

# **National Reporting of Pregnant Women with Zika Communication Toolkit**

**US Zika Pregnancy Registry & Zika Active  
Pregnancy Surveillance System (ZAPSS)**

US States & Territories

May 20, 2016

*Version 2 (Updated)*



## Overview of National Reporting

### What will CDC report?

Two numbers

- The aggregate number of pregnant women reported to the US Zika Pregnancy Registry from the continental US, Hawaii, and the District of Columbia.
- The aggregate number of pregnant women reported to either the US Zika Pregnancy Registry or the Puerto Rico Zika Active Pregnancy Surveillance System (ZAPSS) from US territories

### Who should be reported?

- Women should be reported to the US Zika Pregnancy Registry or ZAPSS if they have any laboratory evidence of possible Zika virus infection during pregnancy or the periconceptual period.\*
- Laboratory evidence includes:
  - Laboratory testing of women during pregnancy (serum, urine, amniotic fluid)
  - Laboratory or pathologic testing of infant (cord blood), placenta, fetus, or products of conception

### What is considered any laboratory evidence of possible Zika virus infection for the purposes of reporting to the US Zika Pregnancy Registry or to ZAPSS?

- Zika RNA detected by RT-PCR in laboratory or pathology samples, or
- Serum Zika IgM positive or equivocal with Zika PRNT titers  $\geq 10$

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\*Periconceptual includes 6 weeks prior to last menstrual period (LMP) to 2 weeks after LMP.

## Bottom Line

As of May 20, 2016, national reporting of the number of US pregnant women affected by Zika virus infection will change. Previously, CDC reported the number of pregnant women with Zika virus disease, which included pregnant women with both laboratory test results *and* symptoms or pregnancy complications consistent with Zika. CDC will now report pregnancy data from two enhanced surveillance systems: the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System, both of which include pregnant women with any laboratory evidence of possible Zika virus infection, with or without symptoms, and their infants.

New numbers will be higher than previous reports because the criteria for a pregnant woman to be included in these systems is broader.

## Key Messages

- Understanding the range of health effects linked with Zika infection during pregnancy as well as how many and which pregnancies may be at risk of poor outcomes is essential for guiding the public health response to the Zika outbreak.
- To gain a more complete picture of the impact of Zika virus infection during pregnancy, CDC is changing the way it reports the number of pregnant women with Zika in the United States, including US territories.
- These new numbers reflect a broader group of pregnant women with any laboratory evidence of possible Zika virus infection, regardless of whether they experience Zika symptoms.
  - Pregnant women with laboratory evidence of possible Zika virus infection include those in whom Zika virus particles have been detected and those with evidence of an immune reaction to a recent virus that is likely to be Zika.
  - This includes pregnant women who are likely to have Zika yet have laboratory test results that might also be compatible with another similar virus.
  - New numbers reported are not comparable to previous reports.
- The new reporting aligns with recommendations for ongoing monitoring of pregnancies at risk for poor outcomes associated with Zika, based on scientists' current understanding of the effects of Zika infection during pregnancy.

## *About the change in reporting*

- For national numbers of pregnant women affected by Zika, CDC is transitioning away from reporting only women with Zika virus disease (meaning, those who have laboratory test results and symptoms or pregnancy complications consistent with Zika), to reporting from the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System. These are newly established surveillance systems that include pregnant women with any laboratory evidence of possible Zika virus infection, with or without symptoms, and their infants.

## *What you can expect*

- You can expect the numbers to be higher in the initial report because the criteria for a pregnant woman to be included in the Zika pregnancy surveillance systems is broader.
  - Until today, CDC has reported the number of pregnant women who met both of the following criteria: 1) they had symptoms or pregnancy complications consistent with Zika virus disease and 2) they had laboratory test results that show evidence of recent Zika virus infection.

- Starting today, CDC will begin reporting the number of pregnant women with any laboratory evidence of possible Zika virus infection, with or without symptoms. Pregnant women with laboratory evidence of possible Zika virus infection include those in whom Zika virus particles have been detected and those with evidence of an immune reaction to a recent virus that is likely to be Zika.

*Importance of national reporting of pregnant women with laboratory evidence of Zika virus infection*

- Our top priority for the public health response to Zika is to protect pregnant women and their fetuses because of the risks associated with Zika virus infection during pregnancy.
- Understanding the range of health effects linked with Zika infection during pregnancy as well as how many and which pregnancies may be at risk of poor outcomes is essential for guiding the public health response.
- This information will help healthcare providers as they counsel pregnant women affected by Zika and is essential for planning at the federal, state, and local levels for clinical, public health, and other services needed to support pregnant women and families affected by Zika.

*Reasons for the change in reporting*

- Until today, CDC has reported the number of people who had Zika virus disease, which included people with both laboratory evidence and symptoms or pregnancy complications consistent with Zika. However, recently published reports indicate that some pregnant women with laboratory evidence of a recent Zika infection but no apparent illness have had infants with microcephaly and other serious brain defects. The US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System monitor pregnant women with any laboratory evidence of possible Zika virus infection, with or without symptoms. Therefore, reporting numbers from these data sources will provide a more complete picture of the impact of Zika in US states and territories.
- Since the Zika virus outbreak began, experts have found that interpretation of laboratory testing for Zika virus infection can be difficult. The Zika pregnancy surveillance systems include pregnant women with any laboratory evidence of possible Zika virus infection. This includes pregnant women who are likely to have Zika yet have laboratory test results that might also be compatible with another similar virus. The systems cast a broad net to ensure that we are monitoring pregnancies at risk for poor outcomes associated with Zika.

*What these updated numbers show*

- These updated numbers reflect counts of pregnant women in the United States, including US territories, with any laboratory evidence of possible Zika virus infection, with or without symptoms or pregnancy complications. Pregnant women with laboratory evidence of possible Zika virus infection include those in whom Zika virus particles have been detected and those with evidence of an immune reaction to a recent virus that is likely to be Zika.
- This information will help healthcare providers as they counsel pregnant women affected by Zika and is essential for planning at the federal, state, and local levels for clinical, public health, and other services needed to support pregnant women and families affected by Zika.

*What these new numbers do not show*

- These new numbers are **not comparable** to the previous reports. These updated numbers reflect a different, broader population of pregnant women.
- These updated numbers are not **real time** estimates. They will reflect the number of pregnant women reported with any laboratory evidence of possible Zika virus infection as of 12 noon every Thursday the week before; therefore, numbers will be delayed one week.

*About the US Zika Pregnancy Registry and the Zika Active Pregnancy Surveillance System:*

- CDC, in collaboration with state, local, tribal, and territorial health departments, established these systems for comprehensive monitoring of pregnancy and infant outcomes following Zika virus infection.
- Health departments are working with healthcare providers to collect information that is needed to counsel pregnant women and to plan for services to meet the needs of families affected by Zika. They are collecting 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.

*Important role of state participation*

- All states and territories were asked to voluntarily participate in this important component of the public health response.
- Given that the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System aim to provide a complete and representative description of Zika-associated pregnancy and infant outcomes, participation by all jurisdictions is encouraged to gather as much data as possible, as quickly as possible, to arm pregnant women, healthcare providers and public health authorities with needed information.
- CDC will report two numbers that reflect the aggregated data from the continental US, Hawaii, and the District of Columbia and separately, the combined total from the US territories. CDC will not report individual state, tribal, territorial or jurisdictional level data, unless CDC has special permission from the state, tribe or territory. Comprehensive national information will facilitate and improve the public health response.

**Internal Q&As****Why are your updated pregnancy numbers so different from the older ones?**

You can expect the numbers to be higher than those reported previously because the criteria for a pregnant woman to be included in these Zika pregnancy surveillance systems is broader. Before May 20, 2016, CDC reported the number of pregnant women who meet both of the following criteria: 1) those who had symptoms or pregnancy complications consistent with Zika virus disease *and* 2) had laboratory testing results that show evidence of Zika virus. Starting May 20, 2016, CDC will begin reporting the number of pregnant women with any laboratory evidence of possible Zika virus infection, with or without symptoms. Pregnant women with laboratory evidence of possible Zika virus infection include those in whom Zika viral particles have been detected and those with evidence of an immune reaction to a recent virus that is likely to be Zika.

These new pregnancy numbers are *not comparable* to the numbers previously reported. These updated numbers reflect a different, broader population of pregnant women. This reporting aligns with recommendations for ongoing

monitoring of pregnancies at risk for poor outcomes associated with Zika, based on scientists' current understanding of the effects of Zika infection during pregnancy.

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

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. While studies to date have linked Zika and 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. CDC has established the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance Systems to provide information about the chances of delivering a baby with a birth defect and about the range of problems associated with Zika infection in pregnancy-- in all women that have laboratory evidence of Zika infection, with and without symptoms.

### **How often will CDC update these numbers?**

CDC will update these numbers weekly at the same time as the numbers for Zika virus disease are posted on CDC's website. The new reporting on the website will be clearly defined as the numbers reported from the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System. These national estimates for pregnant women will not replace the total numbers of people with reported Zika virus disease from ArboNET, the national notifiable disease system for arboviral diseases, which will continue to be reported weekly.

### **Who is included in the updated pregnancy numbers?**

The updated numbers will include pregnant women who have any laboratory evidence of possible Zika virus infection.

- Women should be reported to the US Zika Pregnancy Registry or the Puerto Rico Zika Active Pregnancy Surveillance System if they have any laboratory evidence of possible Zika virus infection during pregnancy or the periconceptional period (6 weeks prior to last menstrual period (LMP) to 2 weeks after LMP).
  - Testing of the following specimens provide laboratory evidence:
    - Samples from women during pregnancy (serum, urine, amniotic fluid)
    - Samples from the infant (cord blood), placenta, fetus or products of conception

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

Any laboratory evidence of possible Zika virus infection in a pregnant women includes positive results from laboratory testing for Zika virus particles (RT-PCR+ in 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+ or equivocal AND Zika PRNT titer ≥ 10).

### **Is reporting to the registry mandatory?**

As an arboviral disease, Zika virus is a nationally notifiable condition. Healthcare providers are encouraged to report suspected cases to their state, local, or territorial health departments to facilitate diagnosis and mitigate the risk of local transmission; requirements for reporting are determined by state and territorial law. State or local and

territorial health departments are encouraged to report laboratory-confirmed cases to CDC through ArboNET, the national surveillance system for arboviral disease.

Reporting by health departments to CDC for the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System is voluntary. Aggregate national data will inform public health efforts at the local level as well as broader recommendations. The data collected through these systems will complement notifiable disease case reporting and will be used to update recommendations for clinical care, to plan for services for pregnant women and families affected by Zika virus, and to improve prevention of Zika virus infection during pregnancy. Participation by all jurisdictions is encouraged to provide the complete picture. Each new data point collected as part of these systems contributes to what we know about Zika and helps guide our public health action.

### **So does this mean that previous and current total state case counts are incorrect?**

No, this update will not affect reporting of overall and state-based case counts of Zika virus disease. The total number of cases in the US states and territories will continue to be reported on the CDC website using data reported to ArboNET.

Pregnant women who meet the narrower definition for inclusion in the ArboNET system (e.g., those with laboratory testing and symptoms or pregnancy complications consistent with Zika virus disease) will still be counted in the total ArboNET numbers, but the subset of pregnant women included in ArboNET will not be shown.

### **How is CDC improving capacity for testing pregnant women? Have the wait times for testing shortened?**

CDC has made substantial progress in addressing the backlog in tests, in part by expanding capacity at CDC, but more importantly by equipping Laboratory Response Networks (LRN) laboratories around the country to do the testing locally. The Food and Drug Administration has issued Emergency Use Authorizations (EUA) for two commercially available Zika tests. Given the risks associated with Zika virus infection during pregnancy, all laboratory testing requests and results reports for pregnant women should clearly indicate pregnancy status to facilitate both prioritization of testing and counting of Zika affected pregnancies.

*[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 data?**

CDC will report two numbers that reflect the aggregated data from the continental US, Hawaii, and the District of Columbia and separately, the combined total from the US territories. CDC will not report individual state, tribal, territorial, or jurisdictional level data, unless CDC has specific permission from a state, tribe, or territory. Comprehensive national information will facilitate and improve the public health response.

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

All laboratory testing requests and results for pregnant women should clearly indicate pregnancy status to facilitate both prioritization of testing and counting of Zika-affected pregnancies.

### **How can clinicians seek assistance if needed?**

Healthcare providers should work closely with the state or local health department to ensure that the appropriate test is ordered and interpreted correctly. *[Add state contact information]*

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).

**Given the emphasis on the need for including asymptomatic pregnant women, have testing recommendations changed to test all pregnant with a history of travel regardless of symptoms?**

Testing recommendations have not changed. Testing can be offered from 2 to 12 weeks after pregnant women have possible exposure to Zika virus (e.g., travel, sexual transmission). Local health officials should determine when to implement testing of asymptomatic pregnant women based on information about levels of Zika virus transmission and laboratory capacity.

**Why are you not publishing outcomes in the MMWR article?**

Many of the pregnancies are ongoing and the outcome data are not yet available. Reporting small numbers of outcomes may allow women and families to be identified, and protecting patient privacy is of the utmost importance.