

US Zika Pregnancy Registry

Request for OMB Approval of a New Information Collection

Supporting Statement B

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No statistical methods are employed in the collection of information.

1. Respondent Universe and Sampling Methods

Registry Population

The population eligible for supplemental surveillance through the Registry includes pregnant women with any laboratory evidence of Zika virus infection and their infants in the 50 U.S. states, the District of Columbia, the US Virgin Islands, American Samoa, and other U.S. territories as needed. A separate active pregnancy surveillance system will be established for Puerto Rico. Pregnancies of interest, including those pending laboratory results, and with epidemiologic or clinical links will be investigated to determine whether they meet Registry eligibility criteria. The following will be eligible to be included in the Registry:

1. Pregnant women in the United States with laboratory evidence of Zika virus infection (positive or equivocal test results, regardless of whether they have symptoms) and periconceptionally, prenatally or perinatally exposed infants born to these women.
2. Infants with laboratory evidence of congenital Zika virus infection (positive or equivocal test results, regardless of whether they have symptoms) and their mothers.

At this point, there is no indication of exactly how many U.S. women may become infected with Zika virus during pregnancy. However, there is historical evidence from the existing pregnancy registry to provide insight into how many women and infants may enroll/report to the registry. As of October 13, there are 905 pregnant women with laboratory evidence of possible Zika virus infection. Currently, 23 liveborn infants with birth defects and 5 pregnancy losses with birth defects have been documented. The annual number of respondents was estimated based on the number of respondents reported to the U.S. Zika Pregnancy Registry to date (OMB Control No. 0920-1101, expiration 8/31/2016).

Identification of Cases and Data Collection

State and territorial health departments report cases meeting the national case definitions for Zika virus disease, including cases among pregnant women, and congenital Zika virus infection to CDC via ArboNET, an electronic passive surveillance system for nationally notifiable arboviral diseases. Cases may come to the attention of state 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. 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.

Registry cases will therefore be identified through mechanisms in addition to ArboNET. CDC will ensure that information about cases not reported to ArboNET will be passed on to health departments. CDC has established a designated Registry email, a clinical inquiry system and pregnancy hotline, and is engaged in Zika Virus response activities including case investigation, which may be alternative mechanisms for case identification that trigger reporting to the U.S. Zika Pregnancy Registry, ArboNET, or both. Finally, cases of Zika virus infection in pregnant women and fetuses/infants may be identified for inclusion in the U.S. Zika Pregnancy Registry, ArboNET, or both, through existing birth defects surveillance activities. When a congenitally infected infant is born to a woman whose Zika virus or unspecified flavivirus infection has not been previously detected, the woman may be included in the U.S. Zika Pregnancy Registry retroactively.

2. Procedures for the Collection of Information

Healthcare providers will be asked to inform their patients meeting Registry inclusion criteria about the Registry. An information sheet “US Zika Pregnancy Registry: What pregnant women need to know” has been developed for health care providers to distribute to patients during routine visits (**Attachment 5a**), and a fact sheet for parents has also been prepared (**Attachment 5b**), as some Zika infections in pregnancy may come to attention after the fact, when the infant is diagnosed with congenital infection. In addition, health care providers will receive a fact sheet and overview letter with information about the Registry and reporting and data collection processes (**Attachments 6, 7a, 7b**). Finally, a fact sheet for health departments about the US Zika Pregnancy Registry will also be disseminated (**Attachment 7c**). These information sheets, along with additional information regarding the Registry, will be available online on a designated Registry website (<http://www.cdc.gov/zika/hc-providers/registry.html>).

Health care providers will be asked to provide information about the woman’s pregnancy by phone, secure fax, or secure email indirectly through State Health Departments or directly to CDC Registry staff (**Attachments 4a and 4b**). Information will again be sought at the time of birth either from the State Health Department contact or through the neonatal/health care provider (**Attachment 8**). Subsequent to the birth of a live-born infant, information about the infant’s health and development (**Attachment 9a**) will be sought from the state health

department or treating pediatrician about routine pediatric visits at 2, 6 and 12 months of age (developmental milestones are provided in **Attachment 9b** to aid in completing the follow-up form). Methods for data collection are the same as for the other data collection forms (by phone, secured fax, secured email, or by provision of medical records). A Laboratory Result Form (**Attachment 4c**) will be used for the collection of laboratory results not performed at CDC laboratories.

Details on the information and the time points for collection are as follows:

1) Evidence of Zika virus infection in a pregnant woman

Information collected (from ArboNET and/or through follow up, prospectively or retrospectively) will include demographics, dates and destination(s) of travel (or exposure through other route [e.g., sexual transmission]), date of illness onset, clinical symptoms, underlying maternal illness, and details of the pregnancy. A supplemental form is provided to allow for reporting of additional prenatal imaging and diagnostics, i.e. when more than 3 are performed (**Attachment 4b**).

2) At delivery of the infant

Each infant born to a mother infected with Zika virus or an unspecified flavivirus during pregnancy will have data gathered in line with published recommendations for evaluation of infants born to Zika virus-infected mothers (**Attachment 8**).

3) At approximately 2, 6 and 12 months of age

Information from routine infant checkups at 2, 6, and 12 months of age will be collected from the infant's healthcare provider (**Attachment 9a**). No additional clinical visits are required for the collection of data at these timepoints; information may be collected retrospectively if necessary.

Data entry will be performed by CDC personnel into an electronic REDCap database. A new record will be established for each eligible mother-infant pair. A Registry identification (ID) number will be assigned to each mother-infant pair. A record can be established when a report has been made by any mechanism detailed above. Registry staff will work with state epidemiologists to determine a point of contact for collection and entry of clinical follow up and outcomes data. Basic case information from ArboNET may be entered into the REDCap Registry database to minimize the reporting burden on states. States may also export data electronically to share with CDC via the Secure Access Management System or other secure mechanisms described in this protocol. CDC will share jurisdiction-specific exports of Registry information from REDCap for case confirmation and upon request.

3. Methods to Maximize Response Rates and Deal with Nonresponse

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

No tests of procedures or methods will be undertaken.

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

Following preparation of the Registry data files, data validation and analysis will be carried out weekly by staff detailed to CDC's Emergency Operations Center (EOC) to monitor numbers of pregnant women with any laboratory evidence of Zika virus infection, their liveborn infants with birth defects and pregnancy losses with birth defects in US States and the District of Columbia, and in US territories. Any additional analysis that may shed further light on important questions related to pregnancy and infant outcomes following Zika virus infection may be performed in addition to analyses conducted for routine monitoring.

Persons providing input on Registry protocol and forms.

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