

CDC Emergency Operations Center Zika Related Clinical Inquiries and Surveillance

Request for OMB Approval of a New Emergency Information Collection

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Supporting Statement B

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1. Respondent Universe and Sampling Methods

Respondents will be state, tribal, territorial and local (STTL) 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 STTL public health authorities or health facilities that are involved in monitoring, diagnosis, and treatment of confirmed cases, persons of interest for Zika virus infection (POIs), and contacts of cases. Therefore, the clinical information collected on Zika virus cases and POIs is also a convenience sample.

The pregnancy registry aims to enroll cases from the 50 United States, the District of Columbia, and US territories (excluding Puerto Rico, which will have its own registry). The following will be eligible to be included in the Registry: 1) pregnant women (or postpartum women for cases diagnosed retrospectively through infant case identification), at any gestational age, who meet the CSTE case definition, approved February 25, 2016, for confirmed or probable Zika virus diseases (Appendix A); 2) symptomatic pregnant women with unspecified flavivirus infection (Zika IgM antibodies detected but specific flavivirus infection unable to be determined); 3) asymptomatic pregnant women with confirmed, probable or unspecified flavivirus infection; and 4) infants born to women who meet criteria 1), 2), or 3), regardless of whether they have evidence of Zika virus infection. B). Unspecified flavivirus infections are included because cross-reactivity in serologic testing will make differentiation between Zika virus and dengue virus infection impossible in some cases; however, in the context of active Zika virus transmission, many infections are likely to be due to Zika virus. Children born to women infected during pregnancy are eligible for follow-up through the Registry, even if they have no apparent congenital infection, because we do not yet know the full spectrum of possible health effects.

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 STTL 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 registry

Registry cases will be identified through one or more mechanisms. Cases may come to the attention of STTL health departments through contacts with health care providers, through Zika virus testing performed by CDC, public health, or commercial laboratories (as testing becomes more widely available), or through contacts between health care providers and CDC. 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. ArboNET will serve as the primary means of case identification for follow-up of outcomes among pregnant women and infants through the U.S. Zika Pregnancy Registry. In addition, the Registry will include cases not reportable to ArboNET, i.e., those among asymptomatic pregnant women with laboratory evidence of Zika infection or unspecified flavivirus infection, symptomatic pregnant women with unspecified flavivirus infection, and infants born to these women who do not have laboratory evidence of congenital Zika virus infection.

Health department or CDC staff will contact the woman’s health care provider and request the information needed to report clinical and outcomes information for cases eligible to be reported to the US Zika Pregnancy Registry. Information regarding the registry will be available online, including fact sheets, and an overview letter will be available for the health care provider. Health care providers will be asked to provide the minimum amount of information needed about the woman’s pregnancy by phone, secured fax, or secured email indirectly through State Health Departments or directly to CDC personnel. Information will again be sought during the pregnancy, 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.

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 registry

For the pregnancy register, health department or CDC staff will ask the woman's health care provider to report cases meeting eligibility criteria for the registry. Information letters will be available for clinicians to assist them in understanding the purpose and value of the registry. A fact sheet will also be available for eligible pregnant women to explain the purpose of the registry, what information will be reported to the registry, and how the information will be used.

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.