IHS Clinical Rounds:
Zika Virus and Implications for Pregnancy

Overview - Dean S. Seneca, MPH, MCURP

State Coordination Task Force, Zika Tribal LNO, Centers for Disease Control and Prevention

August 4, 2016
Topics for Discussion

- Situational Awareness, Zika virus disease in the Americas and the United States
- Sexual transmission risks, patient counseling, education, and contraception
- Review of interim guidelines for healthcare providers for pregnant women and women of childbearing age
- Overview of the U.S. Zika Pregnancy Registry
Zika Virus

- Zika virus was first discovered in 1947 and is named after the Zika Forest in Uganda. In 1952, the first human cases of Zika were detected, and outbreaks of Zika have been reported in tropical Africa, Southeast Asia, and the Pacific Islands.
- Before 2007, at least 14 cases of Zika had been documented.
- Between 2011 and 2014, there were 11 lab-confirmed Zika virus disease cases identified in travelers returning to the U.S. from areas with local transmission.
- Because the symptoms of Zika are similar to those of many other diseases, many cases may not have been recognized.
Zika Virus in the World

As of July 26, 2016
Zika and Travel Around the World

- With the recent outbreaks, the number of Zika cases among travelers visiting or returning to the United States will likely increase.

- To protect travelers from Zika, scientists and travel experts at CDC are monitoring the status of Zika in countries around the world and making appropriate travel recommendations.

- These recommendations are based on a number of factors, including the historical or current presence of Zika in the country.

- Pregnant women should consult with their health care provider and, if they decide to travel, strictly follow steps to prevent mosquito bites.
Zika Virus - USA Situational Awareness

• Lab tests have confirmed Zika virus in travelers returning to the United States. These travelers have gotten the virus from mosquito bites and some non-travelers got Zika through sex with a traveler.

• Florida has identified one neighborhood in Miami where Zika is currently being spread by mosquitoes. During mosquito season, this may occur elsewhere in the United States.

• Zika virus spreads through the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*). These are the same mosquitoes that spread dengue and chikungunya viruses.
Estimated Range of *Aedes aegypti* and *Aedes albopictus* Mosquitoes in the United States

*Aedes aegypti*  
*Aedes albopictus*

*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. Map is not meant to represent risk for spread of disease.*
Zika Virus in the United States

- Currently there are no confirmed blood transfusion transmission cases in the United States.

- CDC has developed various documents including the following:
  - Interim guidance for kindergarten through grade 12 (K–12) district and school administrators for public health actions pertaining to Zika virus infection.
  - Zika Communication Planning Guide.
  - CDC Zika Response Plan (Continental U.S. and Hawaii) Overview: Initial Response to Zika Virus Infections.
    - Describes the CDC response plan for the first locally acquired cases of Zika virus infection in the continental United States and Hawaii.
State of Residence for U.S. Travel-associated Zika Virus Disease Cases Reported to ArboNET, Jan 2015–July 2016

(N=1,306)

<table>
<thead>
<tr>
<th>State</th>
<th>Cases</th>
<th>Percentage</th>
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<td>229</td>
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<td>(3%)</td>
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<tr>
<td>MD</td>
<td>35</td>
<td>(3%)</td>
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</table>
Zika Virus disease in the United States, 2015–2016

**US States as of July 27, 2016**

- Total: 1,658
- Travel-associated cases reported: 1,657
  - Sexually transmitted: 15
- Laboratory acquired cases reported: 1
- Cases in pregnant women: 433 as of July 21, 2016

**US Territories as of July 27, 2016**

- Locally acquired cases reported: 4,727
- Travel-associated cases reported: 21
- Total: 4,750*

*Sexually transmitted cases are not reported for areas with local mosquito-borne transmission of Zika virus because it is not possible to determine whether infection occurred due to mosquito-borne or sexual transmission.*
Objectives of Zika Virus Surveillance in the United States

- Identify local transmission and infections in people at risk for poor outcomes
- Define affected area and populations to direct prevention and control efforts
- Provide a phased response based on size, scope, area, and timing of the outbreak
- Coordinate efforts between state/tribal/local health departments, mosquito control districts, commercial laboratories, blood collection agencies, and CDC and other federal agencies
Topics to Consider

- The risk of transmission in your area
- Having an appropriate surveillance and response plan
- Lab testing availability
- Vector surveillance and control activities
- Public information and communications strategies
- Top Ten Zika Tips can be found at:
  
Zika Virus

Implications for Pregnant Women

Margaret A. Lampe, RN, MPH
Clinical Team, Pregnancy and Birth Defects Task Force

August 4, 2016
“Never before in history has there been a situation where a bite from a mosquito could result in a devastating malformation.”

– Dr. Tom Frieden, CDC Director

*Fortune*, April 13, 2016
Zika Virus Infection in Pregnant Women

- Pregnant women can be infected
  - Through a mosquito bite
  - Through sex with an infected partner

- If infected around conception
  - Zika might present risk to fetus

- If infected during pregnancy
  - Zika can be passed to the fetus during pregnancy or around the time of birth
Zika Infection in Pregnancy

- Incidence of Zika virus infection in pregnant women is not known
- Infection can occur in any trimester
- No evidence of more severe disease compared with non-pregnant people
- No evidence of increased susceptibility

Centers for Disease Control and Prevention, CDC Health Advisory: Recognizing, Managing, and Reporting Zika Virus Infections in Travelers Returning from Central America, South America, the Caribbean and Mexico, 2016.


Zika, Microcephaly, and Other Adverse Outcomes
Zika Is a Cause of Microcephaly
CDC Lab Confirms Zika In Fetal Tissues

- Zika virus identified in:
  - Amniotic fluid
  - Placenta
  - Brain
  - Products of conception
Brain Abnormalities Linked with Zika in the Fetus

- Decreased total brain tissue with resulting microcephaly
- Intracranial calcifications indicating brain damage
- Excess fluid in the brain cavities and surrounding the brain
- Absent or poorly formed brain structures
- Abnormal eye development

Infants With Microcephaly*

Note scattered intracranial calcifications
Note large ventricles and volume loss

*Not for reproduction or dissemination

CT scan images courtesy of Dr. Erin Staples, Division of Vector-Borne Diseases, CDC
Fetal Brain Disruption Sequence

- First described in 1984 but noted in earlier literature
- Brain destruction resulting in collapse of the fetal skull, microcephaly, scalp rugae and neurologic impairment
- Photos and x-ray from 1990 series*; phenotype appears to be present in affected babies in Brazil

Potential Risk of Microcephaly

- 1% - 13% estimated risk of microcephaly due to Zika virus infection in first trimester
  - Modeling based on current outbreak in Bahia, Brazil

- Important to remember:
  - Data limited (infection rates unknown; microcephaly cases still being reported)
  - Microcephaly difficult to detect prenatally
  - Microcephaly only one of a range of possible adverse outcomes

Adverse Outcomes and Zika Virus

- Linked to miscarriage and stillbirth
  - Evidence insufficient to confirm Zika virus as cause

- A range of problems related to brain injury have been detected:
  - Eye abnormalities
  - Hearing impairment
  - Seizures
  - Swallowing impairment
  - Limb abnormalities
  - Severe irritability
  - Developmental delay
  - Growth abnormalities
Many Questions Remain

- What is the full range of potential health problems that Zika virus infection may cause?
- What is the level of risk from a Zika virus infection during pregnancy?
- When during pregnancy Zika virus infection poses the highest risk to the fetus?
- What are other factors (e.g., co-occurring infection, nutrition, symptomatic vs. asymptomatic) that might affect the risk for birth defects?
Updated Pregnancy Guidance

Updates to Guidance

• Expand real-time reverse transcription–polymerase chain reaction (rRT-PCR) testing
  • Emerging data indicate Zika virus RNA can be detected for prolonged periods in some pregnant women
  • Increase the proportion of pregnant women with Zika virus infection who receive a definitive diagnosis
• Testing options vary according to type of possible exposure and timing relative to last possible exposure

Possible Exposure

• Travel to or living in area with Zika virus
• Sex without condom or other barrier that protects against infection, with a partner who has traveled to or lives in in an area with active transmission of Zika virus
Updated Guidance: Symptomatic Pregnant Women

- Symptomatic pregnant women
  - Evaluated <2 weeks after symptom onset
    - Should receive Zika virus rRT-PCR testing of serum and urine
  - Evaluated 2–12 weeks after symptom onset
    - Should first have a Zika virus immunoglobulin (IgM) test
    - If positive or equivocal, serum and urine rRT-PCR should be performed
Updated Guidance: Asymptomatic Pregnant Women

- Who live in areas without active Zika virus transmission, evaluated <2 weeks after their last possible exposure
  - rRT-PCR testing should be performed
    - If the rtRT-PCR test is negative, a Zika IgM test should be performed 2–12 weeks after the exposure

- Who live in an area without active Zika virus transmission, evaluated 2–12 weeks after their last possible exposure
  - Should receive a Zika virus IgM antibody test
    - If positive or equivocal, serum and urine rRT-PCR should be performed

- Who live in areas with active Zika virus transmission
  - Should receive Zika virus IgM antibody testing as part of routine obstetric care during the 1\textsuperscript{st} and 2\textsuperscript{nd} trimesters, with immediate rRT-PCR testing of women who are IgM-positive or equivocal

- Confirm positive or equivocal serology results by PRNT (Zika >10) when rRT-PCR is negative; flavivirus not specified when dengue PRNT also >10
Assessing Exposure to Zika

- All pregnant women should be asked at each prenatal care visit if:
  - They traveled to or live in an area with active Zika virus transmission
  - They had sex without a condom or other barrier that protects against infection with a partner who has traveled to or lives in an area with active Zika virus transmission

- Testing recommendations vary based on timing since onset of symptoms and/or last possible exposure to Zika virus
Tools for Healthcare Providers

Preconception Counseling for Women and Men Living in Areas with Ongoing Spread of Zika Virus - Who Are Interested in Conceiving

**Recommended Key Issues**

**Recommended Questions to Ask**

**Sample Script**

**Answers to Risk of Zika Virus Infection**

- How long do you think you might be pregnant at the time of infection?
- What steps did you take to prevent infection?
- What are the symptoms of Zika virus infection in pregnancy?
- What are the potential risks to the baby if infected?

**Answers to Risk of Zika Virus Infection**

- How long do you think you might be pregnant at the time of infection?
- What steps did you take to prevent infection?
- What are the symptoms of Zika virus infection in pregnancy?
- What are the potential risks to the baby if infected?

**Personal Reasons to Prevent Perinatal Infection**

- Are you willing to get referred to a clinic or hospital for care?
- How long do you think you might be pregnant at the time of infection?
- What steps did you take to prevent infection?
- What are the symptoms of Zika virus infection in pregnancy?
- What are the potential risks to the baby if infected?

**Personal Reasons to Prevent Perinatal Infection**

- Are you willing to get referred to a clinic or hospital for care?
- How long do you think you might be pregnant at the time of infection?
- What steps did you take to prevent infection?
- What are the symptoms of Zika virus infection in pregnancy?
- What are the potential risks to the baby if infected?

**CDC’s Response to Zika**

- For Pregnant Women: A Positive Zika Virus Test

What does it mean for me?

- I tested positive. What happens next?
- If you get a positive test result for Zika virus during pregnancy, what should you tell your doctor and healthcare provider? What are the next steps? What are the steps to take to prevent infection?

What are the risks?

- Ultrasound is a safe and effective way for doctors or healthcare providers to see the fetus during pregnancy. An ultrasound is usually done between 12-20 weeks of pregnancy as part of routine care. What does ultrasound look like? What do doctors look for during ultrasound? What happens if there is a problem during ultrasound?

Does Zika virus cause microcephaly or other problems for the fetus?

- Recent research has shown that Zika virus infection during pregnancy can cause microcephaly and other problems for the fetus. What is microcephaly? What are the symptoms of microcephaly? What are the risks to the baby if infected?

Does a positive Zika virus test mean my baby will have birth defects?

- Studies reported that some, but not all, babies born to women with positive Zika virus test results during pregnancy were born with microcephaly and other problems. At this time, we don’t know how often a baby will have microcephaly or other problems if a woman is infected with Zika while trying to conceive. What are the risks to the baby if infected?

How will my doctor or other healthcare provider know if my baby has microcephaly?

- Your doctor or other healthcare provider will use ultrasound screening to look for microcephaly and other birth defects during your pregnancy. Ultrasound can show some, but not all, problems with your baby’s development during pregnancy. For example, microcephaly can sometimes be seen on the 12-20 week ultrasound but is more commonly detected later in the second trimester or early in the third trimester. For problems after birth, your baby’s doctor will perform a careful physical exam of your baby, recommend routine routine screening, and follow up with more exams and tests as needed.

*Free materials available in English and Spanish*
Pregnancy Planning and Access to Contraception

- Primary strategy to reduce Zika-related pregnancy complications is to support women who want to delay or avoid pregnancy.

- Healthcare providers should:
  - Discuss prevention of unintended pregnancy with women and couples who live in areas with Zika and who want to delay or avoid becoming pregnant.
  - Provide information about birth control methods that best meet their needs (including long-acting reversible contraceptives).
# Most Effective Family Planning Methods

## Most Effective

<table>
<thead>
<tr>
<th>Method</th>
<th>Contraceptive Effectiveness</th>
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<tbody>
<tr>
<td>Implant</td>
<td>0.05%</td>
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<tr>
<td>Pill</td>
<td>0.2%</td>
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<tr>
<td>Copper T</td>
<td>0.8%</td>
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<tr>
<td>Female (Abdominal, Laparoscopic, and Hysteroscopic)</td>
<td>0.5%</td>
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<tr>
<td>Male (Vasectomy)</td>
<td>0.15%</td>
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## Least Effective

<table>
<thead>
<tr>
<th>Method</th>
<th>Contraceptive Effectiveness</th>
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<tbody>
<tr>
<td>Injectable</td>
<td>6%</td>
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<tr>
<td>Pill</td>
<td>9%</td>
</tr>
<tr>
<td>Patch</td>
<td>9%</td>
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<tr>
<td>Ring</td>
<td>9%</td>
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<tr>
<td>Diaphragm</td>
<td>12%</td>
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<td>Male Condom</td>
<td>18%</td>
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<tr>
<td>Female Condom</td>
<td>21%</td>
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<tr>
<td>Withdrawal</td>
<td>22%</td>
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<tr>
<td>Sponge</td>
<td>12% (Nulliparous Women)</td>
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<td>24% (Parous Women)</td>
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## Fertility Awareness-Based Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Contraceptive Effectiveness</th>
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<tr>
<td>Spermicide</td>
<td>28%</td>
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</table>

Other Methods of Contraception:
- Lactational Amenorrhea Method (LAM): a highly effective, temporary method of contraception and
- Emergency Contraception: emergency contraceptive pills or a copper IUD often unruptured intrauterine substantially reduces the risk of pregnancy.

Effective Family Planning Methods

- **Most Effective**
  - Implant (0.05%)
  - Intrauterine Device (IUD) (0.2% LNG, 0.8% Copper T)

- **Permanently Sterilization**
  - Female (Abdominal, Laparoscopic, and Hysteroscopic) (0.5%)
  - Male (Vasectomy) (0.15%)

- **Reversible**
  - Injectable (6%)
  - Pill (9%)
  - Patch (9%)
  - Ring (9%)
  - Diaphragm (12%)

- **Least Effective**
  - Male Condom (18%)
  - Female Condom (21%)
  - Withdrawal (22%)
  - Sponge (24% Nulliparous Women, 24% Parous Women)
  - Spermicide (28%)

**Condoms should always be used to reduce the risk of sexually transmitted infections.**

**Fertility Awareness-Based Methods**

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<th>JANUARY</th>
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**Other Methods of Contraception:**
- **Lactational Amenorrhea Method (LAM):** is a highly effective, temporary method of contraception.
- **Emergency Contraception:** emergency contraceptive pills or a copper IUD after an unplanned intercourse substantially reduce the risk of pregnancy.

# PRECONCEPTION COUNSELING

For Women and Men Living in Areas with Ongoing Spread of Zika Virus Who Are Interested in Conceiving

This guide describes recommendations for counseling women and men living in areas with Zika who want to become pregnant and have not experienced clinical illness consistent with Zika virus disease. This material includes recommendations from CDC’s updated guidance,1 key questions to ask patients, and sample scripts for discussing recommendations and preconception issues. Because a lot of content is outlined for discussion, questions are included throughout the sample script to make sure patients understand what they are being told.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Key Issue</th>
<th>Questions to Ask</th>
<th>Sample Script</th>
</tr>
</thead>
</table>
| Assess pregnancy intentions  | Introduce importance of pregnancy planning | *Have you been thinking about having a baby?*  
*Would you like to become pregnant in the next year?*  
*Are you currently using any form of birth control?* | If you are thinking of having a baby, I would like to help you have a healthy and safe pregnancy. With the Zika virus outbreak, planning pregnancy is more important than ever. Preparing and planning for a healthy pregnancy means getting as healthy as you can before becoming pregnant, and also taking the time now to learn about how best to care for yourself during pregnancy.  
*The best way to prevent Zika is to prevent mosquito bites. To protect yourself at home and work, use air conditioning if possible, install window and door screens and repair any holes to help keep mosquitoes outside. Sleep under a bed net, if air conditioning or screened rooms are not available. Since you live in an area where Zika is spreading, you are at risk of getting Zika. It is important that we discuss the timing of your pregnancy, and ways to prevent infection when you are pregnant.*  
*Knowledge check: What are some ways to protect yourself at home and work?* |
| Assess risk of Zika virus exposure | Environment                        | *Do you have air conditioning in your home? At work?*  
*Do you have window and door screens in your home? At work?*  
*Do you have a bed net? Would you consider using one?*  
*Do you live in an area with a lot of mosquitoes?* |  

<table>
<thead>
<tr>
<th></th>
<th><strong>WOMEN</strong></th>
<th><strong>MEN</strong></th>
</tr>
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<tr>
<td><strong>Recent travel to an area</strong></td>
<td>with Zika or sex without a condom</td>
<td>with an infected partner</td>
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<tr>
<td><strong>Zika virus disease</strong></td>
<td>Wait <em>at least</em> 8 weeks after symptom onset</td>
<td>Wait <em>at least</em> 6 months after symptom onset</td>
</tr>
<tr>
<td><strong>No Zika virus disease</strong></td>
<td>Wait <em>at least</em> 8 weeks after exposure</td>
<td>Wait <em>at least</em> 8 weeks after exposure</td>
</tr>
<tr>
<td><strong>Residence in an area</strong></td>
<td>with Zika</td>
<td></td>
</tr>
<tr>
<td><strong>Zika virus disease</strong></td>
<td>Wait <em>at least</em> 8 weeks after symptom onset</td>
<td>Wait <em>at least</em> 6 months after symptom onset</td>
</tr>
<tr>
<td><strong>No Zika virus disease</strong></td>
<td>Talk with healthcare provider</td>
<td>Talk with health care provider</td>
</tr>
</tbody>
</table>
To prevent sexual transmission of Zika Virus

Use barrier methods consistently and correctly or abstain from sex

- Couples in which a woman is pregnant
  - for the duration of the pregnancy
- Couples who are not pregnant and are not planning to become pregnant
  - If partner had confirmed Zika virus:
    - Men for at least 6 months after onset of illness
    - Women for at least 8 weeks after onset of illness
  - If one partner traveled to or resides in area with active Zika virus transmission but did not develop symptoms:
    - for at least 8 weeks after departure
  - Couples living in area of active Zika virus transmission
    - Consider while active transmission persists
Traveling to Areas with Active Zika Transmission

- Pregnant women should **not** travel to areas with Zika
- If a pregnant woman **must** travel, she should
  - Talk with her healthcare provider before she goes
  - Strictly follow steps to prevent mosquito bites during the trip
  - Take steps to prevent sexual transmission
  - Talk with her healthcare provider after she returns, even if she doesn’t feel sick

US Zika Pregnancy Registry

- **Purpose of registry:**
  To monitor pregnancy and infant outcomes following Zika virus infection during pregnancy and to inform clinical guidance and public health response.

- **How it works:**
  The registry is a supplemental surveillance effort coordinated by CDC and dependent on the voluntary collaboration of the state, tribal, local, and territorial health departments.
US Zika Pregnancy Registry

- **Who is included?**
  Pregnant women with laboratory evidence of Zika virus infection and exposed infants born to these women; infants with laboratory evidence of congenital Zika virus infection and their mothers

- **How can you support the registry?**
  Healthcare providers should contact their state, tribal, local, or territorial health department to arrange for laboratory testing for Zika virus infection in pregnant women and infants who meet the clinical criteria for testing as outlined in the CDC guidelines.
Number of Pregnant Women Who May Be Affected

433*

Pregnant women with any laboratory evidence of possible Zika virus infection in the 50 US States and DC

422**

Pregnant women with any laboratory evidence of possible Zika virus infection in US Territories

*Includes aggregated data reported to the US Zika Pregnancy Registry as of July 21, 2016

**Includes aggregated data from the US territories reported to the US Zika Pregnancy and data from Puerto Rico reported to the Zika Active Pregnancy Surveillance as of July 21, 2016
Reporting Poor Outcomes

- Starting June 16, 2016, CDC began reporting poor outcomes of pregnancies with laboratory evidence of possible Zika virus infection for US states and the District of Columbia (DC).

- As of July 21, 2016, in US states and DC, there were
  - 433 pregnant women reported to the US Zika Pregnancy Registry
  - 13 live-born infants with birth defects
  - 6 pregnancy losses with birth defects
Zika virus infection during pregnancy has been linked to adverse outcomes, including pregnancy loss and microcephaly, absent or poorly developed brain structures, defects of the eye, and impaired growth in fetuses and infants. Despite these observations, very little is known about the risks of Zika virus infection during pregnancy and to infants. Information about the timing, absolute risk, and spectrum of outcomes associated with Zika virus infection during pregnancy and among infants is needed to direct public health action related to Zika virus and guide testing, evaluation and management of pregnant women and infants exposed to Zika virus.

**US Zika Pregnancy Registry**

To understand more about Zika virus infection, CDC established the US Zika Pregnancy Registry and is collaborating with state, tribal, local, and territorial health departments to collect information about pregnancy and infant outcomes among pregnant women with laboratory evidence of Zika virus infection and their infants. The data collected through this Registry will provide additional, more comprehensive information to complement notifiable disease case reporting and will be used to update recommendations for clinical care, to plan for services for pregnant women, children, and families affected by Zika virus and to improve prevention of Zika virus infection during pregnancy.

**How to Participate**

CDC and state, tribal, local, and territorial health department request that healthcare providers participate in the Registry by:

1. Reporting information about pregnant women with laboratory evidence of Zika virus and identifying and reporting suspected congenital Zika virus exposure to their state, tribal, local or territorial health department.
2. Collecting pertinent clinical information about pregnant women with laboratory evidence of Zika virus and their infants on the Pregnancy and Zika Disease Surveillance forms.
3. Providing the information to state, tribal, local or territorial health departments or directly to CDC.

What can Tribal Health Services do?
1. **Educate** about the importance of safe sex and contraception among women and couples who live in areas with local Zika transmission and who want to delay or avoid becoming pregnant.

2. **Assess** availability of contraceptive access for women of reproductive age in your jurisdiction/network/patient population who wish to avoid or delay pregnancy during a local Zika outbreak.

3. **Identify** geographic areas or vulnerable populations who may not have access to contraceptive services.
Once Local Transmission has Occurred

1. **Inform** women and couples who live in areas with local Zika transmission and who want to delay or avoid becoming pregnant about the importance of safe sex and contraception.

2. **Recommend** that healthcare providers ensure that couples who want to delay or avoid pregnancy are informed about birth control methods that best meet their needs, including long-acting reversible contraceptives (IUDs, implants).

3. **Develop** plans to provide contraceptive access for underserved populations.
Thanks to our many collaborators and partners!

For clinical questions, please contact

ZikaMCH@cdc.gov

For U.S. Zika Pregnancy Registry questions, please contact

ZikaPregnancy@cdc.gov

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.
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To understand more about Zika virus infection, CDC established the US Zika Pregnancy Registry and is collaborating with state, tribal, local, and territorial health departments to collect information about pregnancy and infant outcomes among pregnant women with laboratory evidence of Zika virus infection and their infants. The data collected through this Registry will provide additional, more comprehensive information to complement notifiable disease case reporting and will be used to update recommendations for clinical care, to plan for services for pregnant women, children, and families affected by Zika virus and to improved prevention of Zika virus infection during pregnancy.

**How to Participate**

CDC and state, tribal, local, and territorial health department request that healthcare providers participate in the Registry by

1. Reporting information about pregnant women with laboratory evidence of Zika virus and identifying and reporting suspected congenital Zika virus exposure to their state, tribal, local or territorial health department.
2. Collecting pertinent clinical information about pregnant women with laboratory evidence of Zika virus and their infants on the Pregnancy and Zika Disease Surveillance forms.
3. Providing the information to state, tribal, local, or territorial health departments or directly to CDC Registry staff if asked to do so by local health officials.
4. Notifying state, tribal, local or territorial health department staff or CDC Registry staff of adverse events (e.g. spontaneous abortion, termination of pregnancy, and perinatal or infant deaths).

**Who is included in the Registry?**

Pregnant women and infants meeting the following criteria are eligible for the US Zika Pregnancy Registry: 1) pregnant women in the United States with laboratory evidence of Zika virus infection (positive or equivocal test results, regardless of whether they have symptoms) and 2) periconceptionally, prenatally, or perinatally exposed infants born to these women, including infants with any laboratory evidence of congenital Zika virus infection (e.g., detection of Zika virus or Zika virus nucleic acids in a placental, fetal, or neonatal specimens, or serologic evidence of Zika virus in serum or cerebrospinal fluid).

Some infants who meet the above criteria will have been identified prenatally and reported to the health department in accordance with applicable state, tribal, local, and territorial laws supporting notifiable disease surveillance. However, pediatric healthcare providers may also identify previously unrecognized infants with congenital Zika virus infection or with prenatal or perinatal exposure. Information about these infants should be reported to the state, tribal, local, or territorial health department and are eligible to be included in the US Zika Registry. The US Zika Pregnancy Registry will collect supplemental surveillance information from routine medical care of women through pregnancy and infants through the first year of life.
Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure — United States, July 2016

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On July 25, 2016, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr).

CDC has updated its interim guidance for U.S. health care providers caring for pregnant women with possible Zika virus exposure, to include the emerging data indicating that Zika virus RNA can be detected for prolonged periods in some pregnant women. To increase the proportion of pregnant women with Zika virus exposure who receive a definitive diagnosis, CDC recommends expanding real-time reverse transcription–polymerase chain reaction (rRT-PCR) testing. Possible exposures to Zika virus include travel to or residence in an area with active Zika virus transmission, or sex† with a partner who has traveled to or resides in an area with active Zika virus transmission without using condoms or other barrier methods to prevent infection.‡

Testing recommendations for pregnant women with possible Zika virus exposure who report clinical illness consistent with Zika virus disease§ (symptomatic pregnant women) are the same, regardless of their level of exposure (i.e., women with ongoing risk for possible exposure, including residence in or frequent travel to an area with active Zika virus transmission, as well as women living in areas without Zika virus transmission who travel to an area with active Zika virus transmission, or have unprotected sex with a partner who traveled to or resides in an area with active Zika virus transmission). Symptomatic pregnant women who are evaluated <2 weeks after symptom onset should receive serum and urine Zika virus rRT-PCR testing. Symptomatic pregnant women who are evaluated 2–12 weeks after symptom onset should first receive a Zika virus immunoglobulin (IgM) antibody test; if the IgM antibody test result is positive or equivocal, serum and urine rRT-PCR testing should be performed. Testing recommendations for pregnant women with possible Zika virus exposure who do not report clinical illness consistent with Zika virus disease (asymptomatic pregnant women) differ based on the circumstances of possible exposure. For asymptomatic pregnant women who live in areas without active Zika virus transmission and who are evaluated <2 weeks after last possible exposure, rRT-PCR testing should be performed. If the rRT-PCR result is negative, a Zika virus IgM antibody test should be performed 2–12 weeks after the exposure. Asymptomatic pregnant women who do not live in an area with active Zika virus transmission, who are first evaluated 2–12 weeks after their last possible exposure should first receive a Zika virus IgM antibody test; if the IgM antibody test result is positive or equivocal, serum and urine rRT-PCR should be performed. Asymptomatic pregnant women with ongoing risk for exposure to Zika virus should receive Zika virus IgM antibody testing as part of routine obstetric care during the first and second trimesters; immediate rRT-PCR testing should be performed when IgM antibody test results are positive or equivocal. This guidance also provides updated recommendations for the clinical management of pregnant women with confirmed or possible Zika virus infection. These recommendations will be updated when additional data become available.

Introduction

Zika virus continues to spread worldwide, and as of July 21, 2016, 50 countries and territories reported active Zika virus transmission (locations with mosquitoes transmitting Zika virus to persons in the area).¶ Although most persons with Zika virus infection are asymptomatic or have mild clinical disease, infection during pregnancy can cause congenital microcephaly and other brain defects (1). Zika virus has also been linked to other adverse pregnancy outcomes, including miscarriage and stillbirth (1,2). The U.S. Zika Pregnancy Registry (USZPR)** and the Puerto Rico Zika Active Pregnancy Surveillance System (ZAPPS)†† were established in collaboration with state, tribal, local, and territorial health departments to monitor pregnant women with confirmed or possible Zika virus infection to determine the risk for Zika virus infection during pregnancy and the spectrum of conditions associated with congenital Zika virus infection (3). As of July 14, 2016, a total of 400 women in the 50 U.S. states and the District of Columbia, and 378 women in

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* Sex is specifically defined as vaginal sex (penis-to-vagina sex), anal sex (penis-to-anus sex), oral sex (mouth-to-penis sex or mouth-to-vagina sex), and the sharing of sex toys.
† Barrier methods include male or female condoms for vaginal or anal sex, male condoms for oral sex (mouth-to-penis), and male condoms cut to create a flat barrier or dental dams for oral sex (mouth-to-vagina).
§ Zika virus disease is defined as having at least one of the following signs or symptoms: acute onset of fever, rash, arthralgia, conjunctivitis, and laboratory confirmation of Zika virus infection.
all U.S. territories (aggregated territories’ data from the USZPR and ZAPSS) were determined to have laboratory evidence of confirmed or possible Zika virus infection during pregnancy.§§

Data from the USZPR and published case reports indicate that Zika virus RNA can persist in serum of some pregnant women longer than had been previously reported; the longest documented duration of Zika virus RNA detection in serum is 10 weeks after symptom onset (4–7). In addition, recent data indicate that Zika virus RNA might be detected in the serum or urine of some asymptomatic pregnant women (7). The frequency of this finding is unknown, but the detection of Zika virus RNA in serum or urine provides a definitive diagnosis of Zika virus infection. Preliminary data suggest that plaque reduction neutralization testing (PRNT) might not discriminate between Zika virus and other flavivirus infections, particularly in persons with previous flavivirus exposure (8), which complicates interpretation of serologic testing (IgM antibody test and PRNT). Given these challenges, expanded rRT-PCR testing might provide a definitive diagnosis for more pregnant women who are infected with Zika virus.

CDC has revised its interim guidance for U.S. health care providers caring for pregnant women with possible Zika virus exposure. The revised testing recommendations extend the timeframe for rRT-PCR testing of serum and include rRT-PCR testing for some asymptomatic pregnant women. CDC continues to evaluate all available evidence and will update recommendations as new information becomes available.

Updated Recommendations for Evaluating and Testing of Pregnant Women with Possible Zika Virus Exposure

All pregnant women in the United States and U.S. territories should be assessed for possible Zika virus exposure at each prenatal care visit. CDC recommends that pregnant women not travel to an area with active Zika virus transmission (9,10). Pregnant women who must travel to one of these areas should strictly follow steps to prevent mosquito bites during the trip.¶¶ In addition, it is recommended that pregnant women with a sex partner who has traveled to or lives in an area with active Zika virus transmission use condoms or other barrier methods to prevent infection or abstain from sex for the duration of the pregnancy (11).

Symptomatic pregnant women. Pregnant women who report signs or symptoms consistent with Zika virus disease (acute onset of fever, rash, arthralgia, conjunctivitis) should be tested for Zika virus infection (Figure). The testing recommendations for symptomatic pregnant women are the same regardless of the circumstances of possible exposure; however, the type of testing recommended varies depending on the time of evaluation relative to symptom onset. Testing of serum and urine by rRT-PCR is recommended for pregnant women who seek care <2 weeks after symptom onset. This recommendation extends the previous recommendation for testing of serum from <1 week after symptom onset to <2 weeks (Figure). A positive rRT-PCR result confirms the diagnosis of recent maternal Zika virus infection. Symptomatic pregnant women with negative rRT-PCR results should receive both Zika virus IgM and dengue virus IgM antibody testing. If Zika virus rRT-PCR testing is requested from laboratories that do not have IgM antibody testing capacity or a process to forward specimens to another testing laboratory, storing of additional serum samples is recommended for IgM antibody testing in the event of a negative rRT-PCR result (12). If either the Zika virus or dengue virus IgM antibody test yields positive or equivocal results, PRNT should be performed on the same IgM-tested sample or a subsequently collected sample to rule out false-positive results (8).

Symptomatic pregnant women who seek care 2–12 weeks after symptom onset should first receive Zika virus and dengue virus IgM antibody testing (Figure). If the Zika virus IgM antibody testing yields positive or equivocal results, reflex rRT-PCR testing should be automatically performed on the same serum sample to determine whether Zika virus RNA is present. A positive rRT-PCR result confirms the diagnosis of recent maternal Zika virus infection. However, if the rRT-PCR result is negative, a positive or equivocal Zika virus IgM antibody test result should be followed by PRNT. Positive or equivocal dengue IgM antibody test results with a negative Zika virus IgM antibody test result should also be confirmed by PRNT. Interpretation of serologic results has been described (8).

Asymptomatic pregnant women. Testing recommendations for asymptomatic pregnant women with possible Zika virus exposure differ based on the circumstances of possible exposure (i.e., ongoing versus limited exposure) and the elapsed interval since the last possible Zika virus exposure (Figure). Asymptomatic pregnant women living in areas without active Zika virus transmission who are evaluated <2 weeks after possible Zika virus exposure should be offered serum and urine rRT-PCR testing (Figure). A positive rRT-PCR result confirms the diagnosis of recent maternal Zika virus infection. However, because viral RNA in serum and urine declines over time and depends on multiple factors, asymptomatic pregnant women with a negative rRT-PCR result require additional testing to exclude infection. These women should return 2–12 weeks after possible Zika virus exposure for Zika virus IgM antibody testing. A positive or equivocal IgM antibody test result should be confirmed by PRNT.

FIGURE. Updated interim guidance: testing and interpretation recommendations* †, §, ¶ for a pregnant woman with possible exposure to Zika virus** — United States (including U.S. territories)

- Assess for possible Zika virus exposure
- Evaluate for signs and symptoms of Zika virus disease

A

- Symptomatic: <2 weeks after symptom onset, or
- Asymptomatic and NOT living in an area with active Zika virus transmission: <2 weeks after possible exposure

Secondary tree:

- Zika virus rRT-PCR (serum and urine)
- Positive Zika virus rRT-PCR (serum or urine): Recent Zika virus infection
- Negative Zika virus rRT-PCR (serum and urine)
- Dengue virus IgM or dengue virus IgM positive or equivocal and Zika virus IgM negative: Presumptive dengue virus infection
- Zika virus IgM positive or equivocal and any result on dengue virus IgM: Presumptive recent Zika virus or flavivirus infection

B

- Symptomatic: 2–12 weeks after symptom onset, or
- Asymptomatic and NOT living in an area with active Zika virus transmission: 2–12 weeks after possible exposure, or
- Asymptomatic and living in an area with active Zika virus transmission: first and second trimester

Secondary tree:

- Zika virus rRT-PCR (serum and urine)
- Reflex Zika virus rRT-PCR (serum and urine)
- Zika virus IgM and dengue virus IgM (serum)
- Zika virus IgM positive or equivocal and Zika virus IgM negative: Presumptive recent Zika virus or flavivirus infection
- Zika virus IgM positive or equivocal and any result on dengue virus IgM: Presumptive recent Zika virus or flavivirus infection
- Dengue virus IgM or dengue virus IgM positive or equivocal and Zika virus IgM negative: Presumptive recent Zika virus or flavivirus infection
- Zika virus IgM and dengue virus IgM negative: No recent Zika virus infection
- Zika virus IgM or dengue virus IgM positive or equivocal: Presumptive recent Zika virus or dengue virus or flavivirus infection
- Zika virus IgM or dengue virus IgM positive or equivocal: Presumptive recent Zika virus or dengue virus or flavivirus infection
- Zika virus PRNT ≥10 and dengue virus PRNT <10: Recent flavivirus infection, specific virus cannot be identified
- Zika virus PRNT ≥10 and dengue virus PRNT <10: Recent flavivirus infection, specific virus cannot be identified
- Zika virus PRNT <10: No recent evidence of Zika virus infection
- Negative Zika virus rRT-PCR (serum)
- Positive Zika virus rRT-PCR on serum: Recent Zika virus infection
- Positive Zika virus rRT-PCR on serum: Recent Zika virus infection

Abbreviations: IgM = immunoglobulin M; PRNT = plaque reduction neutralization test; rRT-PCR = real-time reverse transcription–polymerase chain reaction.

* A pregnant woman is considered symptomatic if one or more signs or symptoms (acute onset of fever, rash, arthralgia, or conjunctivitis) consistent with Zika virus disease is reported. A pregnant woman is considered asymptomatic if these symptoms are not reported.
† Testing includes Zika virus rRT-PCR on serum and urine samples, Zika virus and dengue virus IgM, and PRNT on serum samples. PRNT results that indicate recent flavivirus infection should be interpreted in the context of the currently circulating flaviviruses. Refer to the laboratory guidance for updated testing recommendations (http://www.cdc.gov/zika/laboratories/lab-guidance.html). Because of the overlap of symptoms in areas where other viral illness are endemic, evaluate for possible dengue or chikungunya virus infection.
§ Dengue virus IgM antibody testing is recommended only for symptomatic pregnant women.
¶ If Zika virus rRT-PCR testing is requested from laboratories without IgM antibody testing capacity or a process to forward specimens to another testing laboratory, storing of additional serum samples is recommended for IgM antibody testing in the event of an rRT-PCR negative result.
** Possible exposure to Zika virus includes travel to or residence in an area with active Zika virus transmission (http://wwwnc.cdc.gov/travel/notices/), or sex (vaginal sex (penis-to-vagina sex), anal sex (penis-to-anus sex), oral sex (mouth-to-penis or mouth-to-vagina sex), and the sharing of sex toys) without a barrier method to prevent infection (male or female condoms for vaginal or anal sex, male condoms for oral sex (mouth-to-penis), and male condoms cut to create a flat barrier or dental dams for oral sex (mouth-to-vagina) with a partner who traveled to, or lives in an area with active Zika virus transmission.
Asymptomatic pregnant women living in an area without active Zika virus transmission, who seek care 2–12 weeks after possible Zika virus exposure, should be offered Zika virus IgM antibody testing (Figure). If the Zika virus IgM antibody test yields positive or equivocal results, reflex rRT-PCR testing should be performed on the same sample. If the rRT-PCR result is negative, PRNT should be performed.

As recommended in previous guidance (9,13), IgM antibody testing is recommended as part of routine obstetric care during the first and second trimesters for asymptomatic pregnant women who have an ongoing risk for Zika virus exposure (i.e., residence in or frequent travel to an area with active Zika virus transmission) (Figure). Reflex rRT-PCR testing is recommended for women who have a positive or equivocal Zika virus IgM antibody test result because rRT-PCR testing provides the potential for a definitive diagnosis of Zika virus infection. Negative rRT-PCR results after a positive or equivocal Zika virus IgM antibody test result should be followed by PRNT. The decision to implement testing of asymptomatic pregnant women with ongoing risk for Zika virus exposure should be made by local health officials based on information about levels of Zika virus transmission and laboratory capacity.

Symptomatic and asymptomatic pregnant women who seek care >12 weeks after symptom onset or possible Zika virus exposure. For symptomatic and asymptomatic pregnant women with possible Zika virus exposure who seek care >12 weeks after symptom onset or possible exposure, IgM antibody testing might be considered. If fetal abnormalities are present, rRT-PCR testing should also be performed on maternal serum and urine. However, a negative IgM antibody test or rRT-PCR result >12 weeks after symptom onset or possible exposure does not rule out recent Zika virus infection because IgM antibody and viral RNA levels decline over time. Given the limitations of testing beyond 12 weeks after symptom onset or possible exposure, serial fetal ultrasounds should be considered.

Updated Recommendations for Prenatal Management of Pregnant Women with Laboratory Evidence of Confirmed or Possible Zika Virus Infection

Laboratory evidence of a confirmed recent Zika virus infection includes 1) detection of Zika virus or Zika virus RNA or antigen in any body fluid or tissue specimen or 2) positive or equivocal Zika virus or dengue virus IgM antibody test results on serum or cerebrospinal fluid with a positive (≥10) PRNT titer for Zika virus together with a negative (<10) PRNT titer for dengue virus (8). However, given that serology test results can be difficult to interpret, particularly in persons who were previously infected with or vaccinated against flaviviruses, and because the adverse outcomes caused by Zika virus infection during pregnancy are not fully described, pregnant women with laboratory evidence of recent flavivirus infection are considered to have possible Zika virus infection and should be monitored frequently (Table).

Pregnant women with confirmed or possible Zika virus infection should be managed in accordance with the updated CDC Interim Guidance (Table). In addition, pregnant women with presumptive recent Zika virus or flavivirus infection (i.e., positive or equivocal Zika virus or dengue virus IgM antibody test result that needs to be confirmed by PRNT) should also be managed in accordance with this updated guidance (Table) until final results are available. Serial fetal ultrasounds (every 3–4 weeks) should be considered to assess fetal anatomy, particularly neuroanatomy, and to monitor growth. Ultrasound findings that have been associated with congenital Zika virus syndrome include microcephaly, intracranial calcifications, ventriculomegaly, arthrogryposis, and abnormalities of the corpus callosum, cerebrum, cerebellum, and eyes (1,14). Consideration of amniocentesis should be individualized, because data about its usefulness in diagnosing congenital Zika virus infection are limited (1,3). The presence of Zika virus RNA in the amniotic fluid might indicate fetal infection (5,15); however, a negative result does not exclude congenital Zika virus infection (1,3). In addition, persistent detection of Zika virus RNA in serum has been reported during pregnancy (7). The clinical implications of prolonged detection of Zika virus RNA in serum are not known; however, repeat rRT-PCR testing has been performed in some cases (5,7).

Updated Recommendations for Postnatal Management of Pregnant Women with Laboratory Evidence of Confirmed or Possible Zika Virus Infection

Infants born to women with laboratory evidence of confirmed or possible Zika virus infection should be evaluated for congenital Zika virus infection in accordance with CDC interim guidance for health care providers caring for infants with possible Zika virus infection. (16). Zika virus testing is recommended for these infants regardless of the presence or absence of phenotypic abnormalities (14). Previous published guidance recommended that testing be performed on cord blood or infant serum; however, the use of cord blood to diagnose other congenital viral infections, such as HIV and syphilis, has sometimes yielded inaccurate results (17–20). Maternal blood can contaminate cord blood specimens leading to false-positive results, whereas Wharton’s jelly in the umbilical cord can yield false-negative results (19,20). Cord blood samples
TABLE. Clinical management of a pregnant woman with suspected Zika virus infection

<table>
<thead>
<tr>
<th>Interpretation of laboratory results*</th>
<th>Prenatal management</th>
<th>Postnatal management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recent Zika virus infection</td>
<td>Consider serial ultrasounds every 3–4 weeks to assess fetal anatomy and growth.† Decisions regarding amniocentesis should be individualized for each clinical circumstance.§</td>
<td>Live births: Cord blood and infant serum should be tested for Zika virus by rRT-PCR, and for Zika IgM and dengue virus IgM antibodies. If CSF is obtained for other reasons, it can also be tested. Zika virus rRT-PCR and IHC staining of umbilical cord and placenta are recommended.¶ Live births: Cord blood and infant serum should be tested for Zika virus by rRT-PCR, and for Zika virus IgM and dengue virus IgM antibodies. If CSF is obtained for other reasons, it can also be tested. Zika virus rRT-PCR and IHC staining of umbilical cord and placenta should be considered.¶</td>
</tr>
<tr>
<td>Recent flavivirus infection; specific virus cannot be identified</td>
<td>Consider serial ultrasounds every 3–4 weeks to assess fetal anatomy and growth.† Amniocentesis might be considered; decisions should be individualized for each clinical circumstance.</td>
<td>Live births: Cord blood and infant serum should be tested for Zika virus by rRT-PCR, and for Zika virus IgM and dengue virus IgM antibodies. If CSF is obtained for other reasons, it can also be tested. Zika virus rRT-PCR and IHC staining of umbilical cord and placenta are recommended.¶ Fetal losses: Zika virus rRT-PCR and IHC staining of fetal tissues should be considered.¶</td>
</tr>
<tr>
<td>Presumptive recent Zika virus infection**</td>
<td>Consider serial ultrasounds every 3–4 weeks to assess fetal anatomy and growth.† Fetal abnormalities consistent with congenital Zika virus syndrome include microcephaly, intracranial calcifications, and brain and eye abnormalities. Amniocentesis should be provided to women with recent or presumptive Zika virus infection to evaluate fetal abnormalities.</td>
<td>Fetal abnormalities present: Repeat Zika virus rRT-PCR and IgM test; base clinical management on corresponding laboratory results. Fetal abnormalities absent: Base obstetric care on the ongoing risk for Zika virus exposure risk to the pregnant woman.</td>
</tr>
<tr>
<td>Presumptive recent flavivirus infection**</td>
<td>Fetal abnormalities consistent with congenital Zika virus syndrome include microcephaly, intracranial calcifications, and brain and eye abnormalities. Fetal abnormalities should be individualized for each clinical circumstance.</td>
<td>Fetal abnormalities present: Repeat Zika virus rRT-PCR and IgM test; base clinical management on corresponding laboratory results. Fetal abnormalities absent: Base obstetric care on the ongoing risk for Zika virus exposure risk to the pregnant woman.</td>
</tr>
<tr>
<td>Recent dengue virus infection</td>
<td>Clinical management in accordance with existing guidelines.††</td>
<td>Clinical management in accordance with existing guidelines.††</td>
</tr>
</tbody>
</table>

No evidence of Zika virus or dengue virus infection | Prenatal ultrasound to evaluate for fetal abnormalities consistent with congenital Zika virus syndrome.† | Prenatal ultrasound to evaluate for fetal abnormalities consistent with congenital Zika virus syndrome.† Prenatal ultrasound to evaluate for fetal abnormalities consistent with congenital Zika virus syndrome.† Cord blood and infant serum should be tested for Zika virus by rRT-PCR and IgM test; base clinical management on corresponding laboratory results. Cord blood and infant serum should be tested for Zika virus by rRT-PCR and IgM test; base clinical management on corresponding laboratory results. Cord blood and infant serum should be tested for Zika virus by rRT-PCR and IgM test; base clinical management on corresponding laboratory results. |

Fetal abnormalities present: Repeat Zika virus rRT-PCR and IgM test; base clinical management on corresponding laboratory results. Fetal abnormalities absent: Base obstetric care on the ongoing risk for Zika virus exposure risk to the pregnant woman. | Clinical management in accordance with existing guidelines.†† | Clinical management in accordance with existing guidelines.†† |

Abbreviations: CSF = cerebrospinal fluid; IgM = immunoglobulin M; IHC = immunohistochemical; PRNT = plaque reduction neutralization test; rRT-PCR = real-time reverse transcription-polymerase chain reaction.

* Refer to the previously published guidance for testing interpretation (http://www.cdc.gov/mmwr/volumes/65/wr/mm6521e1.htm).† Fetal abnormalities consistent with congenital Zika virus syndrome include microcephaly, intracranial calcifications, and brain and eye abnormalities.§ Health care providers should discuss risks and benefits of amniocentesis with their patients. It is not known how sensitive or specific rRT-PCR testing of amniotic fluid is for congenital Zika virus infection, whether a positive result is predictive of a subsequent fetal abnormality, and if it is predictive, what proportion of infants born after infection will have abnormalities.¶ Refer to pathology guidance for collection and submission of fetal tissues for Zika virus testing for detailed information on recommended specimen types (http://www.cdc.gov/zika/laboratories/test-specimens-tissues.html). ** rRT-PCR or PRNT should be performed for positive or equivocal IgM results as indicated. PRNT results that indicate recent flavivirus infection should be interpreted in the context of the currently circulating flaviviruses. Refer to the laboratory guidance for updated testing recommendations (http://www.cdc.gov/zika/laboratories/lab-guidance.html). Because of the overlap of symptoms and areas where other viral illnesses are endemic, evaluate for possible dengue or chikungunya virus infection.†† Refer to pathology report for collection and submission of fetal tissues for Zika virus testing for detailed information on recommended specimen types (http://www.cdc.gov/zika/laboratories/test-specimens-tissues.html).
References


20. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015;64(RR-03)

Enrollment of eligible pregnant women and children in the Registry will not require extra paperwork, and enrolled people will not need to go to extra appointments, have extra tests, or pay money to be part of the Registry. The identity of people in the Registry will be kept confidential, and CDC has obtained a Federal Assurance of Confidentiality, which allows CDC programs to ensure Registry participants that CDC can use no identifiable information for any purpose other than the purpose for which it was supplied unless an individual has consented to that disclosure.

How to Report to the Registry

- Healthcare providers should contact their state, tribal, local, or territorial health department to arrange for laboratory testing for Zika virus infection in pregnant women and infants who meet the clinical criteria for testing as outlined in the CDC guidelines.¹,²
- Healthcare providers can also contact the CDC Zika Pregnancy hotline (available through the EOC Watch Desk at 770-488-7100, ZikaMCH@cdc.gov or ZikaPregnancy@cdc.gov or fax at 404-718-2200) to discuss clinical management of women with laboratory evidence of Zika virus infection. If healthcare providers contact CDC for clinical consultation, Registry staff will ensure that state, tribal, local, and territorial health departments are notified. CDC may also learn about pregnant women and infants with laboratory evidence of Zika virus infection through national surveillance of arboviral diseases.

How the data are collected

Depending on the preference of the state, tribal, local, or territorial health department, either health department staff or CDC Registry staff will contact healthcare providers caring for pregnant women and their infants for data collection. The information collected includes details of the pregnancy, birth history, and findings from physical, developmental, imaging, and laboratory assessments performed during clinical care of the infant at birth and at 2, 6, and 12 months of age.

CDC is requesting the collection of clinical information in identifiable form as a public health authority. As defined in the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations, Standards for Privacy of Individually Identifiable Health Information (45 CFR § 164.501) (“Privacy Rule”), covered entities (e.g., healthcare providers) may disclose protected health information without patient authorization to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease (42 CFR § 164.512). Data to be collected include clinical information pertaining to the pregnant woman’s health, monitoring and testing during pregnancy, results from evaluation and testing conducted at birth, and clinical/developmental information form the infant through the first year of life. As established in the HIPAA Privacy Rule (45 CFR 164.528), individuals have the right to request from covered entities (i.e., you the healthcare provider) an accounting of the disclosures of their protected health information.

More Information about Zika

For more information or to contact CDC Registry staff, call the CDC Emergency Operations Centers watch desk at 770-488-7100 and ask for the Zika Pregnancy Hotline or email ZikaPregnancy@cdc.gov. More information on caring for pregnant women, infants, or children with Zika virus infection is available at http://www.cdc.gov/zika.

CDC Guidance Materials

1. Interim guidance for Health Care Providers Caring for Pregnant Women and Women of Reproductive Age with Possible Zika Virus Exposure – United States, 2016 (April 1, 2016) http://www.cdc.gov/mmwr/volumes/65/wr/mm6512e2.htm
2. Interim Guidelines for Healthcare Providers Caring for Infants and Children with Possible Zika Virus Infection – United States, February 2016 (Feb. 19, 2016) http://www.cdc.gov/mmwr/volumes/65/wr/mm6507e1.htm