Centers for Disease Control and Prevention



CDC Zika IMS Sustaining the Zika Response in 2017 Blood Safety Task Force March 30, 2017

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Overview

- **Zika Virus Background**
- Background on Blood, Organ, and Tissue Collection/Screening
- Blood Donor Screening
- Q&As
- Closing Remarks

Blood Safety Task Force Zika Virus Background

Zika Virus

- Zika virus (ZIKV) is spread to people primarily through infected Aedes species mosquitoes (Ae. aegypti and Ae. albopictus)
- Many people infected with Zika won't have symptoms or will only have mild symptoms
- Zika infection during pregnancy can cause microcephaly and other severe brain defects

Where has Zika Been Found?

- Before 2015, Zika outbreaks occurred in Africa, Southeast Asia, and the Pacific Islands.
 Currently outbreaks are occurring in many
 - countries and territories.



World Map of Areas with Risk of Zika

https://wwwnc.cdc.gov/travel/files/zika-areas-of-risk.pdf

Zika Virus in the US, March 22, 2017



https://www.cdc.gov/zika/intheus/maps-zika-us.html#zika-cases-us

How is Zika Spread?

- Zika can be spread through
 - Mosquito bites
 - From a pregnant woman to her fetus
 - Sex with an infected person
 - Laboratory exposure
- Zika may be spread through blood transfusion.
- No reports of infants getting Zika through breastfeeding.



Zika Virus Vectors: Aedes Mosquitoes

- Aedes species mosquitoes (Aedes aegypti and Aedes albopictus)
- Also transmit other viruses like dengue and chikungunya
- Lay eggs near water-holding containers
- Live in and around homes
- Bite during the day and at night



Aedes aegypti



Aedes albopictus

Ae. aegypti and *Ae. albopictus* Mosquitoes: Estimated Geographic Distribution in the United States

Estimated range of Aedes albopictus and Aedes aegypti in the United States, 2016*



*Maps have been updated from a variety of sources. These maps represent CDC's best estimate of the potential range of Aedes aegypti and Aedes albopictus in the United States. Maps are not meant to represent risk for spread of disease.

https://www.cdc.gov/zika/pdfs/zika-mosquito-maps.pdf

Clinical Presentation

- Clinical illness usually mild
- Most common symptoms
 - Fever (usually low-grade)
 - Rash (maculopapular; often pruritic)
 - Arthritis or arthralgia
 - Non-purulent conjunctivitis
 - Other symptoms include: muscle pain, headache
- Symptoms last several days to a week
- Severe disease uncommon
- Fatalities rare

Other Modes of Transmission

Proven/Probable

- Sexual contact
 - Male (symptomatic and asymptomatic) to female
 - Female (symptomatic) to male
 - Male (symptomatic) to male
- Intrauterine
- Perinatal from a viremic mother to newborn
- Blood transfusions
- Possible
 - Breast milk
 - Organ and tissue transplantation

Blood Safety Task Force Background on Blood, Organ, and Tissue Collection/Screening

Background

Blood

- Types of collection: whole blood and apheresis
- Types of products: red blood cells, platelets, plasma
- Screening: hepatitis B/C, HIV, human T-lymphotropic virus (HTLV), syphilis, West Nile virus, and Zika virus

Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)

- Types of products: corneas, bone, skin, heart valves, hematopoietic stem/progenitor cells (HPCs), reproductive tissues, etc.
- Screening: hepatitis B/C, HIV, HTLV, syphilis, cytomegalovirus, chlamydia, gonorrhea

Solid Organs

Types of products: kidney, heart, liver, etc.

Blood Safety

- No reported ZIKV transfusion-transmitted cases in the United States
- Probable ZIKV transfusion-transmitted cases in Brazil
- US Food and Drug Administration (FDA) issued industry guidance in Feb. 2016¹ and revised guidance in Aug. 2016²
 - Blood collection centers in all states and US territories should perform ZIKV screening on all donations using a screening test authorized for use under an FDA investigational new drug (IND) application, or with a licensed test when available; or use an FDA-approved pathogenreduction device for plasma and certain platelet products

¹ https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM486360.pdf ² https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf 14

Blood Safety

CDC Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™			SEA	ARCH	٩
				CDC A-Z	INDEX 🗸
Zika Virus					
Zika Virus Home	2	CDC > >Zika Virus Home > >Transmission			
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Transmission	- 1				
Zika & Sexual Transmission		BLOOD AND TISSUE COLLECTION CENTERS	AREAS AT RISK		
Zika & Blood Transfusion					
Zika & Animals					
Symptoms, Testing, & Treatment	+ \	What we know			
Areas with Zika	+	 On August 26, 2016, FDA issued revised guidance, recommending that bl whole blood and blood components with a blood screening test authorize 	ood centers in all states and U.S. i d for use by FDA under an invest	territories screen individual u igational new drug (IND) appl	nits of donated ication, or with
Reporting and Surveillance	+	a licensed test when available. Alternatively, and FDA-approved pathogen-reduction device may be used for plasma and certain platelet products.			
Mosquito Control	+	 Most people infected with the Zika virus don't show any symptoms, blood donors may not know they have been infected. To date there have been no confirmed transfusion-transmission cases of Zika virus in the United States. However, cases of Zika virus transmission 			
Health Effects & Risks	+	through platelet transfusions have been documented in Brazil.			
Pregnancy	+ 7	Zika Virus Blood Screening			
Information for Specific Groups	+	 Blood donor screening on the basis of a questionnaire, without a laborato mosquito-borne transmission of Zika virus due to the high rate of asympt 	ry test, is insufficient for identifyi	ing Zika-infected donors in ar	eas with active
For Healthcare Providers	+	Although there is no EDA-licensed test for Zika virus testing for Zika bec	ame available through two senar	ate Investigational New Drug	(1)(D)

Blood and Tissue Safety

The areas listed under "Areas of Active Transmission in the US" can differ from those issued for travel guidance's because of additional concerns about potential risk for blood and tissue safety.



Zika Virus in the US, March 22, 2017

aboratory-confirmed symptomatic Zika virus disease cases and presumptive viremic blood donors reported to ArboNET by states and territories — Jnited States, 2015–2017 (as of March 22, 2017)			
States	Symptomatic disease cases** (N=5,158) No. (%)	Presumptive viremic blood donors† (N=43) No. (%)	
Alabama	40 (1)	O (0)	
Arizona	54 (1)	1 (2)	
Arkansas	15 (<1)	O (0)	
California	434 (9)	5 (12)	
Colorado	57 (1)	O (0)	
Connecticut	58 (1)	O (0)	
Delaware	17 (<1)	O (0)	
District of Columbia	34 (1)	O (0)	
Florida‡	1,109 (22)	26 (60)	
Georgia	110 (2)	O (O)	
Hawaii	16 (<1)	O (O)	

https://www.cdc.gov/zika/intheus/maps-zika-us.html#zika-cases-us

Tissue Safety

- Tissue screening is currently not available outside of research settings
- Tissue donors are screened for risk factors for Zika virus using questions that include residence in and travel history to area(s) of active transmission
- **FDA's March 2016 guidance¹ includes ZIKV-related**
 - Recommendations for living donors
 - Recommendations for non-heart-beating (cadaveric) donors

Organ Safety

- No ZIKV guidance has been issued by Health Resources and Services Administration (HRSA), but the Organ Procurement and Transplantation Network (OPTN) issued a statement on ZIKV in July 2016
 - https://optn.transplant.hrsa.gov/news/guidance-on-zika-virus/
- For questions related to ZIKV organ safety, contact the Blood Safety Task Force at eocevent281@cdc.gov

Blood Safety Task Force Blood Donor Screening

Zika Virus Investigational New Drug (IND) Applications

FDA authorized two IND applications for screening donated blood

- Roche Molecular Systems, Inc. cobas[®] Zika Test
 - Authorized for use on March 30, 2016
 - Began with screening donations in Puerto Rico, now includes continental United States
 - Individual donation testing only
- Grifols Diagnostic Solutions, Inc. Procleix[®] Zika Virus Assay
 - Authorized for use on June 20, 2016
 - Focused on southern US, now includes all donations from continental US
 - Combination of pools (16-donations) and individual donation testing
 - > Pool testing was discontinued after December 11, 2016

Blood Safety Task Force Blood Donor Screening – Roche Molecular Systems, Inc.

cobas[®] Zika Test Algorithm Index Donation



*BSRI – Blood Systems Research Institute, San Francisco, CA

cobas[®] Zika Test Algorithm First Follow Up

Sample collected with 2-weeks of index donation



cobas[®] Zika Test Algorithm Second Follow Up

Sample collected 2-8 weeks after index donation



cobas[®] Zika Test Examples

Donor #	Testing Lab	cobas [®] Zika Repeat tests	Simulated Pool (1:6 dilution)	Alternative NAT	IgM	lgG
1	Lab A	NR/NR	NR	NR	Negative	Negative
2	Lab B	NR/NR	NR	NR	Negative	Negative
3	Lab C	R/R	R	R	Equivocal	Positive
4	Lab C	R/NR	NR	NR	Positive	Equivocal
5	Lab B	R/NR	R	R	Positive	Positive
6	Lab B	NR/NR	NR	NR	Negative	Negative
7	Lab A	R	R	R	Negative	Negative

NR - Non-Reactive; R - Reactive

cobas[®] Zika Test

Testing Laboratories in the United States



Map from Peterson LR, NEJM, April 2016

Modified Image from Roche Molecular Systems, Inc.

Blood Safety Task Force Blood Donor Screening – Hologic, Inc. and Grifols, Inc.

Procleix[®] Zika Virus Assay Algorithm Index Donation



Procleix[®] Zika Virus Assay Algorithm First Follow Up



Procleix[®] Zika Virus Assay Algorithm Additional Follow Ups



Procleix[®] Zika Virus Assay Examples

	Follow-up Sample			
Donor #	Procleix Zika Virus Assay	Alternative NAT	Serology	Procleix Zika Virus Assay, Alternative NAT, and/or Serology
1	Reactive	Reactive	Nonreactive	Nonreactive
2	Reactive	Nonreactive	Nonreactive	Reactive
3	Reactive	Nonreactive	Nonreactive	Nonreactive
4	Reactive	Missing	Nonreactive	Nonreactive
5	Reactive	Nonreactive	Missing	Nonreactive
6	Reactive	Nonreactive	Missing	Reactive

Procleix[®] Zika Virus Assay Testing Site

Testing Sites	Testing Start Date
American Red Cross (Charlotte, NC)	6/20/2016
American Red Cross (St. Louis, MO)	8/29/2016
American Red Cross (Portland, OR)	9/6/2016
Creative Testing Solutions (Phoenix, AZ)	7/18/2016
Creative Testing Solutions (Dallas, TX)	7/18/2016
Oklahoma Blood Institute (Oklahoma City, OK)	9/21/2016
MD Anderson (Houston, TX)	9/21/2016
Blood Assurance (TN)	9/25/2016
Inova Blood Services (VA)	9/28/2016
Rhode Island Blood Center (Providence, RI)	11/19/2016
Labs, Inc. (Centenial, CO)	11/16/2016
Interstate Blood (Memphis, MO)	12/12/2016

Key Messages

- Blood donor screening is now occurring nationwide through two assays
- State health departments (SHDs) and blood banks should ensure procedures are in place for sharing information regarding positive blood donors
 - Examples: FL DOH and OneBlood, TX DSHS and Gulf Coast Regional Blood Center
- Blood donation screening may help public health identify new areas of transmission
- Presumptive viremic donors (PVDs) should be reported to ArboNET
 - Updated ArboNET instructions for reporting blood donors was distributed by CSTE
- Tissue donor screening is not currently included under INDs
- SHDs and tissue banks should strengthen communication regarding ZIKV and tissue donations
- **Resources are available on the CDC Blood Safety Website**
 - Investigational toolkit: Transfusion-Transmitted Infections
 - https://www.cdc.gov/zika/transmsion/blood-transfusion.html



Closing Remarks

TELECONFERENCE OVERVIEW	DATE/TIME/LOCATION
Laboratory Task Force Eddie Ades, Robert Lanciotti, Christy Ottendorfer	Wed 3/15/2017 / 2pm–3pm EDT - Domestic Wed 3/15/2017 / 5 pm–6 pm EDT - Islands Bridge Line: 1(888)972-6716/ Passcode: 6721430
Joint Information Center/Communications	Wed 3/22/2017 / 2pm–3pm / Rm 5116
Cathy Young, John O'Connor	Bridge Line: 1(888)972-6716/ Passcode: 6721430
Epidemiology Task Force	Thurs 3/23/2017 / 2pm–3pm / Rm 5116
Stacey Martin, Carolyn Gould	Bridge Line: 1(888)972-6716/ Passcode: 6721430
Vector Issues Team	Tues 3/28/2017 / 2pm–3pm / Rm 5116
Janet McAllister, Audrey Lenhart	Bridge Line: 1(888)972-6716/ Passcode: 6721430
Policy and Partnerships	Wed 3/29/2017 / 1:30pm–2:30pm / Rm 5116
Sue Visser, Melody Stevens	Bridge Line: 1(888)972-6716/ Passcode: 6721430
Pregnancy and Birth Defects Task Force (including surveillance)	Wed 3/29/2017 / 3pm–4pm / Rm 5116
Peggy Honein, Dana Meaney-Delman, Suzanne Gilboa	Bridge Line: 1(888)972-6716/ Passcode: 6721430
Blood Safety Task Force Sustainment Strategy Discussions Koo Chung, Matt Kuehnert	Thurs 3/30/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Medical Investigations Team Sustainment Strategy Discussions Maleeka Glover	Thurs 3/30/2017 / 3:30pm–4:30pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430

Thank You!

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 <u>www.cdc.gov</u>

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

