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1717 K Street NW, Suite 900, Washington, DC 20006
Tel: 202-393-5725 | Fax: 202-899-2621
www.AmericasBlood.org

Zika virus testing does not support the safety and sustainability of the U.S. blood supply: current realities, risks, and recommendations

Background

- **2016**: Zika virus (ZIKV) was identified as a potential threat to the U.S. blood supply.
- **February 2016**: FDA published its first ZIKV guidance requiring individual donor screening and deferral for significant infectious risks associated with travel and/or sexual contact.
- **July 2018**: Following review of the available data on Zika and based on recommendations from the Blood Products Advisory Committee, FDA published a revised ZIKV guidance that allowed mini-pool testing for ZIKV.

The ZIKV epidemic appears to be over resulting in an extremely low risk of ZIKV transmission by transfusion

- No evidence exists that mosquitoes in the continental U.S. have transmitted ZIKV since 2017.
- Provisional 2019 data through Oct. 3rd reveal 10 case reports in U.S. states, all acquired from travel to affected areas outside the U.S., and 39 cases in U.S. territories, 2 after travel and 37 presumed from local mosquito transmission. None of these cases was identified in connection with blood donations.
- A slight risk persists of travel-related ZIKV infection, though this "translates" to an extremely low threat for U.S.-based transfusion transmission (TT).

Cost-effectiveness of ZIKV testing in the United States

- $137 million per year is spent on donor ZIKV testing at a cost of at least $5.3 million per RNA-positive test.
- Best estimates suggest U.S. testing costs exceed $300 million per quality-adjusted-life-year far exceeds what is spent on any other blood donor screening tests.
- These numbers demonstrate that Zika screening is not cost effective compared to other medical or blood screening interventions.

Protecting the safety and availability of blood for our patients

- Transfusion-dependent patients require and deserve safe, readily available blood products.
- Transfusions are safer now than at any time in the past, even with multiple emerging infections.
- The elimination of costs not materially contributing to transfusion recipient safety is a necessary step in stabilizing the U.S. blood supply, which is operating on minimal operating margins.

Recommendations: Time for change

- ZIKV no longer should be considered a relevant transfusion-transmitted infection under 21 CFR 630.3(h)(2).
- Policy makers must: (1) assess and take into account the cost and subsequent economic effects of presumed safety measures before executing recommendations, and (2) repeal testing requirements that add unnecessary financial burdens without commensurate benefits.
- This policy supports the elimination of ZIKV testing, which is not a cost-effective means for enhancing blood safety in the U.S.

Additional Reading

- Centers for Disease Control and Prevention, Zika virus ("Home Page"). https://www.cdc.gov/zika/geo/index.html – accessed 11/05/19.
- Centers for Disease Control and Prevention, Zika virus ("Prevention and Transmission"). https://www.cdc.gov/zika/prevention/index.html – accessed 11/05/19.
- Code of Federal Regulations Title 21 630.3(h)(2). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=630.3 – accessed 11/05/19.
- Ellingson KD, Kuehnert MJ. Blood safety and emerging infections: Balancing risks and costs (editorial). Ann Intern Med 2019;170:203-4. (https://annals.org/aim/article-abstract/2720165/blood-safety-emerging-infections-balancing-risks-costs -- accessed 11/05/19)
- Ellingson KD, Sapiano MRP, Haass KA, et al. Cost projections for implementation of safety interventions to prevent transfusion-transmitted Zika virus infection in the United States. Transfusion 2017;57, Suppl 2:1625-33. (https://www.ncbi.nlm.nih.gov/pubmed/28591470 -- accessed 11/05/19)
- FDA Guidance for Industry. Recommendations for donor screening, deferral, and product management to reduce the risk of transfusion-transmission of Zika virus. February 2016. https://www.elpasotexas.gov/~/media/files/coep/public%20health/zika%20virus/recommendations%20for%20donor%20screening%20deferral%20and%20product%20management%20to%20reduce%20the%20risk%20of%20transfusion%20transmission%20of%20zika%20virus.ashx?la=en -- accessed 11/05/19.
- FDA Guidance for Industry. Revised recommendations for reducing the risk of Zika virus transmission by blood and blood components. July 2018. https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Revised-Recommendations-for-Reducing-the-Risk-of-Zika-Virus-Transmission-by-Blood-and-Blood-Components--Guidance-for-Industry.pdf – accessed 11/05/19.
- Musso D, Ko AI, Baud D. Zika virus infection – after the pandemic. N Engl J Med 2019; 381:1444-1457. (https://www.nejm.org/doi/full/10.1056/NEJMra1808246 -- accessed 11/05/19)
- Russell WA, Stramer SL, Busch MP, et al. Screening the blood supply for Zika virus in the 50 U.S. states and Puerto Rico: A cost effective analysis. Ann Intern Med 2019;1-11. Doi:10.7326/M18-2238. (https://www.ncbi.nlm.nih.gov/pubmed/30615781 -- accessed 11/05/19)
- Saá P, Proctor M, Foster G, et al. Investigational Testing for Zika Virus among U.S. Blood Donors. N Engl J Med 2018;378:1778-88. (https://www.nejm.org/doi/full/10.1056/NEJMoa1714977 -- accessed 2/24/20).
- Spencer BR, Stramer SL, Dodd RY, et al. Survey to estimate donor loss to 14- or 28-day travel deferral for mitigation of CHIKV, DENV and other acute infections (abstract). Transfusion 2015;55(Suppl):3A. (https://onlinelibrary.wiley.com/doi/10.1111/trf.13294 -- accessed 11/05/19)
- World Health Organization, Zika epidemiology update. July 2019. https://www.who.int/emergencies/diseases/zika/epidemiology-update/en/ – accessed 11/05/19.