16-ID-01

Committee: Infectious Disease

Title: Zika Virus Disease and Zika Virus Infection Without Disease, Including Congenital Infections Case Definitions and Addition to the Nationally Notifiable Diseases List

I. Statement of the Problem
Zika virus (ZIKV) is an emerging mosquito-borne virus that has spread rapidly across the Americas in 2015 and 2016. Subsequent investigations have demonstrated vertical transmission of ZIKV to the fetus in pregnant women. These *in utero* infections have been associated with the potential for devastating outcomes including microcephaly and spontaneous abortions. There is also an association with ZIKV infection and post-infectious Guillain-Barré syndrome (GBS). Because of these epidemiological and clinical features, the World Health Organization declared ZIKV disease a Public Health Emergency of International Concern under the International Health Regulations 2005 on February 1, 2016 (1).

II. Background and Justification
ZIKV, a flavivirus transmitted by *Aedes* species mosquitoes, was first identified in the Zika Forest by the Virus Research Institute in Uganda in a non-human primate in 1947 and from *Aedes africanus* mosquitoes in 1948 (2). Before 2007, there had been only 14 human ZIKV disease cases documented. In 2007, an outbreak of ZIKV disease occurred on Yap Island, Federated States of Micronesia and the ensuing investigation included the first population-based epidemiological study of ZIKV infection and disease (3). It was estimated that 75% (attack rate) of the island's inhabitants were infected with ZIKV resulting in 18% symptomatic and 82% asymptomatic infections. The most common symptoms documented in this outbreak were maculopapular rash, fever, arthralgia, and conjunctivitis. From 2013 to 2014 there was a large outbreak in French Polynesia where *Aedes aegypti* was considered the most important vector. There continues to be ongoing transmission in the Pacific Islands.

In May 2015, the Pan American Health Organization issued an alert regarding the first confirmed ZIKV infection in Brazil. Since that time, local transmission has been reported in many other countries and territories in Latin America and the Caribbean. Brazil reported widespread ZIKV disease in adults and children, and a concomitant and significant rise in the number of infants born with microcephaly, as well as increases in miscarriages. There is now evidence to support ZIKV as a cause of congenital microcephaly and other brain abnormalities, and ZIKV has been associated with fetal losses (5-7). Additionally, increased incidence of GBS has been reported in several countries experiencing ZIKV epidemics and this syndrome is now being linked to ZIKV. Lastly, sexual transmission of ZIKV has been documented (8-10). The extent to which sexual transmission is driving the current outbreak is not known.

Due to the rapidly evolving epidemic of Zika virus infection, the CSTE Executive Board developed an interim position statement to establish standardized case definitions for Zika virus disease and ZIKV congenital infection dated February 26, 2016, and add these conditions to the Nationally Notifiable Diseases List. As laboratory testing for ZIKV has been more widely performed, limitations of the interpretation of serologic test results, including plaque reduction neutralization testing have been recognized, necessitating revisions to the laboratory criteria of the case definitions (11). Additionally, numerous asymptomatic persons, particularly pregnant women are tested for ZIKV infection and will meet laboratory criteria for infection. Because asymptomatic infection might be epidemiologically significant, revisions to the interim surveillance case definitions are proposed to include ZIKV infections without disease. Public health jurisdictions are encouraged to evaluate, report, and monitor identified ZIKV infections, particularly in pregnant women, that don't meet the clinical criteria of the confirmed and probable congenital and non-congenital disease case classifications.
III. Statement of the desired action(s) to be taken

1. Utilize standard sources (e.g. reporting*) for case ascertainment for ZIKV disease and ZIKV infections. Surveillance for ZIKV disease should use the following recommended sources of data to the extent of coverage presented in Table III.

   Table III. Recommended sources of data and extent of coverage for ascertainment of cases of ZIKV disease and ZIKV infections

<table>
<thead>
<tr>
<th>Source of data for case ascertainment</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Population-wide</td>
</tr>
<tr>
<td>Clinician reporting</td>
<td>x</td>
</tr>
<tr>
<td>Laboratory reporting</td>
<td>x</td>
</tr>
<tr>
<td>Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)</td>
<td>x</td>
</tr>
<tr>
<td>Death certificates</td>
<td>x</td>
</tr>
<tr>
<td>Hospital discharge or outpatient records</td>
<td>x</td>
</tr>
<tr>
<td>Extracts from electronic medical records</td>
<td>x</td>
</tr>
<tr>
<td>Birth Defect Registries or birth certificates</td>
<td>x</td>
</tr>
<tr>
<td>Telephone survey</td>
<td>x</td>
</tr>
<tr>
<td>School-based survey</td>
<td>x</td>
</tr>
<tr>
<td>Other</td>
<td>x</td>
</tr>
</tbody>
</table>

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for ZIKV disease and add ZIKV congenital and non-congenital disease and congenital and non-congenital ZIKV infections that do not meet clinical case criteria to the Nationally Notifiable Condition List.
   - 2a. Immediately notifiable, extremely urgent (within 4 hours)
   - 2b. Immediately notifiable, urgent (within 24 hours)
   - 2c. Routinely notifiable

CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.

Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: NNDSS is transitioning to HL7-based messages for case and infections notifications; the specifications for these messages are presented in MMGs. When CSTE recommends that a new condition be made nationally notifiable, CDC must obtain OMB PRA approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.

3. CDC should publish data on ZIKV congenital and non-congenital disease cases as appropriate in MMWR and other venues (see Section IX).

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined above.
IV. Goals of Surveillance
To provide information on the emerging temporal, geographic, and demographic occurrence of ZIKV disease to facilitate prevention and control for this vector-borne infection.

V. Methods for Surveillance: Surveillance for ZIKV disease should use the recommended sources of data and the extent of coverage listed in Table III. Surveillance for ZIKV disease should use the recommended sources of data and the extent of coverage listed in Table III.

VI. Criteria for case identification
A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

Report any illness or laboratory finding to public health authorities that meets any of the following criteria:

- Any person with a clinically compatible illness for ZIKV infection that includes one or more symptoms of acute fever (reported or measured), rash, arthralgia, or conjunctivitis; OR Guillain-Barré syndrome or other neurologic manifestations; AND potential ZIKV exposure:
  - Residence or travel to an area with ongoing ZIKV transmission within 2 weeks of symptom onset; or
  - Epidemiologic link to a person with laboratory evidence of recent ZIKV infection.
  - Recipient of blood products, or tissue or organ transplantation within previous 30 days.

- Any person with laboratory evidence of recent ZIKV infection as indicated by:
  - Culture of ZIKV from blood, body fluid, or tissue
  - Demonstration of ZIKV-specific antigen or RNA in serum, cerebrospinal fluid (CSF), tissue, or other specimen (e.g., amniotic fluid, umbilical cord blood, urine, semen, saliva)
  - ZIKV-specific immunoglobulin M (IgM) antibodies in CSF or serum

- A fetus or infant with congenital microcephaly (4), congenital intracranial calcifications, structural brain or eye abnormalities, or other congenital central nervous system-related abnormalities including defects of clubfoot or multiple joint contractures:
  - Whose mother lived in or traveled to an area with ongoing ZIKV transmission during the pregnancy; or
  - Whose mother had sexual contact with a confirmed case of Zika virus infection; or
  - Whose mother had evidence of ZIKV or unspecified flavivirus infection during the pregnancy.

- Any person whose healthcare record contains a diagnosis of a ZIKV infection

- Any person whose death certificate lists ZIKV infection as a cause of death or a significant condition contributing to death.
### B. Table of criteria to determine whether a case should be reported to public health authorities

**Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities.**

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Zika Virus Disease, non-congenital</th>
<th>Congenital Zika Virus Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Evidence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Acute fever (reported or measured)</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Guillain-Barré syndrome not known to be associated with another diagnosed etiology</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Neurologic manifestations not known to be associated with another diagnosed etiology</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Congenital microcephaly</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Congenital intracranial calcifications</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Congenital structural brain or eye abnormalities</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other congenital central nervous system abnormalities</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Healthcare record contains a diagnosis of Zika virus disease</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Death certificate lists ZIKV as a cause of death or a significant condition contributing to death</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td><strong>Laboratory Evidence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culture of ZIKV from blood, body fluid, or tissue</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Detection of ZIKV-specific RNA in specimens of serum, CSF, tissue or other clinical specimen (e.g., amniotic fluid, umbilical cord blood, urine, semen, saliva)</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Demonstration of ZIKV antigen by immunohistochemical staining of tissue specimen</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>ZIKV-specific IgM antibodies in serum or CSF</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td><strong>Epidemiologic Evidence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residence or travel to an area with known ZIKV transmission within two weeks of symptom onset</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Mother lived in or traveled to an area with ongoing ZIKV transmission during pregnancy</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Epidemiologic link to a person with laboratory evidence of recent ZIKV infection (e.g., sexual contact)</td>
<td>O</td>
<td>O (mother)</td>
</tr>
<tr>
<td>Laboratory evidence of ZIKV or unspecified flavivirus infection in mother during pregnancy</td>
<td></td>
<td>O</td>
</tr>
<tr>
<td>Blood transfusion within 30 days of symptom onset</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Organ or tissue transplant recipient within 30 days of symptom onset</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>
Notes:
S = This criterion alone is Sufficient to report a case.
N = All “N” criteria in the same column are Necessary to report a case.
O = At least one of these “O” (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all “N” criteria in the same column—is required to report a case.
* A requisition or order for any of the “S” laboratory tests is sufficient to meet the reporting criteria.

C. Disease-specific data elements

Clinical information
- Underlying chronic illness
- Immune suppression
- Blood transfusion in past 30 days
- Blood donation in past 30 days
- Organ or tissue transplant recipient in past 30 days
- Organ or tissue donor
- Pregnant
- Prenatal exposure
- Breast fed
- Congenital abnormalities
- Outcome of pregnancy (full term, premature, abortion, etc.)
- Fetal demise (and evidence of ZIKV infection in the fetus, if available)

Laboratory exposure
- Hospitalized
- Fatality

Epidemiologic Risk Factors
- Occupation
- Travel within 14 days prior to onset of illness
- If pregnant, any travel during pregnancy
- Sexual contact with a person with laboratory confirmed or probable ZIKV infection or with recent travel to a country with known ZIKV transmission
- Country, state, or territory where infection was presumed to be contracted
- Mosquito vector exposure
- Association in time and place with a person with laboratory confirmed or probable ZIKV infection

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Clinical Criteria

ZIKV disease case, non-congenital
A person with one or more of the following not explained by another etiology:
- Clinically compatible illness that includes
  - acute onset of fever (measured or reported), or
  - maculopapular rash, or
  - arthralgia, or
  - conjunctivitis
- Complication of pregnancy
  - fetal loss; or
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• fetus or neonate with congenital microcephaly, congenital intracranial calcifications, other structural brain or eye abnormalities, or other congenital central nervous system-related abnormalities including defects such as clubfoot or multiple joint contractures
  • Guillain-Barré syndrome or other neurologic manifestations

ZIKV disease case, congenital
Liveborn infant with congenital microcephaly, or intracranial calcifications, or structural brain or eye abnormalities, or other congenital central nervous system-related abnormalities not explained by another etiology

(As part of the complete evaluation of congenital microcephaly or other CNS birth defects, testing for other congenital infections such as syphilis, toxoplasmosis, rubella, cytomegalovirus infection, lymphocytic choriomeningitis virus infection, and herpes simplex virus infections should be considered. An assessment of potential genetic and other teratogenic causes of the congenital anomalies should also be performed.)

Laboratory Criteria

Recent ZIKV infection
  • Culture of ZIKV from blood, body fluid, or tissue; OR
  • Detection of ZIKV antigen or viral RNA in serum, CSF, placenta, umbilical cord, fetal tissue, or other specimen (e.g., amniotic fluid, urine, semen, saliva), OR
  • Positive ZIKV IgM antibody test in serum or CSF with positive ZIKV neutralizing antibody titers and negative neutralizing antibody titers against dengue or other flaviviruses endemic to the region where exposure occurred

Recent flavivirus infection, possible ZIKV
  • Positive ZIKV IgM antibody test of serum or CSF with positive neutralizing antibody titers against ZIKV and dengue virus or other flaviviruses endemic to the region where exposure occurred
  • Positive ZIKV IgM antibody test AND negative dengue virus IgM antibody test with no neutralizing antibody testing performed

Epidemiologic Linkage

• Resides in or recent travel to an area with known ZIKV transmission; OR
• Sexual contact with a confirmed or probable case within the infection transmission risk window of ZIKV infection or person with recent travel to an area with known ZIKV transmission; OR
• Receipt of blood or blood products within 30 days of symptom onset; OR
• Organ or tissue transplant recipient within 30 days of symptom onset; OR
• Association in time and place with a confirmed or probable case; OR
• Likely vector exposure in an area with suitable seasonal and ecological conditions for potential local vectorborne transmission
CASE CLASSIFICATION

**Zika Virus Disease, non-congenital**

**Confirmed disease case**
Meets clinical criteria for non-congenital disease; AND

Has laboratory evidence of recent ZIKV infection by:
- Detection of ZIKV by culture, viral antigen or viral RNA in serum, CSF, tissue, or other specimen (e.g. amniotic fluid, urine, semen, saliva); OR
- Positive ZIKV IgM antibody test of serum or CSF with positive ZIKV neutralizing antibody titers and negative neutralizing antibody titers against dengue or other flaviviruses endemic to the region where exposure occurred.

**Probable disease case**
Meets clinical criteria for non-congenital disease; AND

Has an epidemiologic linkage; AND

Has laboratory evidence of recent ZIKV or flavivirus infection by:
- Positive ZIKV IgM antibody test of serum or CSF with:
  - positive neutralizing antibody titers against ZIKV and dengue or other flaviviruses endemic to the region where exposure occurred; OR
  - negative dengue virus IgM antibody test and no neutralizing antibody testing performed.

**Infection that Does Not Meet Clinical Criteria, non-congenital**

**Confirmed ZIKV Infection**
A person who does not meet clinical criteria for non-congenital disease; AND

Has laboratory evidence of recent ZIKV infection by:
- Detection of ZIKV by culture, viral antigen or viral RNA in serum, CSF, tissue, or other specimen (e.g. amniotic fluid, urine, semen, saliva); OR
- Positive ZIKV IgM antibody test of serum or CSF with positive ZIKV neutralizing antibody titers and negative neutralizing antibody titers against dengue or other flaviviruses endemic to the region where exposure occurred.

**Probable ZIKV Infection**
A person who does not meet clinical criteria for non-congenital disease; BUT

Has an epidemiologic linkage; AND

Has laboratory evidence of recent ZIKV infection by:
- Positive ZIKV IgM antibody test of serum or CSF with:
  - positive neutralizing antibody titers against ZIKV and dengue or other flaviviruses endemic to the region where exposure occurred; OR
  - negative dengue virus IgM antibody test and no neutralizing antibody testing performed.
Zika Virus Disease, Congenital

**Confirmed Congenital Disease Case**
A neonate meets the clinical criteria for congenital disease AND meets one of the following laboratory criteria:

- ZIKV detection by culture, viral antigen, or viral RNA in fetal tissue, umbilical cord blood, or amniotic fluid; OR neonatal serum, CSF, or urine collected within 2 days of birth; OR
- Positive ZIKV IgM antibody test of umbilical cord blood, neonatal serum or CSF collected within 2 days of birth with positive ZIKV neutralizing antibody titers and negative neutralizing antibody titers against dengue or other flaviviruses endemic to the region where exposure occurred.

**Probable Congenital Disease Case**
A neonate meets clinical criteria for congenital disease; AND

The neonate’s mother has an epidemiologic linkage or meets laboratory criteria for recent ZIKV or flavivirus infection; AND

The neonate has laboratory evidence of ZIKV or flavivirus infection by:

- Positive ZIKV IgM antibody test of serum or CSF collected within 2 days of birth; and
  - positive neutralizing antibody titers against ZIKV and dengue or other flaviviruses endemic to the region where exposure occurred;
  - negative dengue virus IgM antibody test and no neutralizing antibody testing performed.

**Infection that Does Not Meet Clinical Criteria, Congenital**

**Confirmed Congenital Infection without disease**
Neonate who does not meet clinical criteria for a congenital disease case; BUT

The neonate has laboratory evidence of recent ZIKV or flavivirus infection by:

- ZIKV detection by culture, viral antigen or viral RNA in fetal tissue, umbilical cord blood, or amniotic fluid; OR neonatal serum, CSF, or urine collected within 2 days of birth; OR
- Positive ZIKV IgM antibody test of umbilical cord blood, neonatal serum or CSF collected within 2 days of birth with positive ZIKV neutralizing antibody titers and negative neutralizing antibody titers against dengue or other flaviviruses endemic to the region where exposure occurred.

**Probable Congenital Infection without disease**
Neonate who does not meet clinical criteria for a congenital disease case; BUT

The neonate’s mother has an epidemiologic linkage or meets laboratory criteria for recent ZIKV or flavivirus infection; AND

The neonate has laboratory evidence of ZIKV or flavivirus infection by:

- Positive ZIKV IgM antibody test of serum or CSF collected within 2 days of birth; and
  - negative dengue IgM antibody test and no neutralizing antibody testing performed; or
  - positive neutralizing antibody titers against ZIKV and dengue or other flaviviruses endemic to the region where exposure occurred.
B. Classification Tables

Table VII-B. Criteria for defining a case of Zika virus disease or infection.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Zika Virus Disease</th>
<th>Zika Virus Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prob</td>
<td>Conf</td>
</tr>
<tr>
<td>Clinical Evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever of acute onset</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Maculopapular rash</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Guillain-Barré syndrome</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Neurologic manifestation</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Complications of pregnancy including fetal loss, or fetus or neonate with congenital microcephaly or intracranial calcifications</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Congenital microcephaly</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Intracranial calcifications</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Congenital structural brain or eye abnormalities</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other congenital central nervous system abnormalities</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Absence of clinical criteria listed above</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Liveborn infant</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Illness not explained by another etiology</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Laboratory Evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detection of ZIKV by culture, viral antigen or viral RNA in serum, CSF, tissue, or other specimen (e.g., amniotic fluid, urine, semen, saliva)</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Detection of ZIKV by culture, viral antigen, or viral RNA in fetal tissue, umbilical cord blood, or amniotic fluid</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Detection of ZIKV by culture or viral RNA in neonatal serum, CSF, or urine collected within 2 days of birth</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Positive ZIKV IgM antibody test of serum or CSF</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Positive ZIKV IgM antibody test of umbilical cord blood, neonatal serum, or CSF collected within 2 days of birth</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Positive ZIKV neutralizing antibody titers</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Negative neutralizing antibody titers against dengue or other endemic flaviviruses in region where exposure occurred</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Negative dengue-specific IgM antibody test</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>
Positive neutralizing antibody titers against ZIKV and dengue or other flaviviruses endemic to the region where exposure occurred

| No neutralizing antibody testing performed | N | N | N | N | N |

**Epidemiological Evidence**

| Resides in or has recently traveled to an area with known ZIKV transmission | O | O | O |
| Direct epidemiologic linkage to a person with laboratory evidence of recent ZIKV infection (e.g., sexual contact, blood transfusion, organ transplantation) | O | O | O |
| Laboratory evidence of maternal infection with ZIKV or flavivirus infection during pregnancy | O | O | O |
| Maternal history of epidemiologic risk factors associated with non-congenital disease or infection during pregnancy | O | O | O |
| Association in time and place with a confirmed or probable case | O | O | O |
| Vector exposure in an area with suitable seasonal and ecological conditions for potential local ZIKV vectorborne transmission | O | O | O |

Notes:

- **S** = This criterion alone is Sufficient to classify a case.
- **N** = All “N” criteria in the same column are Necessary to classify a case. A number following an “N” indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the Absence of criterion as a Necessary component.
- **O** = At least one of these “O” (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all “N” criteria in the same column—is required to classify a case. (These “O” criteria are alternatives, which means that a single column will have either no O criteria or multiple O criteria; no column should have only one O.) A number following an “O” indicates that this criterion is only required for a specific disease/condition subtype.

**VIII. Period of Surveillance**

Surveillance should be ongoing. In collaboration with state, local and territorial health departments, CDC established two registries to monitor pregnancies and congenital outcomes among women with any laboratory evidence of Zika virus infection residing in the U.S. and territories: 1) the U.S. Zika Pregnancy Registry (USZPR), which monitors pregnant women residing in the U.S. states and all territories except Puerto Rico, and 2) the Zika Active Pregnancy Surveillance System (ZAPSS), which monitors pregnant women residing in Puerto Rico. All jurisdictions are encouraged to report to these surveillance systems.

**IX. Data sharing/release and print criteria**

- State and territorial health departments should report confirmed and probable cases of ZIKV disease and infections to CDC.
- CDC Division of Vector-Borne Diseases (DVBD) staff review, analyze, and summarize the national data at least weekly. Provisional state-specific arboviral disease case counts are provided and updated at regular intervals in national summary reports displayed on the CDC website; tables and maps are also provided on the CDC DVBD and U.S. Geologic Survey (USGS) websites. These
provisional data are used to: 1) Monitor the epidemiology and geographic spread of ZIKV and other arboviral diseases; 2) Provide timely information regarding regional and national trends in ZIKV disease reporting to public health officials and others; and 3) Identify geographic areas where additional prevention and control efforts may be needed. In circumstances where there is a potential for an international health impact, data from these notifications may be shared with international partners (e.g., PHAC, ECDC, WHO, PAHO).

- Because of the need to monitor pregnant women and their infants, and to ascertain additional information on the clinical and laboratory findings of ZIKV infection during pregnancy, separate surveillance and reporting will occur through the pregnancy registries because ArboNET does not include pregnancy surveillance information (e.g., gestational age, pregnancy exposures or pregnancy outcomes). Individual states’ participation in the U.S. Zika Pregnancy Registry may vary per state laws and human subjects review outcomes in their respective public health jurisdictions. Reporting and active monitoring of pregnant women with laboratory evidence that could represent Zika virus infection during pregnancy is critical to understanding the full impact of Zika virus infection in the fetus and neonate. All confirmed and probable cases of Zika virus disease or asymptomatic infection in pregnant women and/or infants will be reported through ArboNET to the U.S. Zika Pregnancy Registry or the Zika Active Pregnancy Surveillance System managed by CDC’s Division of Congenital and Developmental Disorders (DCDD). Data will be updated on the CDC Zika Website.

- Provisional data on confirmed and probable congenital and non-congenital ZIKV disease cases may be published weekly in the provisional Morbidity and Mortality Weekly Report (MMWR) tables and posted on the CDC DVBD website. Final data are published annually in the MMWR Summary of Notifiable Diseases and presented or published at scientific meetings. Additional tables and limited use datasets may be made available to researchers, pharmaceutical companies, media, and the general public upon request to the CDC DVBD or CDC DCDD. These final data are used to: 1) Monitor the epidemiology, incidence, and geographic spread of arboviral diseases; 2) Identify geographic areas in which it may be appropriate to conduct analytic studies of control methods, risk factors, disease severity, or other public health aspects; and 3) Evaluate ZIKV preparedness and response funding needs and allocate resources.

- All cases are verified with the state health departments before publication. Individual case notifications are made to state and local health departments depending on circumstances. For example, transplant or transfusion-associated cases require rapid notification and investigation.

- To facilitate access to ArboNET data while maintaining patient confidentiality, and to ensure that users understand the limitations of the data, the CDC Arboviral Diseases Branch has developed data sharing and release guidelines, a data request form, and a data use agreement. These policies and procedures are consistent with those developed by CDC and the CSTE for the release and sharing of data reported to the Nationally Notifiable Diseases Surveillance System (NNDSS).

- The U.S. Zika Pregnancy Registry and the Zika Active Pregnancy Surveillance System have an Assurance of Confidentiality, the highest level of protection for confidential personally identifiable data.

X. Revision History

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<tr>
<th>Position Statement ID</th>
<th>Section of Document</th>
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<tr>
<td>16-ID-01 Interim</td>
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<td>New</td>
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<tr>
<td>16-ID-01 Ordinary Process</td>
<td>Revisions throughout all sections of position statement</td>
<td>Revisions to interim position statement for adoption through the ordinary process</td>
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XI. References


XII. Coordination

Agencies for Response

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