CDC Emergency Operations Center Zika Related Clinical Inquiries and Surveillance

Request for OMB Approval of a New Emergency Information Collection

February 10, 2016

Supporting Statement B

Contact:
Lee Samuel
Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
1600 Clifton Road, NE, Mailstop C12
Atlanta, GA 30333
Llj3@cdc.gov
404-718-1616

Table of Contents

1. Respondent Universe and Sampling Methods

Respondents will be STL public health authorities, clinicians, and other providers that are entrusted with monitoring, diagnosis, and treatment of persons at risk for zika virus in the US and internationally.

No statistical sampling methods are used. The Call Center is operated as a service to the US and international public. Callers to the CDC Emergency Operations Center (EOC) Call Center are a self-selected convenience sample of STL public health authorities or health facilities that are involved in monitoring, diagnosis, and treatment of confirmed cases, POIs, and contacts of cases. Therefore, the clinical information collected on zika virus cases and POIs is also a convenience sample.

The pregnancy register aims aim to enroll all pregnant women infected with Zika virus from the 50 United States. A pregnant woman, at any gestational age, who meets any of the following case definitions for evidence of Zika virus infection will be included in the registry. A confirmed Zika virus infection will be defined as Zika virus ribonucleic acid (RNA) detected by reverse transcriptase polymerase chain reaction (RT-PCR) or positive Zika virus IgM with confirmatory neutralizing antibody titers that are ≥4-fold higher than dengue virus neutralizing antibody titers in serum. A probable Zika virus infection will be defined as a positive Zika IgM result and negative dengue IgM result without neutralizing antibody testing conducted. A possible (unspecified flavivirus) infection will be defined as positive Zika IgM result with neutralizing antibody titers that are <4-fold higher than dengue virus neutralizing antibody titers in serum.

All pregnant women with Zika virus infection from the 50 U.S. states will be invited to participate in the registry. At this point, there is no indication of how many U.S. women may become infected with Zika virus during pregnancy, so there is no estimate for how many women may be enrolled.

The mosquito surveillance survey will be distributed to public, private, and nonprofit organizations as well as individual researchers who have the ability to contribute to county-level mosquito surveillance efforts.

2. Procedures for the Collection of Information

Call center

The CDC EOC Call Center receives public inquiries from STL public health authorities or health facilities that are involved in monitoring, diagnosis, and treatment of confirmed cases, POIs, and contacts of cases. During the discussion, the Call Center staff person records clinical information directly into the "Domestic Zika Virus Clinical Inquiries Database," or enters the information from hand written notes after the call.

Pregnancy register

Registry cases will be identified through one or more mechanisms. Health care providers in the United States report Zika virus disease cases to State and Local Health Departments. Health departments report cases that meet the national case definition to ArboNET, an electronic passive surveillance system for nationally notifiable arboviral diseases. Zika virus disease cases may be identified in this way. In addition, confirmed Zika virus infections in pregnant women may be identified in conjunction with Zika virus testing performed at CDC.

Health department or CDC staff will contact the woman's health care provider and request they ask their patients to voluntarily participate in the national surveillance registry for Zika virus infection during pregnancy. Information regarding the registry will be available online and an overview letter so that physician and/or patient may have immediate access to them in the clinic or home setting. If a woman agrees to participate, health care providers will be asked to provide minimal information about the woman's pregnancy by phone, fax, or secured email indirectly through State Health Departments or directly to CDC personnel. Information will again be sought at the time of birth and subsequent to the birth of live-born infants about the infant's health and development. Infant health will be assessed periodically (at 2, 6 and 12 months of age) through the first year of life.

Mosquito surveillance survey

Vector control professionals, entomologists, and public health biologists will be contacted by e-mail, primarily through listserves of professional organizations. They will be asked for their voluntary participation in a short survey to assess the distribution of *Aedes aegypti* and *Aedes albopictus* at the county spatial scale in the contiguous U.S. There are a total of 3,110 counties or county equivalents in the contiguous U.S. We are aware of approximately 720 recognized vector control districts that cover a portion of these counties. In addition to these potential 720 respondents, we might receive responses from state health departments (n= up to 50) and academic researchers (~50). If a single or multiple presence records are reported per county, the county will be considered to have the vector present. To better determine whether the mosquito is established or transient, we will record the number of years for which the vector is reported (1, 2, 3+), but if respondents provide the same information for a single county and a single year, the data will be counted as only a single record for that place and time. Therefore, responses for the same county and the same year will not confound our study.

Data on field counts is not captured because this is an additional burden on respondents and would be largely uninformative given the lack of systematic practices in surveillance. We believe name, e-mail, and affiliation is sufficient information to capture. We expect most will have .gov or .edu email addresses which serves to validate authenticity. Submission by an entomologist or program chief is not required, as this information is often available in databases that can be captured by administrative staff.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Call center
Because the CDC EOC Call Center operates at the convenience of the public, the need to maximize response rates is not applicable, as the respondents have voluntarily initiated the calls themselves. It is anticipated they will voluntarily provide clinical information about the cases, contacts, and POIs under discussion.

Mosquito surveillance survey
To maximize response rate to the mosquito surveillance survey, CDC is distributing the surveys through professional organizations and using a snowball sampling approach in which it is encouraged that respondents forward the link to the survey to their colleagues.

Pregnancy register
For the pregnancy register, health department or CDC staff will contact the woman's health care provider and ask them to invite their patients to voluntarily participate in the national surveillance registry for Zika virus infection during pregnancy. Information letters will be available for clinicians to assist them in understanding the purpose and value of the registry in order for them to encourage their patients to participate. Brochures will also be available for pregnant women infected with Zika virus so they understand the importance of their participation in the registry.

4. Tests of Procedures or Methods to be Undertaken

For the mosquito surveillance vector mapping portion, the survey instrument was tested internally by CDC entomologists and biologists.

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

There are no statistical sampling methods used in this collection. On occasion, descriptive statistical analysis will be performed by CDC staff assigned to the CDC Domestic Inquiries Team in the EOC.

The mosquito surveillance survey will result in a map without statistical analysis. If used for species distribution modeling, CDC will use published methodologies.