Protecting the Blood Supply
ZIKA

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Keeping the Blood Supply Safe

- Blood is kept safe through the following mechanisms:

Donor screening

Self deferral

Testing the blood supply

Post Donation Information

Objectives

- Identify recent concerns with emerging pathogens
- Identify the changes to the recommendations and FDA guidance
- Explore strategies to combat emerging pathogens

Concerns: ZIKA in the blood supply

- How infective is ZIKA thought to be in the blood supply?
- Modes of transmission: do we know all of the facts yet?
- What we do know:
  - Vector Borne
  - Sexually Transmitted
  - Transmitted through the Blood Transfusion
  - Person to person

FDA issues first guidance for ZIKA

February 2016, FDA Guidance for Blood Centers:

- Blood Centers were required to provide educational material for donors prior to donation. Donors that had traveled to ZIKA risk areas were asked to self-defer. Recommended self-defer for 4 weeks after resolution of symptoms or travel.
- Self-defer for 4 weeks after last sexual contact with a man diagnosed with ZIKA or who traveled to or resided in an area with Active transmission in the 3 months prior to that instance of sexual contact.
- Recommended blood center update their donor history questionnaire.

FDA issues first Guidance for ZIKA, continued

- Recommended for areas with active transmission of ZIKA, obtain blood from other areas and test when a licensed test becomes available.
- May collect platelets and plasma locally if you implement pathogen reduction technology for platelets and plasma using an FDA-approved pathogen reduction device.

AABB Association Bulletin #16-04

- Bulletin published March 1, 2016
- Education materials for donors
- Deferral for travel
- Deferral for sexual contact risk
- Post donation materials for donors
- Post donation education for donors
- Post donation deferral
- Lookback
- Consignee notification

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AABB Assocation Bulletin #16-06

Bulletin issued August 16, 2016

- Developed by the AABB Transfusion-Transmitted Diseases Committee, is intended to supplement Association Bulletin #16-04, "Zika, Dengue, and Chikungunya Viruses," that provides additional information about:
- The potential for transfusion-transmitted ZIKA virus infections.
- Recommendations for altering the donor history questionnaire for active or inactive areas to include ZIKA Additional Questions.
- Recommendations to facilitate self-deferrals due to travel/residence, sexual contact or a ZIKA virus diagnosis or ZIKA-related symptoms.
- Post-donation information (PDI) materials and recommendations for collection facilities and transfusion services in response to PDI received from donors.

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AABB issues Technical Buletin for Zika, continued

- Availability and use of investigational blood donation screening tests for ZIKA virus.
- Use of licensed or investigational pathogen reduction technologies (PRT) for inactivating ZIKA virus.
- Actions following the recognition of local transmission as a result of voluntary investigational blood donation testing programs.
- Posting of data to the AABB ZIKA Virus Biovigilance Network.
- Florida areas must begin testing or import blood.

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FDA issues revised Guidance for ZIKA

Revised Guidance issued on August 26, 2016 recommends that blood centers begin testing blood supply.

- The following states must implement testing using Individual donor nucleic acid test (ID-NAT) under the IND (Individual New Drug) application that are currently available until licensed tests are available or use pathogen reduction technologies if available.
- Testing must be implemented within 4 weeks (September 23, 2016)

Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina, Texas

- All other states must implement testing within 12 weeks

(November, 18, 2016)

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Testing for ZIKA

- Limited tests available under the IND (Investigational New Drug) application.
- Must get approval from the vendor's IRB (Investigational Review Board)
- Will receive results same as with all other infectious disease testing.

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Pathogen Reduction Technology

- Treats the blood product and inactivates the pathogen (bacteria and virus)
- Available for plasma and platelet products only- not available to date for red blood cells.
- New technology in the US. Has been available in other countries for some time. Only a few blood centers are live yet, but many blood centers plan to implement in the future. No blood centers are licensed yet, so products can only be used locally.
- If pathogen reduction technology was available for all of the products, there is no need to test for ZIKA.

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Deferral and Lookback

- Donors that were ill from ZIKA or tested positive will be deferred for 120 days.
- Post Donation Information criteria will apply as it does for all blood products.
- Notification of positive testing will follow current notification processes:
  - Dispose of all in-date product
  - Notify the consignee to dispose of any in-date products
  - Lookback for 120 days and determine recipients of blood products from lookback
  - Notify physician of recipients of blood products from lookback
- AABB has established a ZIKA Virus Biovigilance Network

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Resources for Additional Information

FDA Guidance:
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf

AABB:

http://www.aabb.org/Pages/default.aspx search for ZIKA

CDC regarding ZIKA:

http://www.cdc.gov/zika/index.html

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Resources Continued

- http://www.cdc.gov/zika/state-labs/biosafety-guidance.html
- http://www.cdc.gov/zika/pdfs/zika-mac-elisa-fact-sheet-for-hcp.pdf
- http://www.who.int/mediacentre/factsheets/zika/en/
- http://www.cdc.gov/zika/pdfs/denvchikvzikv-testing-algorithm.pdf
- https://www.cdc.gov/zika/geo/united-states.html

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