# Zika Virus Enhanced Surveillance of Selected Populations

Request for OMB approval of an Emergency Information Collection

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**Supporting Statement A**

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- **Goal of the study:** To support state health departments to better define the public health burden and clinical characteristics of Zika virus disease.
- **Intended use of the resulting data:** To allow for more timely identification of Zika virus disease cases and improved public health response which should mitigate the risk for local transmission of Zika.
- **Methods to be used to collect:** Via ArboNET, a national arboviral surveillance system managed by CDC and state health departments and standardized forms.
- **The subpopulation to be studied:** Health departments collecting data on Zika virus disease cases deemed eligible for inclusion in the enhanced surveillance project.
- **How data will be analyzed:** Continuous variables will be presented by summary statistics (i.e., mean and standard deviation). Demographics, co-morbidities, and clinical information will be compared using applicable statistical tests (e.g., Fisher exact test or $X^2$ test).

CDC is seeking emergency OMB approval for an information collection entitled "Zika Virus Enhanced Surveillance of Selected Populations." Approval is sought for three months. Information collection activities are not expected to last longer than three months, but if it's determined that more than three months are needed, a standard ICR will be submitted.

## 1. Circumstances Making the Collection of Information Necessary

Zika virus is a mosquito-borne flavivirus primarily transmitted to humans by *Aedes* mosquitoes. Zika virus infections can also be transmitted congenitally, at the time of birth from a viremic mother to her newborn, sexually, through blood transfusion, and through inadvertent laboratory exposure. Most Zika virus infections are asymptomatic. Clinical illness, when it occurs, is generally mild and characterized by acute onset of fever, maculopapular rash, arthralgia, and/or nonpurulent conjunctivitis. As routine surveillance data have been reported to CDC, it has become apparent that the full spectrum of Zika virus disease may have been underestimated. In addition, there has been recent recognition that some non-congenital infections are quite severe. Guillain-Barre syndrome, other neurologic manifestations, and thrombocytopenia have been reported following Zika virus infections, but specific clinical findings and outcomes are not well described. Additionally, there are few published reports describing postnatally-acquired Zika virus disease among children, but there is some indication that the disease presentation in children may differ from that seen in adults. Identifying risk factors for developing more severe disease with Zika virus infections and better describing the full spectrum of Zika virus disease is important to obtain prior to the next transmission season in order develop or revise existing guidance used by clinicians and public health officials.

This information is essential to the CDC's ongoing Zika response in order to be able to develop more specific guidance and other informational tools for clinicians who care for patients and assist public health officials in targeting prevention messages towards high risk groups. This information will help healthcare providers recognize Zika virus disease among their patients and allow them to alert their state or local health department of suspect cases to facilitate diagnosis and mitigate the risk for local transmission.

Zika virus disease and infections are nationally notifiable and are reported by state health departments to CDC through ArboNET (OMB Control No. 0920-0728). ArboNET is a passive surveillance system that captures selected information on demographics, travel history, clinical features, and laboratory test results. However, reporting of many fields in ArboNET is optional, leading to incomplete data, particularly for clinical features. In addition, more specific information regarding some clinical symptoms and outcomes are not captured in ArboNET.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

**2. Purpose and Use of Information Collection**

The objective of this proposal is to support state health departments better define the public health burden and clinical characteristics of severe manifestations of Zika virus disease. Improved clinician awareness of the spectrum of disease presentations will allow for more timely identification of disease cases and improved public health response which should mitigate the risk for local transmission.

CDC cannot reasonably comply with the normal OMB clearance procedures given the need for these data to evaluate and revise existing guidance documents and informational products prior to the summer months when we anticipate that Zika virus transmission in the Americas will substantially increase.

Accelerated OMB review is requested to provide CDC with the ability to rapidly answer urgent remaining questions that will shape the course of this public health emergency response.

The specific goals and objectives are:

1. Describe the clinical manifestations and outcomes among:
    a. Patients hospitalized for Zika virus disease.
    b. Children <18 years of age with postnatally acquired Zika virus disease.
    c. Children of different age groups.
    d. Persons with neurologic symptoms associated with Zika virus disease.
2. Assess for unique clinical feature of Zika virus disease in children <18 years of age.
3. Compare demographics, underlying medical conditions, and acute symptoms among cases hospitalized and not hospitalized for Zika virus disease.

Basic demographic information, clinical, and laboratory data will be collected by participating health departments from patients/guardians, providers, or medical records as appropriate. Many of the data elements included in the Enhanced Surveillance Forms (Attachments 3-5) are standard ArboNET variables covered by OMB Control No. 0920-0728.

Additional data elements requested for this enhanced surveillance project are sometimes already routinely collected by health departments but are not reported to CDC. These elements include:

- Descriptions of fever (measured versus subjective, max temp) and rash (type, pruritic, distribution)
- Presence of sore throat, lymphadenopathy, edema, paresthesia, abdominal pain, thrombocytopenia, cough
- Emergency department care
- Dates of hospitalization or number of days hospitalized
- Admission and discharge diagnoses
- Lumbar puncture and complete blood count findings; findings of imaging and other tests conducted during hospitalization
- Travel dates
- Estimated due date or last menstrual period for pregnant women
- Co-morbidities and medications
- Dengue virus test results

Once eligible cases are identified by participating health departments, staff will extract data already collected using pre-existing case report forms and available medical records (Attachments 3-5).

If data are missing in existing records, patients/caregivers or healthcare providers will be contacted telephonically using a standard script (Attachments 6A, 6B, 6C) and the case investigation form to collect any additional data elements needed.

Once data are collected, participating sites will submit data to CDC through secure means. Data will be coded prior to submission to CDC for analysis purposes.

| Participating health departments | |
|---|---|
| Neurologic symptoms associated with Zika virus disease | CA, IN, LA, MA, MD, MN, MO, NJ, NY, PA, VA |
| Postnatally acquired Zika virus disease among children aged <18 years | CA, IN, LA, MA, MD, MN, MO, NJ, NY, PA, TX, VA |
| Hospitalization associated with Zika virus disease | CA, IN, LA, MA, MD, MN, MO, NJ, NY, PA, TX, VA |

**3. Use of Improved Information Technology and Burden Reduction**

Data reported through ArboNET are collected using improved information technology. If data are missing in existing records, patients/caregivers or healthcare providers will be contacted telephonically using a standard form and the case investigation forms to collect any additional data elements needed for cases.

The minimum amount of data will be collected to achieve the project's objectives.

**4. Efforts to Identify Duplication and Use of Similar Information**

CDC is not aware of the availability of any similar information. The table below describes various CDC activities during the ongoing Zika response and the unique contributions of this proposed project.

| **Project** | **Contribution added** |
|---|---|
| Persistence of Zika virus in semen and urine of adult men in the United States with confirmed Zika virus infection (OMB Control No. 0920-1139) | Not applicable - The proposed project does not include specimen collection or laboratory testing of any kind. |
| Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico (ZIPER Study) (0920-1140) | Not applicable - The proposed project does not include specimen collection or laboratory testing of any kind. |
| Zika Virus Associated Neurologic Illness Case Control Study in Puerto Rico (0920-1141) | The aim of this study is to determine if persons with severe neurologic illnesses are more likely to be infected with Zika than persons without neurologic illness. The proposed project aims to capture the full spectrum of neurologic manifestations (not only severe) and assess risk factors associated with neurologic outcomes following infection. Puerto Rico residents may have different constellations of risk factors influencing outcomes of infection than the general US population. |
| The Effect of Community-Wide Vector Control Initiatives on Zika Virus Transmission in Puerto Rico, 2016 (0920-1137) | Not applicable – The proposed project does not address vector control |
| Evaluation of In2Care Traps during the Zika Outbreak in Puerto Rico (0920-1071) | Not applicable – The proposed project does not address vector control |
| Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease (0920-1136) | Not applicable – The proposed project does not assess knowledge, attitudes or practices related to Zika. |
| Integrated Aedes aegypti Vector Control Intervention in Caguas City, Puerto Rico to Prevent and Control Zika Virus Infections (PRA N/A) | Not applicable – The proposed project does not address vector control |
| Migrant Farm Workers Understanding and Use of Measures to Prevent Zika Transmission (0920-1126) | Not applicable – The proposed project does not assess knowledge, attitudes or practices related to Zika. |
| US Zika Pregnancy Registry (0920-1101; 0920-1143) | Project focuses on U.S. pregnant women with laboratory evidence of Zika virus infection and outcomes in congenitally infected infants. The proposed project does not assess pregnancy/infant outcomes; congenital infections are explicitly excluded. |
| Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus infections (0920-1118) | Not applicable – The proposed project does not assess the effectiveness of specific interventions in preventing Zika virus infection |
| Assessment of Contraceptive Use and Needs, Puerto Rico, 2016 (0920-1114) | Not applicable – The proposed project does not assess contraceptive use and needs |

| | |
|---|---|
| Enhanced Surveillance of Pregnancy and Infant Outcomes following with Zika Virus infection in Pregnancy, Colombia (PRA N/A) | Not applicable – The proposed project does not assess pregnancy/infant outcomes. Congenital infections are explicitly excluded. |
| Characterization of Guillain-Barré Syndrome Cases in the Setting of Zika Virus Transmission—Colombia, 2016 (PRA N/A) | This study focused on GBS cases in Colombia. The proposed project aims to capture the full spectrum of neurologic manifestations (not only GBS) and assess risk factors associated with neurologic outcomes following infection. Colombia residents may have different constellations of risk factors influencing outcomes of infection than the general US population. |
| Formative Evaluation of Zika Prevention Kits for Pregnant Women in Puerto Rico (0920-1071) | Not applicable – The proposed project does not propose any program evaluation. |
| Case-control microcephaly study in Brazil (0920-1011) | Not applicable – The proposed project does not assess pregnancy/infant outcomes. Congenital infections are explicitly excluded. |
| Collection of serum and plasma from patients with antibodies reactive with Zika virus and other arboviruses (PRA N/A) | Not applicable - The proposed project does not include specimen collection or laboratory testing of any kind. |
| Mosquito Surveillance Survey (0920-1101; 0920-1146) | Not applicable – The proposed project does not include non-human surveillance data |
| Case-control GBS study in PR – Surveillance (0920-1106) | This study focused on GBS cases in Puerto Rico. The proposed project aims to capture the full spectrum of neurologic manifestations (not only GBS) and assess risk factors associated with neurologic outcomes following infection. Puerto Rico residents may have different constellations of risk factors influencing outcomes of infection than the general US population. |
| Case-control GBS study in PR - Records Abstraction (PRA N/A) | This study focused on GBS cases in Puerto Rico. The proposed project aims to capture the full spectrum of neurologic manifestations (not only GBS) and assess risk factors associated with neurologic outcomes following infection. Puerto Rico residents may have different constellations of risk factors influencing outcomes of infection than the general US population. |
| Formative evaluation among partners of pregnant women about Zika in PR (0920-0572) | Not applicable – The proposed project does not propose any program evaluation. |
| Zika Postpartum Emergency Response Survey, Puerto Rico (0920-1127) | Not applicable – The proposed project does not involve postpartum surveys. |
| Monitoring & Evaluation for the Zika Contraception Access Network (0920-1164) | Not applicable – The proposed project does not monitor and evaluate contraceptive use and needs. |

### 5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

### 6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection.

### 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

### 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Because this is a request for emergency OMB review, the 60-day Federal Register Notice will be published concurrently with OMB review (Attachment 2)

B. No consultations outside of CDC occurred.

### 9. Explanation of Any Payment or Gift to Respondents

There will be no payment or gift to respondents.

### 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

NCEZID's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. Once data are collected, participating sites will submit data to CDC through secure means. Data will be coded prior to submission to CDC for analysis purposes.

Analysis will be conducted with coded data and will generate aggregate output which will not present any individual data. Data collected on case report forms or in other records will be maintained at the participating health departments, included in the individual case investigation files, for the specified duration of that entity's records retention policy. Only coded data will be transmitted to CDC and will be stored on a secure CDC database server which is separate from the web-facing server. User accounts and passwords will be required to access the data. The database server is routinely backed-up.

Written informed consent will not be sought as the data are being collected as part of routine public health surveillance case investigations of arboviral disease cases. Informal verbal consent will be obtained. Data would be collected from patients of any age meeting the inclusion criteria; adults will respond on behalf of children for whom they are guardians if the child is <12 years of age and in some cases when the child is ≥12 years of age at the discretion of the state/parent.

The Privacy Impact Assessment for ArboNET describes the data captured (Attachment 7).

### 11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects (Attachment 8). This activity contributes to the ongoing Zika response. This project is not designed to contribute to generalizable knowledge of Zika virus disease, but is intended to better characterize the disease in order to improve guidance documents and other informational products for clinicians about the disease.

Justification for Sensitive Questions

No planned sensitive questions.

**12. Estimates of Annualized Burden Hours and Costs**

A. Estimated Annualized Burden Hours

States were invited to participate based on the number of cases of interest reported from their jurisdictions. Of the 13 states invited to participate, 12 opted to participate in two of the enhanced surveillance sub-studies, while one, Texas, opted to participate in two of the sub-studies, but not the investigation of neurologic cases.

The estimated average burden per response includes time needed for health departments to abstract data, complete the forms, and follow-up with patients if necessary.

| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
|---|---|---|---|---|---|
| Health Departments | Zika Virus Disease Enhanced Surveillance – Neurologic symptoms associated with Zika virus disease | 11 | 3 | 4 | 132 |
| | Zika Virus Disease Enhanced Surveillance – Postnatally acquired Zika virus disease among children aged <18 years | 12 | 10 | 1 | 120 |
| | Zika Virus Disease Enhanced Surveillance – | 12 | 5 | 2 | 120 |

| | | | | | |
|---|---|---|---|---|---|
| | Hospitalization associated with Zika virus disease | | | | |
| **Total** | | | | | 372 |

B. Estimated Annualized Burden Costs

The estimated annualized cost to respondents is presented in the table below. The mean hourly wage for epidemiologists—$34.05—was used. Source: https://www.bls.gov/oes/current/oes_nat.htm.

| Type of Respondent | Form Name | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|
| Health Departments | Zika Virus Disease Enhanced Surveillance – Neurologic symptoms associated with Zika virus disease | 132 | $34.05 | $4,494.60 |
| | Zika Virus Disease Enhanced Surveillance – Postnatally acquired Zika virus disease among children aged <18 years | 120 | $34.05 | $4,086.00 |
| | Zika Virus Disease Enhanced Surveillance – Hospitalization associated with Zika virus disease | 120 | $34.05 | $4,086.00 |
| **Total** | | | | $12,666.60 |

**13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no costs to respondents other than their time to participate.

**14. Annualized Cost to the Government**

The total estimated annualized cost to the government is $8,130. The table below describes how this estimate was reached.

| Estimated Annualized Cost to the Government per Activity | |
|---|---|
| Cost Category | Estimated Annualized Cost |
| 1 GS-12; 25% time; 12 weeks | $4,900 |

| | |
|---|---|
| 1 GS-15; 10% time; 12 weeks | $3,230 |

### 15. Explanation for Program Changes or Adjustments

This is a new information collection.

### 16. Plans for Tabulation and Publication and Project Time Schedule

Results from all sites will be collated and analyzed for publication in a peer-reviewed journal with a public health and clinician readership. Results will not be released by state. No identifying information will be included in any publication or notification of the results.

| Activity | Time Schedule |
|---|---|
| Data collection | Immediately after OMB approval; May-July 2017 |
| Data analysis and drafting of manuscript | July-September 2017 |

### 17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

### 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

**Attachments**

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2. 60-day Notice
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7. PIA
8. IRB Determination