

**National Reporting**

**Adverse Outcomes of Pregnancies**

**Affected by Zika**



**Communication Toolkit**

**US Zika Pregnancy Registry**

June 16, 2016

## Key Messages

**Starting June 16, 2016, CDC is reporting poor outcomes of pregnancies with laboratory evidence of possible Zika virus infection for the 50 US states and the District of Columbia. Specifically, CDC will report outcomes that fall into two groups: 1) live-born infants with birth defects and 2) pregnancy losses with birth defects.**

- As of June 9, 2016, in the US states and the District of Columbia, there were (insert numbers after release)
  - X pregnant women reported to the US Zika Pregnancy Registry
  - X live-born infants with birth defects
  - X pregnancy losses with birth defects
- These numbers come from the US Zika Pregnancy Registry. In a few weeks, we plan to begin reporting poor pregnancy outcomes linked with Zika in the US Territories.

### Importance:

- Our top priority for the Zika response is to protect pregnant women because of the potential risks associated with Zika virus infection during pregnancy.
- After releasing the initial numbers of pregnant women with laboratory evidence of possible Zika virus infection, CDC received many requests for information about pregnancy outcomes. These requests have come from federal, state and local health officials, healthcare providers and pregnant women and their families.
- Reporting these outcomes ensures that the most up-to-date information about pregnancy outcomes linked with Zika virus is publicly available. This information will contribute to our understanding of the ongoing impact of Zika virus among pregnant women in the US.
- This information will help healthcare providers counsel pregnant women affected by Zika.
- Understanding the outcomes from Zika virus infection during pregnancy is essential for planning at the federal, tribal, state, and local levels for clinical, public health, and other services needed to support pregnant women and families affected by Zika.

### What the outcomes information shows

- The new information from CDC reflects the poor health outcomes of pregnancies with laboratory evidence of possible Zika virus infection reported to the US Zika Pregnancy Registry.
- The number of live-born infants and pregnancy losses with birth defects are combined for the US states and DC. To protect the privacy of the women and children affected by Zika, CDC will not report individual state, tribal, territorial or jurisdictional level data.
- The poor birth outcomes reported include those that have been detected in infants infected with Zika before or during birth, including microcephaly, calcium deposits (intracranial calcifications) in the brain indicating possible brain damage, excess fluid (ventriculomegaly) in the brain cavities and surrounding the brain, absent or poorly formed brain structures, abnormal eye development, or other problems resulting from damage to the brain that affects nerves, muscles and bones, such as clubfoot or tightening of the joints (contractures).

### **About the US Zika Pregnancy Registry:**

- CDC, in collaboration with state, local, tribal, and territorial health departments, established the US Zika Pregnancy Registry for comprehensive monitoring of pregnancy and infant outcomes following possible Zika virus infection.
- Health departments and CDC are working with healthcare providers to collect information about exposure to Zika, the presence or absence of symptoms and pregnancy complications, prenatal Zika testing, pregnancy and birth outcomes, and infant health and development.
- The data collected through the US Zika Pregnancy Registry will be used to inform pregnant women about the risks of Zika, update recommendations for clinical care, plan for services and support for pregnant women and families affected by Zika virus, and improve prevention of Zika virus infection during pregnancy.

### **Q&As**

\*For use during media interviews, in response to internal inquiries, etc.

#### **Why are you starting to report on outcomes of these pregnancies now?**

We take Zika virus and its effects on families very seriously. Most of the women included in the US Zika Pregnancy Registry are still pregnant. To protect the privacy of affected families, we have not reported the small numbers of specific outcomes until now.

However, since the initial release of numbers of pregnant women with laboratory evidence of possible Zika virus infection, CDC has received many requests for information about pregnancy outcomes. These requests have come from federal, state and local health officials, health care providers, and pregnant women and their families.

Poor pregnancy outcomes can be reported without compromising confidentiality or privacy by reporting combined numbers from across the United States. CDC is not reporting the location of these pregnancies by state or jurisdiction. Reporting these outcomes in aggregate will ensure that the most up-to-date information about pregnancy outcomes linked with Zika virus is publicly available. This reporting will contribute to our understanding of the ongoing impact of Zika virus among pregnant women in the US.

#### **Who is included in this outcome information?**

CDC will report outcomes that fall into two groups: 1) live-born infants with birth defects and 2) pregnancy losses with birth defects. These numbers reflect poor health outcomes of pregnancies reported to the US Zika Pregnancy Registry with laboratory evidence of possible Zika virus infection.

The poor birth outcomes reported are those that have been detected in infants infected with Zika before or during birth. These include microcephaly, calcium deposits in the brain indicating brain damage, excess fluid in the brain cavities and surrounding the brain, absent or poorly formed brain structures, abnormal eye development, or other problems resulting from damage to the brain that affects nerves, muscles, and bones, such as clubfoot or tightening of the joints.

**When will you begin reporting cases of microcephaly and other poor outcomes?**

CDC will begin reporting these outcomes starting June 16, 2016.

**What is considered laboratory evidence of Zika virus infection for purposes of reporting to the US Zika Pregnancy Registry?**

Any laboratory evidence of possible Zika virus infection in a pregnancy includes positive results from laboratory testing for Zika virus particles (RT-PCR positive serum, urine, amniotic fluid, or tissue samples) or evidence of an immune reaction to a recent virus that is likely to be Zika (serum Zika IgM positive or equivocal or inconclusive AND Zika PRNT titer  $\geq 10$ ).

**Will all pregnant women with Zika virus have a baby with a birth defect?**

No. Recognizing that Zika is a cause of certain birth defects does not mean that every pregnant woman infected with Zika will have a baby with a birth defect. It means that infection with Zika during pregnancy increases the chances for these problems. Although studies to date have linked Zika with certain birth defects or other pregnancy problems, it's important to remember that even in places with active Zika transmission, women are delivering infants that appear to be healthy.

**How many babies will be born in the US with microcephaly linked to Zika virus infection during pregnancy?**

At this time, we cannot predict how many infants in the United States will have microcephaly linked to Zika virus infection during pregnancy. The US Zika Pregnancy Registry relies on reporting by healthcare providers and health officials. This system may not include all pregnant women with laboratory evidence of possible Zika virus infection and all infants with microcephaly.

**Have there been any birth defects linked to local human-mosquito-human transmission of Zika virus in the continental US?**

- No, to date, there have been no birth defects linked to *locally* acquired Zika virus infection during pregnancy in the continental United States or Hawaii.
- Local transmission means that mosquitoes in the area have been infected with Zika virus and can spread it to people.
- Zika has not been spread by mosquitoes in the continental United States.

**What is the most recent information?**

As of June 9, 2016,

- In the US states and the District of Columbia, there were (insert numbers after release):
  - X pregnant women reported to the US Zika Pregnancy Registry
  - X live-born infants with birth defects
  - X pregnancy losses with birth defects
- In the future, CDC will add information on poor pregnancy outcomes linked with Zika in US Territories.

**Were these outcomes caused by Zika?**

Although these outcomes occurred in pregnancies with laboratory evidence of Zika virus infection, we do not know whether they were caused by Zika virus infection or other factors.

**How often will this information be updated?**

CDC will update this information weekly at the same time as ongoing weekly reporting of the number of pregnant women with laboratory evidence of possible Zika virus infection. The pregnancies and pregnancy outcomes are reported on CDC's website (<http://www.cdc.gov/zika/geo/pregwomen-uscases.html>).

**What does pregnancy loss with birth defects include? How are pregnancy losses with birth defects identified?**

Pregnancy loss with birth defects includes pregnancies in which the fetus had evidence of birth defects and the pregnancy resulted in miscarriage, stillbirth, or termination. During pregnancy, doctors or other healthcare providers can use ultrasound screening to look for microcephaly and other birth defects. Ultrasounds can show some, but not all, problems with a fetus's development during pregnancy. For example, microcephaly can sometimes be seen by ultrasound at 18-20 weeks' gestation, but is more commonly detected later in the second trimester or early in the third trimester. After a pregnancy loss, a physical examination or autopsy can also help identify birth defects.

**How are you protecting the confidentiality of the health information about the pregnant women and infants in [State or Territory]?**

We take the protection of private health information very seriously. During public health emergencies or outbreaks, we work collaboratively with CDC to gather information as quickly as possible to help guide our activities and plan for services to support affected families. We follow strict standards to make sure that the information is only used for the purpose for which it is collected, and that no information made public compromises the privacy of individuals.

**How is CDC improving capacity for testing pregnant women? Is the waiting time for results shorter?**

CDC has made substantial progress in addressing the backlog in testing, in part by expanding capacity at CDC, but more importantly by equipping Laboratory Response Network (LRN) laboratories around the country to do the testing locally. To date, the Food and Drug Administration has issued [Emergency Use Authorizations](#) for two Zika tests from CDC (Zika MAC-ELISA and Trioplex Real-time RT-PCR Assay) Zika Virus RNA and two commercial Zika tests (Real Star's Zika Virus RT-PCR Kit and Focus Diagnostics' Zika Virus RNA Qualitative Real-Time RT-PCR). Given the inherent risks associated with Zika virus infection during pregnancy, all laboratory testing requests and results reports for pregnant women should clearly indicate pregnancy status and should follow standardized laboratory interpretation [guidelines](#) to facilitate prioritization of testing, ascertainment of pregnancies affected by Zika and consistent interpretation of laboratory results.

*NOTE: If your state has a lab(s) testing for Zika, you can add information here about your state's lab capacity*

**Will CDC report state-level or jurisdictional-level data?**

CDC is not reporting individual state, tribal, territorial, or jurisdictional level information regarding Zika-related poor pregnancy outcomes. For the 50 states and the District of Columbia, CDC will report poor pregnancy outcomes related to Zika virus infection that fall into two groups: live-born infants with birth defects and pregnancy losses with birth defects.

We follow strict standards to make sure that the information is only used for the purpose for which it is collected, and that no information made public compromises the privacy of individuals.

### **Are pregnant women prioritized for laboratory testing?**

To facilitate prioritization of testing, ascertainment of pregnancies affected by Zika, and consistent interpretation of laboratory results, all laboratory testing requests and result reports for pregnant women should clearly indicate pregnancy status. We are working to incorporate pregnancy status when ordering laboratory testing.

### **How can clinicians get help with testing?**

Healthcare providers should work closely with the state, local, or territorial health department to ensure that the appropriate test is ordered and interpreted correctly. In addition, CDC maintains a 24/7 Zika consultation service for health officials and healthcare providers caring for pregnant women. To contact the service, call 770-488-7100 and ask for the Zika Pregnancy Hotline or email [ZIKAMCH@cdc.gov](mailto:ZIKAMCH@cdc.gov).

## **Messages for Expectant Parents**

### **What is microcephaly?**

- Microcephaly is a condition where a baby's head is much smaller than expected.
- During pregnancy, a baby's head grows because the baby's brain grows. Microcephaly can occur because a baby's brain has not developed properly during pregnancy or has stopped growing after birth, which results in a smaller head size.

### **What are the signs and symptoms of microcephaly?**

- The main symptom of microcephaly is a head size that is much smaller than normal.
- Depending upon how severe their microcephaly is, infants with microcephaly may experience other problems, such as developmental delay, feeding problems, and seizures.

### **How is microcephaly diagnosed during pregnancy?**

During pregnancy, microcephaly can sometimes be diagnosed with an ultrasound test (which creates pictures of the body). To see microcephaly during pregnancy, the ultrasound test should be done late in the 2nd trimester or early in the third trimester.

### **How is microcephaly diagnosed after birth?**

Microcephaly is diagnosed when an infant's head is smaller than expected as compared to infants of the same age (or gestational age) and sex. For the purpose of evaluating an infant for possible congenital Zika virus infection, microcephaly is defined as head circumference less than the third percentile, based on standard growth charts for sex and age. For a diagnosis of microcephaly to be made, the head circumference should be disproportionately small in comparison with the length of the infant and not explained by other causes (e.g., other birth defects).

### **Is there a cure for microcephaly?**

- There is no known cure or standard treatment for microcephaly.
- Because microcephaly can range from mild to severe, treatment options can range as well.
  - Infants with mild microcephaly often don't experience any other problems besides small head size. These infants will need routine check-ups to monitor their growth and development.

- Infants with more severe microcephaly will need care and treatment focused on managing their related health problems. Getting connected to services early can help infants with microcephaly improve and maximize their physical and intellectual abilities.

### **Can treatments help a baby with microcephaly?**

Developmental services early in life can help some babies with microcephaly improve and maximize their physical and intellectual abilities. These services, known as early intervention, can include speech, occupational, and physical therapies. Sometimes medications also are needed to treat seizures or other symptoms.

### **What should parents do if they have questions about a diagnosis during pregnancy?**

If families would like to speak to someone about a possible Zika virus infection or diagnosis during pregnancy and the risk to the baby, please contact MotherToBaby. This service offers counseling for exposures during pregnancy and might be a valuable resource for families to discuss individual circumstances in more detail.

MotherToBaby experts are available to answer questions in English and Spanish by phone, text, or chat. The free and confidential service is available Monday-Friday from 8am-5pm (local time). To reach MotherToBaby:

- Call 1-866-626-6847
- Text questions to 855-999-3525 (standard text messaging rates may apply)
- Chat live or send an email through the [MotherToBaby](#) website

### **What should parents do who give birth to an infant with microcephaly?**

Parents who give birth to an infant with microcephaly should take two important steps:

- First, talk to their child's doctor about their concerns and appropriate care for their infant.
- At the same time, call their local early intervention program or school system for a free evaluation of their child. This free evaluation can help connect them to the critical services they need to improve and maximize their child's physical and intellectual abilities. They do not need to wait for a doctor's referral or medical diagnosis to make this call.

Parents may also find it useful to seek out the support of other parents who have infants with special healthcare needs. To find a parent support group in their state, parents can visit Family Voices website ([www.familyvoices.org](http://www.familyvoices.org)).