CDC Zika IMS Jurisdiction and Partner Sustainment Strategy

Wednesday, March 1, 2017

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Director, Division of State and Local Readiness
Office of Public Health Preparedness and Response

Michael Beach, PhD
Deputy Incident Manager for the CDC Zika Virus Response
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- Task Force Presentations
- Closing Remarks
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<td>Medical Investigations Team</td>
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<tr>
<td>• Maleeka Glover</td>
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Speakers for the March 1st “Sustaining the Zika Response in 2017” Presentations

Epidemiology Task Force - Carolyn Gould

Pregnancy and Birth Defects Task Force - Peggy Honein/Dana Meaney-Delman

Laboratory Task Force - Eddie Ades/Wendi Kuhnert-Tallman

Blood Safety Task Force - Koo-Whang Chung

Medical Investigations Team - Maleeka Glover

Joint Information Center - Erin Connelly

Policy & Partnerships - Sue Visser/Melody Stevens

Vector Issues Task Force – John-Paul Mutebi
Zika virus in the United States

- From 2007–2014, 14 Zika virus disease cases identified in US travelers
- With recent outbreaks in the Americas, cases among US travelers increased substantially
- Limited local mosquito-borne transmission identified in two states (Florida and Texas)
- Outbreaks in three US territories (Puerto Rico, US Virgin Islands, and American Samoa)

Laboratory-confirmed Zika virus disease cases reported to ArboNET by states or territories — United States, 2015–2017 (as of Feb 15, 2017)

<table>
<thead>
<tr>
<th></th>
<th>States N=5,040</th>
<th>Territories N=37,023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel-associated</td>
<td>4,748 (94%)</td>
<td>141 (&lt;1%)</td>
</tr>
<tr>
<td>Locally acquired</td>
<td>220 (4%)</td>
<td>36,882 (99%)</td>
</tr>
<tr>
<td>Other routes*</td>
<td>72 (1%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

*Includes sexual transmission (n=44), congenital infection (n=26), laboratory transmission (n=1), and person-to-person through an unknown route (n=1)

State of residence for reported Zika virus disease and presumptive viremic blood donor cases — U.S. states, 2015–2017 (as of Feb 15, 2017)

<table>
<thead>
<tr>
<th>State</th>
<th>Symptomatic disease cases (N=5,040)</th>
<th>Presumptive viremic blood donors† (N=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York</td>
<td>1,020 (21%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Florida</td>
<td>1,069* (21%)</td>
<td>24 (67%)</td>
</tr>
<tr>
<td>California</td>
<td>420 (9%)</td>
<td>5 (14%)</td>
</tr>
<tr>
<td>Texas</td>
<td>306* (6%)</td>
<td>3 (8%)</td>
</tr>
<tr>
<td>New Jersey</td>
<td>176 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>173 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Maryland</td>
<td>130 (3%)</td>
<td>0 (0%)</td>
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† People who reported no symptoms at the time of donating blood, but whose blood tested positive when screened for the presence of Zika virus RNA by the blood collection agency. Some presumptive viremic blood donors develop symptoms after their donation or may have had symptoms in the past. These individuals may be reported as both Zika virus disease cases and presumptive viremic blood donors.

* Include 210 cases in FL and 6 cases in TX acquired through presumed local mosquito-borne transmission

Reported Zika virus disease and presumptive viremic blood donor cases — U.S. territories, 2015–2017 (as of Feb 15, 2017)

<table>
<thead>
<tr>
<th>Territory</th>
<th>Symptomatic disease cases (N=37,023)</th>
<th>Presumptive viremic blood donors† (N=318)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puerto Rico</td>
<td>35,930 (97%)</td>
<td>318 (100%)</td>
</tr>
<tr>
<td>US Virgin Islands</td>
<td>973 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>American Samoa</td>
<td>120 (&lt;1%)</td>
<td>0 (0%)</td>
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† People who reported no symptoms at the time of donating blood, but whose blood tested positive when screened for the presence of Zika virus RNA by the blood collection agency. Some presumptive viremic blood donors develop symptoms after their donation or may have had symptoms in the past. These individuals may be reported as both Zika virus disease cases and presumptive viremic blood donors.

Month of illness onset for Zika virus disease cases — US states and territories, 2015–2017 (as of Jan 25, 2017)

Number of cases

- States (N=4,930)
- Territories (N=35,784)
Objectives of Zika virus surveillance in the United States

- Quantify and describe disease burden
- Identify and define areas with local mosquito-borne transmission
- Direct prevention and control efforts
- Identify and monitor infections in people at risk for poor outcomes
Continued reporting of Zika virus diseases cases

- Zika virus disease and infection are nationally notifiable
  - CSTE updated case definitions in 7/2016*
    • Includes non-congenital and congenital infection and disease
- Healthcare providers should continue to report suspected cases to their state or local health department
- State health departments should continue to report laboratory-confirmed cases to CDC according to CSTE case definitions
- Timely reporting allows health departments to assess and reduce the risk of local transmission or mitigate further spread

Surveillance strategies to identify possible local transmission during mosquito season

- Survey household members and neighbors of travel-associated cases
- Monitor blood donor screening
- Investigate unusual clusters of rash illness in areas at high risk
- Expand testing for people with no known exposure but more specific constellation of clinical findings
  - For example: patient with fever, rash, and conjunctivitis in area with known vector mosquitoes
Preparing for next season

- Reassess risk areas, populations, and timing
- Continue to educate healthcare providers and local public health officials about Zika virus
- Reassess public health laboratory testing and surge capacity
- Revisit testing capacity and reporting with commercial laboratories
- Update response plans with mosquito control districts
- Continue to coordinate with blood collection agencies
Ongoing challenges for the next season

- Optimal and cost effective approaches to identifying local transmission
- Surveillance strategies for determining extent of local transmission
- Defining travel exposure risk (e.g., border region)
- Identifying likely exposure location of confirmed cases
- Diagnostic issues – cross-reactivity, false positives
  - Differential diagnosis may require testing for other pathogens
- Communicating risk and delineation of risk areas
- Timely and appropriate travel and testing guidance
- Correlating human risks with vector surveillance data
Pregnancy and Birth Defects Task Force
What have we learned?

Established that **Zika is a cause** of microcephaly, serious brain defects, and is linked to potentially other birth defects.

Estimated that among pregnancies with evidence of Zika infection in the 1st trimester, about 11% of fetuses and infants had birth defects.

Recognized pattern of birth defects associated with Zika virus infection called **congenital Zika syndrome**.

Identified that Zika infections during the 1st and 2nd trimester have been associated with birth defects.
What worked?

Successful Partnerships

- CDC collaborated with state and local jurisdictions on travel and testing guidance of pregnant women for Health Alert Network (HAN) notices
- Deployed pregnancy and birth defects expert as part of the CDC Emergency Response Team
- Partnered with state and local jurisdictions and local chapters of clinical partner organizations to increase outreach to healthcare providers
What worked?

Development of Clinical Tools and Guidance

Zika Pregnancy Testing Algorithm

Pretest Counseling Materials
Assessing for Zika During Pregnancy

- All pregnant women should be assessed for possible Zika exposure, signs, and symptoms at each prenatal care visit. They should be asked if they
  - Traveled to or live in an area with active Zika transmission
  - Had sex without a condom with a partner with potential exposure to Zika

CDC Recommendations: Who Should be Tested

Pregnant women with possible exposure to Zika virus and signs or symptoms should be tested for Zika virus infection.

Pregnant women with possible exposure to Zika virus who do not report symptoms also should be tested.

Pregnant women with ongoing risk of Zika virus exposure and who do not report symptoms should be tested in the 1st and 2nd trimesters of pregnancy.

http://www.cdc.gov/mmwr/volumes/65/wr/mm6529e1.htm?s_cid=mm6529e1_e
What worked?
Collaboration with Jurisdictions on US Zika Pregnancy Registry & US Zika Birth Defects Surveillance

- Regular reporting and joint publication of findings
- ELC M2: Funding to support US Zika Pregnancy Registry efforts
- Provided funding to support population-based surveillance of birth defects potentially related to Zika virus
Pregnant Women with Any Laboratory Evidence of Possible Zika Virus Infection

**USZPR Completed Pregnancies**

- Completed Pregnancies with or without birth defects: 1,047
  - Includes aggregated data reported to the US Zika Pregnancy Registry

**USZPR Pregnancy Outcomes**

- Pregnancy Outcomes in the United States and the District of Columbia
  - Liveborn infants with birth defects*: 43
    - Includes aggregated data reported to the US Zika Pregnancy Registry as of February 7, 2017
  - Pregnancy losses with birth defects**: 5
    - Includes aggregated data reported to the US Zika Pregnancy Registry as of February 7, 2017

**US States and the District of Columbia***

- 1,455
  - *Includes aggregated data reported to the US Zika Pregnancy Registry as of February 7, 2017

**US Territories**

- 3,156
  - **Includes aggregated data from the US territories reported to the US Zika Pregnancy Registry and data from Puerto Rico reported to the Zika Active Pregnancy Surveillance System as of February 7, 2017**
What worked?

Local Health Department Field Support

16 jurisdictions applied for CDC resource assignee to support:

- Clinical outreach
- Community outreach / health communications
- Medical abstraction
- Data collection, validation, investigation
- Monitoring and follow up
- Referral to services
Successes

- CDC-developed MAC-ELISA (February 26, 2016) and Trioplex rRT-PCR (March 17, 2016) tests receive first FDA EUA to diagnose Zika virus infection
- CDC continues to manufacture and distribute reagents for these assays domestically and internationally
- CDC laboratories provide confirmatory testing and surge capacity for Zika virus

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Number of Specimens Received</th>
<th>Number of Specimens Tested by rRT-PCR</th>
<th>Number of Specimens Tested by Zika IgM MAC-ELISA</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC-Atlanta</td>
<td>5,023</td>
<td>3,464</td>
<td>2,827</td>
</tr>
<tr>
<td>CDC-Fort Collins</td>
<td>18,262</td>
<td>3,926</td>
<td>15,571</td>
</tr>
<tr>
<td>CDC-San Juan</td>
<td>81,667</td>
<td>45,136</td>
<td>48,015</td>
</tr>
<tr>
<td>LRN</td>
<td>60,788</td>
<td>25,439</td>
<td>35,349</td>
</tr>
<tr>
<td>Total</td>
<td>165,269</td>
<td>77,965</td>
<td>101,762</td>
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Updated 1/2017
Concerns

• Limited data on viral persistence and impact on testing algorithms
• Specificity of diagnostic assays
  • In-house evaluation of 3 commercial assays with MAC-ELISA as gold standard

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<tr>
<th>Manufacturer</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>InBios (EUA approved)</td>
<td>82%</td>
<td>85%</td>
</tr>
<tr>
<td>NovaTec NovaLisa</td>
<td>70%</td>
<td>98%</td>
</tr>
<tr>
<td>Euroimmun</td>
<td>72%</td>
<td>95%</td>
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• Usefulness of PRNT
  • Crossreactivity due to past flavivirus infections
• Turn around time from sample receipt to when results reach physicians
  • Discussions ongoing to pursue HL7 messaging to decrease time from test completion to results being available to a physician
2017 Anticipated Plans

- Provide Zika virus SME and reference laboratory support in Fort Collins
- Maintain surge laboratories for Zika diagnostic testing in Atlanta
- Assist state and territorial laboratories, as needed
- Refine performance of diagnostic assays
- Move testing to commercial laboratories
- New research
Move testing to commercial laboratories

• Early in response CDC entered into agreements with the 4 nation-wide commercial laboratories
  • Provided MAC-ELISA reagents free of charge to encourage testing until additional serology assays achieved EUA approval
  • Challenges with reporting and assay performance
• Movement of testing will decrease surge needs for CDC laboratories
  • 12 PCR assays currently approved (including Trioplex)
  • 2 IgM assay currently approved (including MAC-ELISA)
New Research: Improvement of Molecular and Serologic Diagnostic Tools for Zika Virus (all CDC laboratories)

- Improve sensitivity of high-throughput rRT-PCR by specimen volume or type
  - Studies ongoing to evaluate serum, whole blood and urine to evaluate sensitivity of each
- Development of a Zika Virus multiplex Bead Assay (IgM/IgG)
  - Investigation of more specific antibodies
- Development of rapid and specific IgM diagnostic test using mass spectrometry
- Refinement of recombinant antigens in testing platforms to eliminate the need for inactivation of live virus
Blood Safety Task Force
Background on Blood, Organ, and Tissue Collection/Screening

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.
Zika and Blood Transfusion

What we know

- On August 26, 2016, FDA issued revised guidance recommending that blood centers in all states and U.S. territories screen individual units of donated whole blood and blood components with a blood screening test authorized for use by FDA under an Investigational new drug (IND) application, or with a licensed test when available. Alternatively, and FDA-approved pathogen-reduction device may be used for plasma and certain platelet products.

- 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 through platelet transfusions have been documented in Brazil.

Zika Virus Blood Screening

- Blood donor screening on the basis of a questionnaire without a laboratory test is insufficient for identifying Zika-infected donors in areas with active mosquito-borne transmission of Zika virus due to the high rate of asymptomatic infection.

- Although there is no FDA-licensed test for Zika virus, testing for Zika became available through two separate Investigational New Drug (IND) studies. The INDs are sponsored by two different companies: Progenics Pharmaceuticals Inc. and Vir Biotechnology, Inc. The tests, which are called OraQuick and Prosika, respectively, are being evaluated for safety and effectiveness in transfusion settings.
The areas listed under “Areas of Active Transmission in the U.S.” can differ from those issued for travel guidance's because of additional concerns about potential risk for tissue safety.
Blood Safety Task Force

Tissue Safety
• FDA’s March 2016\(^1\) guidance included Zika virus-related:
  • Recommendations for living donors
  • Recommendations for non-heart-beating (cadaveric) donors

Organ Safety
• No Zika virus guidance has been issued by Health Resources and Services Administration (HRSA), but the Organ Procurement and Transplantation Network (OPTN) issued a statement on Zika virus on July 2016\(^2\)
  • For questions related to ZIKV organ safety, contact the Blood Safety Taskforce at eocevent281@cdc.gov

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\(^1\) [https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceandregulatoryinformation/guidances/tissue/ucm488582.pdf](https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceandregulatoryinformation/guidances/tissue/ucm488582.pdf)

Blood Safety Task Force

Key Messages

• Blood donation screening can help public health identify new areas of transmission

• State health departments (SHDs) and blood banks should ensure procedures are in place for sharing information regarding positive blood donors
  • Presumptive viremic donors (PVDs) should be reported to ArboNET

• SHDs and tissue banks should strengthen communication regarding Zika virus and tissue donations
Joint Information Center (JIC)
Zika—a threat like no other

- The most complex communication challenge in CDC (and US public health) history
  - More risks and more unknowns
  - Diverse audiences, various languages and divided opinions

- Guiding communication principles for response
  - Evidence-based communication strategy
  - Coordination and consistency at all levels of government
  - Research to understand audience needs and behaviors in the midst of rapidly changing information
  - Collaboration with the community to inform strategy, mobilize partners, and amplify messages
  - Continuous, real-time evaluation driving adjustments to strategies and tactics
Communication – One Year Later

- Intensive, multisector initiatives, including health marketing and private-sector partnerships, can influence awareness and behaviors.
- In some higher risk areas, not all pregnant women are aware of Zika, its effects on health, or how to protect themselves.
- Preventive actions most often mentioned by audiences aware of Zika were:
  - 1) Wearing repellent
  - 2) Dumping accumulated water
- “Invisibility” of Zika may contribute to complacency among audiences who aren’t personally at risk.
Communication Strategy

- **ZAP Summit communication planning— Spring 2016**
  - Create a written, strategic communication plan
  - Include goals, objectives, target audiences, tactics, key messages and evaluation metrics
  - Revisit and update the plan throughout the response
  - Currently updating for 2017

- **Incorporate core risk communication principles in the plan**
  - Show empathy
  - Say what you know, what you don’t know, and what you’re doing to find out
  - Crisis & Emergency Risk Communication (CERC) resources: [https://emergency.cdc.gov/cerc](https://emergency.cdc.gov/cerc)

- **Direct all communication activities toward achieving the goals of the plan**
Joint Information Center

Communication Response

- Coordinate between local, state, and federal entities through clear lines of communication
  - Harmonize and amplify communication strategy
  - Consistent messaging builds credibility with the public

- Communicate with the public about the things that are important to them
  - Understand the public’s concerns and respond to them
  - Provide frequent press briefings and media access to the response

- Strengthen the response through robust engagement with community partners, all types
  - Those with other points of view can help to identify communication needs and gaps
  - Engaged partners can act as channels to reach other audiences
Communication Research

- Ground your strategy in research
  - Use convenient and ad hoc information sources to learn about what people do and do not know
    - Monitor local media and social media for themes, misinformation, and gaps
    - Track questions through all public and media inquiry sources (phone calls, emails, social media)
  - Real-time communication research can track message uptake and behavior change

- Refine the communication strategy based on what you learn
  - Add or revise tactics, channels, spokespeople, and messages
  - Update and reinforce information through your own channels, the news media, and partners
  - As the response evolves and you (and your audiences) learn more, focus messaging on addressing gaps
Policy and Partnerships
Partnerships Team Mission

In partnership with the CDC Foundation, CDC continues to grow vital relationships with public and private sector partners.

The partnerships team cultivates partnerships in the areas of:

- Protecting pregnant women
- Ensuring access to contraception
- Executing a comprehensive vector control program
Leveraging Partnerships to Help Decrease the Health Impact of Zika

- Zika Prevention Kits
- ZAP Summit
- Vector Summit
- Americas-Region Communication Campaign
- Zika Contraception Access Network
- Community Engagement
White House Blog on Zika and Business Engagement

“This is a fight that will continue to require the best we can offer from the government, the private sector, and our communities – and it will require partnerships at every level.”

Amy Pope, Immediate Past Deputy Homeland Security Advisor and Deputy Assistant


Funding provided via the ELC M1 mechanism for Zika vector control and surveillance

- Aug 2016: FY16 funding ($18M) awarded to 63 entities, including CONUS states as well as some CONUS cities, AK, HI, PR and Territories

- Dec 2016: FY17 funding ($27M) awarded to 23 entities, mostly southern CONUS states, HI, and territories

Guidelines for Aedes aegypti and Aedes albopictus Surveillance and Insecticide Resistance Testing in the United States

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Part 2: Insecticide Resistance Testing for Known Mosquito Vectors of Zika, Dengue, and Chikungunya Viruses

9. Addendum 1: Overview of Insecticide Resistance Testing Algorithm
10. Addendum 2: Extended Background on Insecticide Resistance
11. References

Second *Stegomyia* survey

- Updated survey for county-level records, Jan 1995 to Dec 2016

- Records for *Ae. aegypti* from 220 counties across 28 states and D.C. (38 new counties, mostly in TX, KS, CA; 2 new states, AL, IL)
- Records for *Ae. albopictus* from 1,368 counties across 40 states and D.C. (127 new counties, mostly in TX, KS, AR, NC)
141 counties in Texas now have documented presence of one or both *Stegomyia* species (*Ae. aegypti* and *Ae. albopictus*):

- 65 counties have documented the presence of both species
- 55 counties have documented the presence of *Ae. albopictus* only
- 21 counties have documented the presence of *Ae. aegypti* only
MosquitoNET online mosquito surveillance and insecticide resistance data reporting

MOSQUITONET WEB APPLICATION USER’S GUIDE
VERSION 1.0.2

CENTERS FOR DISEASE CONTROL AND PREVENTION
DIVISION OF VECTOR-BORNE DISEASES

Projecting MosquitoNET outputs

- **Key outputs from the data collected and reported to CDC**
  - **Moving toward more standardized vector surveillance**
    - Improved data/knowledge on the biology of immatures and adults across CONUS, and evaluation of data for specific surveillance methods, should lead to revised, more standardized surveillance schemes
  - **Mapping**
    - County-based presence of *Ae. aegypti* and *Ae. albopictus*
    - Point locations for collections of *Ae. aegypti* and *Ae. albopictus*
    - County-based insecticide susceptibility/resistance patterns
  - **Modeling**
    - Sub-county level predictive models for presence of *Ae. aegypti* and *Ae. albopictus*
    - Sub-county level predictive models for abundance of *Ae. aegypti* and *Ae. albopictus*
    - And more.....
Ongoing CONUS mosquito control initiatives

- **New CDC-funded mosquito control initiatives**
  - Regional Centers of Excellence for Vector-Borne Diseases have been funded and are active (FL, TX, NY, WI): **$40M**
  - BARDA call for sole source contract to Evolva to develop EPA-registered natural product (nootkatone)-based mosquito repellents and toxicants closed 2/15: **$9M**
  - Five new mosquito control research projects are being funded (BAA): **$5M**
  - AMCA was funded to strengthen national mosquito control capacity: **$1.6M**
    - Manual for best mosquito management practices has been updated and is available online
    - New online and hands-on mosquito control training programs are nearing completion
    - Master-trainers for these programs will be trained in March

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<tr>
<td>• Erin Connelly</td>
<td>Thurs 3/23/2017 / 2pm–3pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<td><strong>Epidemiology Task Force</strong></td>
<td>Tues 3/28/2017 / 2pm–3pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<tr>
<td>• Stacey Martin, Carolyn Gould</td>
<td>Wed 3/29/2017 / 3pm–4pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<td><strong>Vector Issues Task Force</strong></td>
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<td>• Janet McAllister, Audrey Lenhart</td>
<td>Thurs 3/30/2017 / 3:30pm–4:30pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<td><strong>Pregnancy &amp; Birth Defects Task Force</strong></td>
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<td>• Peggy Honein, Dana Meaney-Delman, Suzanne Gilboa</td>
<td>Thurs 3/30/2017 / 2pm–3pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<td><strong>Blood Safety Task Force</strong></td>
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<td>• Koo Chung, Matt Kuhnert, Craig Hooper</td>
<td>Thurs 3/30/2017 / 2pm–3pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<td><strong>Medical Investigations Team</strong></td>
<td>Thurs 3/30/2017 / 3:30pm–4:30pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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<td>• Maleeka Glover</td>
<td>Thurs 3/30/2017 / 3:30pm–4:30pm / Rm 5116&lt;br&gt;Line: TBA / Code: TBA</td>
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Thank You!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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.