Current Considerations for Reducing the Risk of Transfusion-Transmitted ZIKV

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Blood Product Advisory Committee
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Exploring Alternatives to Universal Testing for ZIKV in the U.S.

- Available information indicates a decline of ZIKV in the U.S. and Americas
- FDA is re-evaluating its July 2018 recommendations on testing blood donations for ZIKV using MP or ID NAT
- FDA seeks advice from the Committee on the following three testing strategies

Options 1-3:

1. No policy change; continue universal testing for ZIKV by MP or ID NAT
2. Regional testing for ZIKV with MP or ID NAT; with considerations for regional options
3. Eliminate all testing for ZIKV

Caveats

- FDA is not proposing predonation assessment for ZIKV risk factors (e.g., exposure through travel or sexual contact)
  - Most infected persons and their sexual partners are asymptomatic and unaware they are infected
- As the outbreak in the Americas has waned, many countries no longer perform active ZIKV surveillance
- FDA-approved pathogen reduction technologies remain an alternative to testing when used with platelets and plasma
- Proposed testing strategies have inherent pros and cons

Option 1: No Policy Change

Continue universal MP or ID NAT testing of blood collections for ZIKV

Pro:

- Provides nationwide coverage against all modes of ZIKV transmission (e.g., local vector-borne, sexually-transmitted and travel-related cases)

Con:

- Maintains a resource-intensive approach in the face of diminishing resources

Option 2: Regional MP or ID NAT

Discontinue testing in most states, but maintain regional testing for ZIKV using MP or ID NAT in at-risk US states and territories:

- (considerations for regional options listed below)

1. **FL, TX, PR, USVI** where documented local, mosquito-borne ZIKV transmission has occurred;

and

2. **CA, NY** where the mosquito vectors are present, and the states accounted for a significant proportion of ZIKV-reactive donations from travelers returning from ZIKV-affected countries during the 2016 outbreak;

and

3. **HI, U.S. territories** where the mosquito vectors are present and documented transmissions of other *Aedes*-borne arboviruses (e.g., DEN, CHIK) have occurred.

Option 2: Regional MP or ID NAT

Pro:

- Reduces the volume of testing and alleviates burden in states with low or absent risk of mosquito-borne ZIKV transmission
- Continues testing in areas of highest risk of ZIKV cases from local mosquito-borne ZIKV transmission and with high numbers of returning travelers
- Maintains capability to rapidly respond to re-emergence of ZIKV in U.S. states and local outbreaks

Con:

- Maintains a regionally resource-intensive approach on the blood system for testing donations for ZIKV in the face of significantly diminished risk
- Will not detect an outbreak if one occurs in states that are not testing and will not detect ZIKV infections among returning travelers or sexual contacts in states that are not testing

Option 3: Eliminate All ZIKV Testing

Eliminate all testing for ZIKV, pending another outbreak in the United States

Pro:

- Provides relief from ZIKV testing when ZIKV risk is substantially reduced or absent
- Increases the availability of resources for other blood safety initiatives

Con:

- Reduces preparedness against possible resurgence of the ZIKV epidemic
- Will not prevent transfusion transmission of ZIKV and poses risk of ZIKV complications among at risk patients (i.e., pregnant women)

Questions for the Committee:

Please discuss and vote on each question

1. At this time, do the available data support continuing universal testing for ZIKV using MP or ID NAT, as recommended in the July 2018 Final Guidance (no policy change as this time)(Option 1)?
2. Do the available data support a regional testing option strategy for ZIKV using MP or ID NAT in at-risk U.S. states and territories (Option 2)?
3. Do the available data support the elimination of all testing for ZIKV without re-introduction of donor screening for risk factors (e.g., travel) in areas with no risk of ZIKV infection, pending another outbreak in the United States (Option 3)?

Question 1:

1. At this time, do the available data support continuing universal testing for ZIKV using MP or ID NAT, as recommended in the July 2018 Final Guidance (no policy change as this time)(Option 1)?

Question 2:

2. Do the available data support a regional testing option strategy for ZIKV using MP or ID NAT in at-risk U.S. states and territories (Option 2)?

Question 2 (discussion of regional options):

a. **Florida, Texas and Puerto Rico, U.S. Virgin Islands** where documented local, mosquito-borne ZIKV transmission has occurred

and

b. **California and New York** where the mosquito vectors are present, and the states previously accounted for a significant proportion of the ZIKV-reactive donations from travelers returning from ZIKV-affected countries

and

a. **Hawaii, U.S. territories** where the mosquito vectors are present and documented transmissions of other *Aedes*-borne arboviruses (DEN, CHIK) have occurred

Question 3:

3. Do the available data support the elimination of all testing for ZIKV without re-introduction of donor screening for risk factors (e.g., travel) in areas with no risk of ZIKV infection, pending another outbreak in the United States (Option 3)?


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