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.
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