

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 **Emergency Zika Package:** Zika Postpartum Emergency Response Survey (ZPER), 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

Emergency Zika Package: Zika Postpartum Emergency Response Survey (ZPER), Puerto Rico, 2016- New ICR - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In December 2015, Puerto Rico Department of Health (PRDH) reported the first locally acquired (index) case of Zika virus disease in a jurisdiction of the United States in a patient from southeastern Puerto Rico. Subsequently, passive and enhanced surveillance for Zika virus disease identified 30 laboratory-confirmed cases. Because the most common mosquito vector of Zika virus, *Aedes aegypti*, is present throughout Puerto Rico, Zika virus is expected to continue to spread across the island. Due to Puerto Rico's high probability of local Zika transmission, the island is designated at the highest level of risk according to a 3-tiered scale of Zika infection risk as defined by CDC's Emergency Operations Center (EOC).

While pregnant women do not differ from the general population in terms of susceptibility to Zika virus infection or severity of disease, they are at risk for adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy including pregnancy loss, congenital microcephaly, other brain malformations, ocular birth defects, severe arthrogryposis in the legs and arms, club foot and shortened neck. After review of the available evidence, CDC recently concluded that Zika virus infection during pregnancy is a cause of microcephaly and other brain defects.

Given the adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy, it is more important

than ever to understand the Zika-related concerns of pregnant women, interactions regarding Zika between pregnant women and their health care providers, sources of information that pregnant women consult regarding Zika virus, and use of recommended precautions by pregnant women to reduce the risk of exposure to Zika virus. With neither a vaccine nor medication available to prevent Zika virus infection, awareness, education, and understanding by pregnant women and their prenatal providers of the risks and recommendation related to Zika virus transmission during pregnancy are key to preventing Zika virus-affected infants.

Information from pregnant women on their awareness of Zika virus, their acceptance and use of recommended preventive measures, and the services and information provided to them by prenatal health care providers, including testing for Zika virus infection during pregnancy is currently unavailable in Puerto Rico. This would be the first population-based, representative sample assessing these items among pregnant women, and specifically among women who were pregnant during the early period of the Zika outbreak when knowledge about the virus and its impact on birth outcomes were just being discovered.

The objective of this assessment is to collect scientifically valid, current information on maternal behaviors and experiences related to Zika virus from a representative

sample of women of who just gave birth in Puerto Rico. This information will provide the Puerto Rican government and CDC's emergency response team a basis on which to make decisions regarding resources and programs targeting pregnant women and their health care providers to mitigate the risk of Zika virus infection during pregnancy, as well as other information valuable in formulating responses to the Zika virus outbreak.

This assessment will be designed to answer several important questions related to the experiences and behaviors of recently pregnant women in Puerto Rico that will be useful in order to help minimize the risk of Zika-related birth defects among newborn. These questions include:

- How concerned are women about getting infected with Zika virus during pregnancy or having a Zika-affected infant?
- What are the most trusted sources of information related to Zika virus for pregnant women?
- What percentage of pregnant women are reporting that their prenatal health care providers are offering testing, conducting testing, and diagnosing Zika virus based on test results?
- What percentage of pregnant women are using mosquito repellent and other measures to prevent mosquito bites? What are barriers to use?
- What percentage of pregnant women are using condoms during

sex to prevent sexual transmission from a male partner?

What are barriers to use?

There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Women with recent births	Assessment questionnaire	2,760	1	15/60	690
Total					690

Dated:

Leroy A. Richardson
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