

BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-xxxx]

[Docket No. CDC-2016-xxxx]

**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 Assessment to Estimate the Effect of Community-Wide Vector Control Initiatives on Zika Virus Transmission in Puerto Rico, 2016.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-**2016-xxxx** by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.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](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.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 the 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

Assessment to Estimate the Effect of Community-Wide Vector Control Initiatives on Zika Virus Transmission in Puerto Rico, 2016 - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Aedes aegypti mosquitoes are endemic throughout the tropics and sub-tropics, and are responsible for the transmission of dengue (DENV), chikungunya (CHIKV), and Zika virus (ZIKV). Local transmission of ZIKV was first identified in the Americas in 2015, and has since expanded across nearly all areas of the tropics and sub-tropics in the Americas and Caribbean. Many individuals infected with ZIKV will experience either no symptoms of disease (i.e., asymptomatic infection) or a mild illness characterized by rash, fever, myalgia, and/or arthralgia, which will self-resolve within a week or less. However, ZIKV infection in pregnant women has recently been shown to cause microcephaly and other congenital anomalies, and has been associated with development of Guillain-Barré syndrome and severe thrombocytopenia. Hence, though initially perceived to be a relatively innocuous infection, the emergence of ZIKV in the Americas has revealed multiple associations with high-morbidity conditions and sequelae.

Traditional approaches to community-wide control of *Ae. aegypti* populations (e.g., fumigation, indoor/outdoor residual spraying, community education campaigns) have a long history of minimal to no success. Novel approaches (e.g., genetically-modified mosquitoes, Wolbachia-infected mosquitoes, improved

mosquito traps) show much promise, but have not yet been shown to be effective in reducing the incidence of disease caused by viruses that are transmitted by *Ae. aegypti*. Therefore, a combination of approaches may be necessary to effectively reduce the impact of disease outbreaks caused by viruses transmitted by *Ae. aegypti*.

Passive surveillance for ZIKV disease commenced in the US territory of Puerto Rico in late 2015 by adapting the passive dengue and chikungunya surveillance systems to incorporate reporting of and diagnostic testing for suspected ZIKV disease. Local transmission of ZIKV was first detected in Puerto Rico in November, 2015. After expanding across much of the island, to date >5,500 laboratory-positive ZIKV disease cases have been reported to the Puerto Rico Department of Health (PRDH) via the Passive Arboviral Diseases Surveillance System (PADSS). In order to employ all possible approaches that are safe to humans and the flora and fauna of Puerto Rico to reduce the incidence of ZIKV infections in Puerto Rico, in early June 2016 the Director of the CDC recommended to PRDH and the Governor of Puerto Rico that a combination of aerial spraying, deployment of autocidal gravid ovitraps (AGO traps), indoor/outdoor residual spraying, and/or intensive community education campaigns be utilized to attempt to reduce the burden of ZIKV infections in Puerto Rico. Such efforts are currently slated to begin in early July 2016.

Because *Aedes* species mosquitoes live in and around homes and other areas where humans congregate (e.g., schools) and do not typically fly more than a few hundred meters, the geographic distribution of both chikungunya and dengue virus infections tend to be highly focal. Because *Aedes* species mosquitos are most active during the daytime, particularly at dusk and dawn, hours when most household members are at home, dengue and chikungunya cases frequently cluster within households. Previous dengue cluster investigations demonstrated rates of DENV infection of 2.2–12.4% among household members and neighbors residing within 10–100 meters of confirmed dengue cases. These studies enabled identification of household-level risk factors for DENV infection, such as uncovered water storage containers being a risk factor for DENV infection, and piped household water and use of mosquito nets as being protective against DENV infection. Dengue and chikungunya cluster investigations have also enabled identification of asymptomatic and sub-clinical infections that would not otherwise have been detected through traditional passive surveillance, thereby providing additional information about the incidence and consequence health burden of infection.

Household-based cluster investigations have not yet been conducted during ZIKV outbreaks in Puerto Rico or elsewhere. Such investigations would enable enhanced case finding and subsequent extrapolation of current rates of under-reporting of ZIKV disease

cases (due either to lack of presentation for care, clinical misdiagnosis, or failure for cases to be reported), description of the symptomatology of infected individuals, and elucidation of risk factors for infection among the individuals included in the investigation, which may or may not be the same as those amongst the larger population.

Simultaneously performing dengue, chikungunya, and Zika diagnostic testing may enable identification of differences in clinical and epidemiologic aspects of the three illnesses. More importantly, however, conducting such investigations in areas with and without intensive vector control efforts would provide the opportunity to extrapolate cluster-specific rates of ZIKV infection to then assess the effectiveness of vector control interventions. This information may be utilized to improve surveillance for and characterization of ZIKV disease in Puerto Rico, and provide ongoing feedback to public health partners regarding if the various approaches to vector control are having an appreciable effect on reducing ZIKV infections.

Utilization of both passive surveillance data and household-based cluster investigations are expected to be associated with limitations in interpretation of findings with regard to if and how well they represent the epidemiologic trends in ZIKV infection. Nonetheless, due to the urgent need for rapid assessment of the relationship between community-wide

interventions and the concomitant incidence of ZIKV infections and/or ZIKV disease, such approaches are the only available methodology to rapidly gather such information. If findings from both passive surveillance data and household-based cluster investigations are considered together, they may provide a more informed interpretation of the community-wide patterns of ZIKV infections. Nonetheless, a community-wide serosurvey may be a more reliable approach to estimate the incidence of ZIKV infections in intervention and non-intervention community to thereby assess community-wide vector control interventions. Should such an assessment be conducted in the future, it will be submitted as a separate information collection request to OMB. Findings will be used to develop or refine messaging to the public and medical communities to improve case-seeking behavior and case reporting, respectively.

This information collection request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). There is no cost to respondents other than the time to participate. The total number of estimated annualized burden hours is 560.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in	Total Burden (in hrs.)

				hrs.)	
General public	Household questionnaire	200	1	18/60	60
	Individual questionnaire	500	2	30/60	500
Total					560

Dated:

Jeffrey M. Zirger
Acting Chief, Information Collection Review Office

Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention