Zika Virus Enhanced Surveillance of Selected Populations

Request for OMB approval of an Emergency Information Collection

May 1, 2017

Supporting Statement B

Contact:
Lee Samuel
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: llj3@cdc.gov

Table of Contents

This project is not designed to contribute to generalizable knowledge of Zika virus disease, but is intended to better characterize the disease in select populations in order to improve guidance documents and other informational products for clinicians about the disease. Improved clinician awareness of the disease presentation in these populations will allow for more timely identification of disease cases and improved public health response.

1. Respondent Universe and Sampling Methods

The respondent universe consists of the public health departments in California, Indiana, Louisiana, Massachusetts, Maryland, Minnesota, Missouri, New Jersey, New York, Pennsylvania, Texas, and Virginia. These twelve state health departments were asked if they would like to participate in these enhanced surveillance activities because they reported (relatively) high numbers of cases of interest (e.g., children, hospitalized, neurologic) to ArboNET. One state, Texas, opted not to participate in the project to investigate the spectrum of neurologic disease associated with Zika virus infection. All states voluntarily submit case notifications for nationally notifiable conditions to CDC. No statistical sampling methods are used.

2. Procedures for the Collection of Information

Since January 2016, Zika virus disease has been a nationally reportable condition. Health departments are notified of suspected Zika virus disease cases by electronic lab reporting, faxed laboratory results, or reports from healthcare providers. State and local health departments collect data on jurisdiction-specific case report forms. Data from these forms are routinely abstracted and entered into ArboNET, the passive national arboviral disease surveillance system at CDC.

Zika virus disease cases will be eligible for inclusion if they: (1) meet the 2016 CSTE national case definition for confirmed or probable disease and (2) have illness onset in 2016 or 2017.

Enhanced surveillance will be carried out from three selected populations:

1. Persons with neurologic symptoms associated with Zika virus disease
2. Children <18 years of age with postnatally acquired Zika virus disease
3. Patients hospitalized for Zika virus disease

Enhanced surveillance among persons with neurologic symptoms associated with Zika virus disease

A neurologic case will be defined as any central or peripheral neurologic symptom reported either by a patient or their healthcare provider. Potential neurologic cases will be identified through careful review of existing records collected by the state health departments through routine case investigation. We anticipate few cases with neurologic symptoms and expect that their clinical presentation may vary substantially. The goal is to describe the spectrum of signs and symptoms of these cases, not to compare them to any other group of cases.

Enhanced surveillance among children <18 years of age with postnatally acquired Zika virus disease

A pediatric case will be defined as a person aged <18 years at the time of illness onset (excluding congenital and perinatal infections). A matched adult (aged 18-49 years) Zika virus disease case will be identified for each included pediatric case. Pediatric cases will be matched to adult cases based on pregnancy status and case status (e.g., confirmed vs probable). This method will allow for the identification of differences to improve messaging and case identification for the ongoing response efforts.

States will develop lists of eligible adult cases in each group (pregnancy and case status) and sort by illness onset date. The adult case with the onset date closest to the pediatric case will be selected for inclusion. Once an adult case is selected, it will then be removed from the eligible list. If an adult case cannot be identified within the case state of residence, one will be identified from another of the participating states, using the same methodology.

Enhanced surveillance among patients hospitalized for Zika virus disease

A hospitalized case will be defined as a person hospitalized as a result of his/her acute Zika virus disease. The occurrence should be within 6 weeks of their illness onset and considered by the clinical care team or health department to be related to their acute Zika virus disease. Patients treated only in an urgent care or emergency department setting will not be included. Additionally, pregnant women hospitalized for delivery will not be included. A matched non-hospitalized Zika virus disease case will be identified for each included hospitalized case. This method will allow for the identification of differences to improve messaging needed for the ongoing response efforts. Cases will be matched based on age (+/- 5 years), pregnancy status, and case status (e.g., confirmed vs probable). Non-hospitalized cases with neurologic symptoms will not be eligible to serve as controls. States will develop lists of eligible non-hospitalized cases in each group (age strata, pregnancy, and case status) and sort by illness onset date. The non-hospitalized case with the onset date closest to the hospitalized case will be selected for inclusion. Once a non-hospitalized case is selected, it will then be removed from the eligible list. If a non-hospitalized case cannot be identified within the case state of residence, one will be identified from another of the participating states, using the same methodology.

Data collection

Once cases are identified by participating health departments, staff will retrieve the data already collected using pre-existing case report forms and available medical records. For the enhanced

surveillance of hospitalized patients and for children <18 years of age with postnatally acquired Zika virus disease, matching cases will be identified. Once a state has successfully extracted information for a case, staff will identify a matching case in their state or will let CDC staff know they need to identify a case from another state. Clinical information and outcomes of cases will be compared.

Once data are collected, participating sites will submit data to CDC through secure means using the Zika Virus Disease Enhanced Surveillance forms (Attachments 3-5). 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. Categorical variables will be presented by frequency distribution (e.g., frequency counts, percentages, and 95% confidence intervals). Continuous variables will be presented by summary statistics (i.e., mean and standard deviation). Clinical information will be compared using applicable statistical tests (e.g., Fisher exact test or X^2 test).

3. Methods to Maximize Response Rates and Deal with No Response

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

4. Tests of Procedures or Methods to be Undertaken

No pre-tests are planned.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

No individuals consulted on statistical aspects of the design. All state health departments listed will collect the data. Data will be analyzed by Nicole Lindsey and Erin Staples of the Arboviral Diseases Branch of the Centers for Disease Control and Prevention.