



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17AHW; Docket No. CDC-2017-0052]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on an information collection titled "Zika Virus Enhanced Surveillance of Selected Populations." This information collection will help state health departments better define the public health burden and clinical characteristics of Zika virus disease.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0052 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

**Zika Virus Enhanced Surveillance of Selected Populations -
Emergency ICR - National Center for Emerging and Zoonotic
Infectious Diseases (NCEZID), Centers for Disease Control and
Prevention (CDC).**

Background and Brief Description

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.

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.

CDC will request an accelerated OMB review to give CDC 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 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.

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.

If data are missing in existing records, patients/caregivers or healthcare providers will be contacted telephonically using a standard script 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.

There is no cost to respondents other than the time to participate.

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

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
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 - Hospitalization associated with Zika virus disease	12	5	2	120
Total					372

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Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,*

Centers for Disease Control and Prevention.
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