is required by the FDA.

Regarding donors, prolonged persistence of ZIKV has been observed in certain HCT/Ps such as semen, and scientific knowledge in this area continues to evolve with studies taking place to investigate tissue tropism for ZIKV. HCT/Ps from living donors, such as donors of reproductive, gestational, and hematopoietic progenitor/stem cells from peripheral blood or cord blood, appear to have increased potential for transmission of ZIKV.

Regarding recipients, the potential populations receiving HCT/Ps from living donors may also be considered when evaluating this new information. Examples may include women of child-bearing age, including those seeking assisted reproductive technology (ART) treatments to conceive, and immunocompromised persons.

References

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