Updated Interim Zika Clinical Guidance for Reproductive Age Women and Men, Sexual Transmission of Zika, and the U.S. Zika Pregnancy Registry

Clinician Outreach and Communication Activity (COCA) Call April 12, 2016



Office of Public Health Preparedness and Response

Division of Emergency Operations

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Objectives

At the conclusion of this session, the participant will be able to:

- Describe current CDC guidance for clinicians caring for women and men of reproductive age with possible Zika exposure
- Explain the purpose and scope of the US Zika Pregnancy Registry and clinicians' role in ensuring its success
- Interpret pediatric testing guidance in newborns and infants with possible Zika virus infection

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Zika Virus

Updates on Interim Zika Virus Clinical Guidance, Recommendations, and U.S. Zika Pregnancy Registry

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April 12, 2016

Topics to be covered

- Brief overview
- Updated Interim Guidance for Prevention of Sexual Transmission of Zika Virus
- Updated Interim Guidance for Health Care Providers Caring for Women of Reproductive Age with Possible Zika Virus Exposure
- Preventing Transmission of Zika Virus in Labor and Delivery Settings Through Implementation of Standard Precautions
- Interpretation of Pediatric Testing Guidance
- U.S. Zika Pregnancy Registry

What is Zika virus disease?

- Disease spread primarily through the bite of an Aedes mosquito infected with Zika virus
 - Aggressive daytime biters, live indoors and outdoors
 - Can also bite at night
- Symptoms are mild and last for several days to a week:
 - Fever, maculopapular rash, arthralgia, conjunctivitis
 - Myalgia, headache
 - Severe disease requiring hospitalization is uncommon



Aedes aegypti mosquito

Transmission of Zika virus

- Other modes of transmission
 - Intrauterine and perinatal transmission
 - Sexual transmission
 - Laboratory exposure
- Theoretical modes of transmission
 - Blood transfusion
 - Organ or tissue transplantation
 - Breast milk
 - Fertility treatment
- 33 countries and territories in the Americas and 41 countries worldwide reporting active Zika virus transmission (as of 4/11/16)

Status of Zika Virus in the 50 states and DC

- Local vector-borne transmission of Zika virus has not been reported in the continental United States
- With current outbreak in the Americas, cases among U.S. travelers will likely increase
- Imported cases may result in virus introduction and local transmission in some areas of U.S.
- Zika Action Plan Summit at CDC 4/1/16 to assist states in the development of response plans

Zika Virus in Pregnancy



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

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.* Besnard, M., et al., Evidence of Perinatal Transmission of Zika Virus, French Polynesia, December 2013 and February 2014. Euro Surveill, 2014. 19(14): p. 1-5. Oliveira Melo, A., et al., Zika Virus Intrauterine Infection Causes Fetal Brain Abnormality and Microcephaly: Tip of the Iceberg? Ultrasound in Obstetrics & Gynecology, 2016. 47(1): p. 6-7.

Zika Virus – Fetal Brain Abnormalities

- 2016 Brazil study: 42 women with laboratory-confirmed Zika virus infection with prenatal ultrasound
 - 12 (29%) abnormalities detected, including 2 intrauterine fetal deaths
 - 7 (17%) structural brain anomalies (microcephaly, calcifications, cerebellar atrophy, ventriculomegaly)
- 2013-14 outbreak in French Polynesia
 - 8 cases of microcephaly identified
 - Modeling estimated infection with Zika during 1st trimester of pregnancy resulted in microcephaly risk of ≈1%

Brasil P, Pereira JP Jr, Raja Gabaglia C, et al. Zika virus infection in pregnant women in Rio de Janeiro—preliminary report. N Engl J Med 2016. Published online March 4, 2016. <u>http://dx.doi.org/10.1056/NEJMoa1602412</u> Cauchemez S, Besnard M, Bomopard P, et al. Association between Zika virus and microcephaly in French Polynesia, 2013-15: a retrospective study. Lancet 2016. Published online March 15, 2016. <u>http://dx.doi.org/10.1016/S0140-6736(16)00651-6</u>

Zika Virus – Fetal Brain Abnormalities and Prolonged Viremia

2016 case report: pregnant woman with symptom onset 12 weeks' gestation

- Prenatal ultrasound
 - No prenatal diagnosis of microcephaly
 - Decrease in head circumference from 47th to 24th percentile 16-20 weeks
 - Abnormal intracranial anatomy at 19 weeks
 - Fetal MRI at 20 weeks: brain abnormalities, including diffuse cerebral atrophy
- Postmortem evaluation
 - Diffuse cerebral cortical thinning
 - High levels of Zika virus RNA; positive viral culture



UPDATE: Interim Guidance for Prevention of Sexual Transmission of Zika Virus – United States, 2016

Speaker: John T. Brooks, MD



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Interim Guidelines for Prevention of Sexual Transmission of Zika Virus — United States, 2016

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Zika virus is a mosquito-borne flavivirus primarily transmitted by *Aedes aegypti* mosquitoes (1,2). Infection with Zika virus is asymptomatic in an estimated 80% of cases (2,3), and when Zika virus does cause illness, symptoms are generally mild and selflimited. Recent evidence suggests a possible association between The following recommendations, which apply to men who reside in or have traveled to areas with active Zika virus transmission (http://wwwnc.cdc.gov/travel/notices/) and their sex partners, will be revised as more information becomes available.



April 1, 2016

Morbidity and Mortality Weekly Report

Update: Interim Guidance for Prevention of Sexual Transmission of Zika Virus — United States, 2016

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On March 25, 2016, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr). CDC issued interim guidance for the prevention of sexual transmission of Zika virus on February 5, 2016 (1). The following recommendations apply to men who have traveled to or reside in areas with active Zika virus transmission* and their female or male sex partners. These recommendations replace the previously issued recommendations and are updated to onset; RT-PCR of blood at that time was negative (7). Because serial semen specimens were not collected for these three cases, the duration of persistence of infectious Zika virus in semen remains unknown.

All reported cases of sexual transmission involved vaginal or anal sex with men during, shortly before onset of, or shortly after resolution of symptomatic illness consistent with Zika virus disease. It is not known whether infected men who never

Sexual Transmission of Zika Virus: What We Know and What We Do Not Know

What we know:

- Zika virus can be sexually transmitted by a man to his sex partners (female and male), and this is of particular concern during pregnancy
 - All reported cases of sexual transmission involved sex without a condom with men who had or developed symptoms
 - Zika virus can be transmitted when the man has symptoms, before symptoms start, and after symptoms end
- Sexual transmission of many infections, including those caused by other viruses, is reduced by consistent and correct use of latex condoms

Sexual Transmission of Zika Virus: What We Know and What We Do Not Know

What we do not know:

- Whether infected men who never develop symptoms can transmit Zika virus to their sex partners.
- How long Zika virus persists in the semen.
 - Infectious virus (culture) in semen at least 14 days after symptoms of infection began
 - Virus particles (RT-PCR) in semen at least 62 days after symptoms of infection began
- Whether women with Zika infection can transmit Zika virus to their sex partners
- Whether Zika can be transmitted from oral sex
 - It is known that Zika is infectious in semen
 - It is unknown if Zika is infectious in other body fluids exchanged by oral sex, including saliva and vaginal fluids

Sexual Transmission of Zika Virus: CDC Recommendations for Men²¹ Who Live in or Traveled to an Area of Active Zika Virus Transmission

Couples in which a woman is pregnant

Use condoms consistently and correctly or abstain from sex for the duration of the pregnancy

Other couples concerned about sexual transmission

- If man had confirmed Zika virus infection or clinical illness consistent with Zika virus disease
 - Should consider using condoms or abstaining from sex for at least 6 months after illness onset
- If man traveled to an area with active Zika virus transmission but did not develop symptoms
 - Should consider using condoms or abstaining from sex for at least 8 weeks after departure from the area
- If man resides in an area with active Zika virus transmission but has not developed symptoms
 - Might consider using condoms or abstaining from sex while active transmission persists

Oster AM, et al. Interim Guidelines for Prevention of Sexual Transmission of Zika Virus — United States, 2016. MMWR Morb Mortal Wkly Rep 2016;65:323-325

Sexual Transmission of Zika Virus: CDC Recommendations for Men Who Live in or Traveled to an Area of Active Zika Virus Transmission

Testing to determine risk of sexual transmission not recommended

- Tests to detect Zika virus in semen are not widely available
- We have limited understanding of how to interpret the results of such tests
 - Inadequate data on the incidence, persistence, and shedding pattern of Zika in semen to make recommendations

Communicating about the Prevention of Sexual Transmission

Talking about the sexual transmission of Zika virus can be complicated

- Anyone concerned about getting Zika virus from sex can use condoms or choose not to have sex
- To be effective, condoms must be used correctly from start to finish, every time during sex
- Sex includes vaginal, anal and oral (mouth-to-penis) sex
- There may be barriers to accessing and using condoms including availability, price, and a person's ability to convince their partner to use condoms
- Couples who do not desire pregnancy should use the most effective contraceptive methods that can be used correctly and consistently in addition to condoms (also effective against STDs)*
- Religious beliefs may restrict a person's ability to use condoms or other contraception

* Discussed in more detail in the following: Petersen EE, Polen KN, Meaney-Delman D, et al. Update: interim guidance for health care providers caring for women of reproductive age with possible Zika virus exposure—United States, 2016. MMWR Morb Mortal Wkly Rep 2016. Published online March 25, 2016.



Update: Interim Guidance for Health Care Providers Caring for Women of Reproductive Age with Possible Zika Virus Exposure — United States, 2016

Speaker: Christine K. Olson, MD, MPH, CAPT, USPHS

CDC Guidance

- Interim Guidelines for Pregnant Women During a Zika Virus Outbreak United States, 2016 (January 22, 2016)
- Update: Interim Guidelines for Health Care Providers Caring for Pregnant Women and Women of Reproductive Age with Possible Zika Virus Exposure — United States, 2016 (February 12, 2016)
- Update: Interim Guidance for Health Care Providers Caring for Women of Reproductive Age with Possible Zika Virus Exposure — United States, 2016 (March 25, 2016)



Morbidity and Mortality Weekly Report

Update: Interim Guidance for Health Care Providers Caring for Women of Reproductive Age with Possible Zika Virus Exposure — United States, 2016

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On March 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 women of reproductive age with possible Zika virus exposure (1) to include recommendations on counpartners (3,5,7–10). Based on data from a previous outbreak, most persons infected with Zika virus are asymptomatic (11). Signs and symptoms, when present, are typically mild, with the most common being acute onset of fever, macular or papular rash, arthralgia, and conjunctivitis (11).

CDC Recommendations: Pregnant Women and Women of Reproductive Age With Possible Zika Virus Exposure

- Updated guidance includes:
 - Recommendations for women and couples who want to conceive
 - Special considerations for women and couples seeking infertility treatment and women living along the US-Mexico border
 - Minor modifications to the pregnancy guidance/algorithm

Definitions

Possible exposure:

- travel to or residence in an area of active Zika virus transmission
- sex (vaginal, anal, or oral [penis-to-mouth]) without a condom with a man who traveled to or resided in an area of active transmission*
- Zika virus infection: laboratory-confirmation of Zika virus, including asymptomatic persons
- Zika virus disease: having at least one of the following signs or symptoms: acute onset of fever, rash, arthralgia, conjunctivitis and laboratory-confirmation of Zika virus infection

*http://www.cdc.gov/zika/geo/active-countries.html

Recommendations for Women and Men Interested in Conceiving Who <u>DO NOT</u> Reside In an Area With Active Zika Virus Transmission

For **Women** With Possible Exposure to Zika Virus

- Health care providers (HCPs) should discuss signs and symptoms and potential adverse outcomes associated with Zika
- If Zika virus disease diagnosed, wait at least 8 weeks after symptom onset to attempt conception
- If NO symptoms develop, wait at least 8 weeks after last date of exposure before attempting conception

Recommendations for Women and Men Interested in Conceiving Who <u>DO NOT</u> Reside In an Area With Active Zika Virus Transmission

For **Men** With Possible Exposure to Zika Virus

- If Zika virus disease diagnosed, wait **at least 6 months** after symptom onset
- If NO symptoms develop, wait at least 8 weeks after exposure
- Discuss contraception and use of condoms

Recommendations for Women and Men Interested in Conceiving Who <u>Reside</u> In an Area With Active Zika Virus Transmission

- Women and men interested in conceiving should talk with their HCPs
- Factors that may aid in decision-making:
 - Reproductive life plan
 - Environmental risk of exposure
 - Personal measures to prevent mosquito bites
 - Personal measures to prevent sexual transmission
 - Education about Zika virus infection in pregnancy
 - Risks and benefits of pregnancy at this time



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 guidance¹, 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.

Recommendation	Key Issue	Questions to Ask	Sample Script
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.
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?	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?

http://www.cdc.gov/zika/pdfs/preconception-counseling.pdf

Recommendations for Women and Men Interested in Conceiving Who <u>Reside</u> In an Area With Active Zika Virus Transmission

- If couples decide to attempt conception:
 - Recommended use of EPA-registered insect repellent and safety to use during pregnancy
- Recommendations to wait to attempt conception if one or both members of the couple have Zika virus disease:
 - For at least 8 weeks for women who have Zika virus disease
 - For **at least 6 months for men** who have Zika virus disease
- Recommendation for correct and consistent use of condoms or abstaining from sex for duration of pregnancy

Recommendations for Women and Men Interested in Conceiving Who <u>Reside</u> In an Area With Active Zika Virus Transmission

- If couples decide to wait to conceive, HCPs should discuss
 - Strategies to prevent unintended pregnancy
 - Use of the most effective contraceptive methods that can be used correctly and consistently
 - Role of correct and consistent use of condoms in reducing the risk for STIs, including Zika

Special Considerations

Special Considerations: Women Undergoing Infertility Treatment

- No known Zika virus transmission during infertility treatment
- Transmission through donated gametes or embryos theoretically possible
- Virus unlikely to be destroyed by cryopreservation
- Couples using own gametes or embryos should follow recommendations for men and women attempting conception

Special Considerations: Women Undergoing Infertility Treatment – FDA Guidance for Donated Tissues During Zika Outbreak

Living donors ineligible for anonymous donation if:

- Medical diagnosis of Zika virus infection in the past 6 months
- Resided in or traveled to an area with active Zika virus transmission in past 6 months
- Within the past 6 months had sex with a male partner who, during the 6 months before the sexual contact, was diagnosed with or experienced an illness consistent with Zika virus disease or had traveled to an area of active Zika virus transmission

Special Considerations – Pregnant Women Living Along the U.S.-Mexico Border

- HCPs should assess patients' travel histories
 - Frequency of cross-border travel and destinations
 - Include discussion of sexual partners' travel
- Local health officials to determine when to implement testing of asymptomatic pregnant women based on
 - Information about local levels of transmission
 - Lab capacity

Testing Recommendations

CDC Recommendations: Diagnostic testing

- Reverse transcription-polymerase chain reaction (RT-PCR) for viral RNA in serum collected ≤7 days after symptom onset
- Serology for immunoglobulin M (IgM) in serum collected ≥4 days after illness onset
- HCPs need to work with their health departments to arrange testing

CDC Recommendations: Testing for Asymptomatic Pregnant Women with Possible Zika Virus Exposure

- Serologic (IgM) testing can be offered to asymptomatic pregnant women
- Negative IgM result within 2-12 weeks after exposure could suggest a recent infection did not occur and obviate serial ultrasounds
- Information about performance of testing of asymptomatic persons limited

42 Testing of PREGNANT Women With Possible Zika Virus Exposure Who <u>DO NOT</u> Reside in An Area With Active Zika Virus Transmission

- If one or more signs/symptoms of Zika virus disease within 2 weeks of travel, serum testing should be performed
- Testing can be offered to asymptomatic pregnant women with possible exposure
 - History of travel to an area with active Zika virus transmission or
 - Sex without a condom with a symptomatic male
- Testing is not currently recommended for pregnant women with possible sexual exposure to Zika virus if both partners are <u>asymptomatic</u>

Interim Guidelines (3/25/16): Pregnant Women <u>With Possible Zika Virus Exposure NOT</u> <u>Residing</u> in an Area With Active Zika Virus Transmission



Updated Recommendations: Testing for PREGNANT Women <u>Residing</u> in An Area With Active Zika Virus Transmission

- If one or more signs/symptoms of Zika virus disease, testing should be performed at presentation
- If the woman does not report one or more signs/symptoms of Zika virus disease, serum IgM testing for Zika virus can be offered:
 - Upon initiation of prenatal care, and (if negative)
 - In mid-second trimester
- Repeat testing if develops symptoms

Interim Guidelines (3/25/16): Pregnant Women Residing in Areas With Active Zika Virus Transmission



Preventing Transmission of Zika Virus in Labor and Delivery Settings Through Implementation of Standard Precautions

CDC Recommendations: Zika Virus Disease in Labor and Delivery Settings

- Zika virus has been detected in blood, amniotic fluid, urine, saliva, and semen
- No reports to date of transmission of Zika virus transmission from infected patients to HCP or other patients
- Healthcare personnel (HCP) working in these settings must adhere to Standard Precautions

Standard Precautions

- Standard precautions basic measures to prevent infections that apply to all patient care
 - Prevent contact between a patient's body fluids and HCPs' mucous membranes, skin, and clothing
 - Prevent HCP from transmitting potentially infectious material from one patient to another
 - Avoid exposure to contaminated sharp implements
- Include: hand hygiene, personal protective equipment (PPE), safe injection practices, safe handling of contaminated materials

Risk Assessment and Choosing Appropriate PPE

- HCPs must asses their risk for exposure and select appropriate PPE
 - Examples of obstetric procedures that require increasing levels of PPE:
 - Vaginal exam particularly during amniotomy
 - Vaginal delivery including manual removal of placenta
 - Operative procedures
- Factors to consider
 - Anticipated exposure to blood and body fluids, including splashes
 - Protection of mucous membranes, particularly the eyes

Additional measures

- Placement of disposable absorbent material on floor around procedure and delivery area
- Accessibility and availability of PPE and infection control supplies during emergencies
- Standard cleaning and disinfection for environmental surfaces

Reporting and Ongoing Education and Training

- Report all occupational exposures to facility's occupational health clinic
- Provide ongoing education/training about Standard
 Precautions and PPE
- Address barriers to use of Standard Precautions PPE when identified



Updated Guidelines – Application to Infants

and

U.S. Zika Pregnancy Registry

Speaker: Jefferson M. Jones, MD, MPH, LCDR, USPHS





55 **Guidelines for Evaluation and Testing of Infants Whose Mothers** Traveled to or Resided in an Area with Ongoing Transmission During Pregnancy Infant whose mother traveled to or resided in an area with Zika virus transmission during pregnancy Microcephaly or intracranial calcifications detected No microcephaly or intracranial calcifications prenatally or at birth detected prenatally or at birth Positive or inconclusive test for Zika Negative or no Zika virus testing senormed on mother virus infection in mothe Conduct thorough physical examination and Conduct thorough physical Routine care of infant, including examination and perform Zika virus appropriate follow-up on any perform Zika virus testing in infant (Box 1) testing in infant (Box 1) clinical findings Positive or inconclusive test for Positive or inconclusive test for Negative tests for Negative tests for Zika Zika virus infection in infant Zika virus infection Zika virus infection in infant virus infection in infant in infant Perform additional clinical Perform additional clinical Routine care of infant, evaluation (Box 2), report case, Evaluate and treat evaluation (Box 2), report case, including appropriate and assess for possible longand assess for possible longfor other possible follow-up on any clinical term sequelae (Box 3) term sequelae (Box 3) findings etiologies

U.S. 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

U.S. 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? Spread the word about the US Zika Pregnancy Registry and assist with health department follow-up for pregnant women and infants who are part of the registry



More information about Zika

- More information is available on the U.S. Zika Pregnancy Registry website at <u>www.cdc.gov/zika/hc-providers/registry.html</u> To contact CDC Registry staff, call the CDC Emergency Operations Center watch desk at 770-488-7100 and ask for the Zika Pregnancy Hotline or email <u>ZIKApregnancy@cdc.gov</u>
- More information on caring for pregnant women, infants, or children with Zika virus infection is available at <u>www.cdc.gov/zika/index.html</u>.



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) TTY: 1-888-232-6348 www.cdc.gov

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