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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-18ANU]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Communities Organized To Prevent Arboviruses: Assessment of Knowledge, Attitudes, and Vector Control Practices and Sero-Prevalence and Incidence of Arboviral Infection in Ponce, Puerto Rico (COPA Study) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on July 20, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th

Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Communities Organized To Prevent Arboviruses: Assessment of Knowledge, Attitudes, and Vector Control Practices and Sero-Prevalence and Incidence of Arboviral Infection in Ponce, Puerto Rico (COPA) – Existing Collection in use without an OMB Control Number – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Recent years have seen the emergence of two epidemic arthropod-borne viruses (arboviruses) that are transmitted by Aedes aegypti mosquitoes. Chikungunya virus was introduced into the Caribbean in late 2013, and caused large epidemics of fever with severe joint pain throughout the Caribbean and Americas in 2014. Zika virus was first detected in the Americas in Brazil in 2014, spread throughout the Americas, and has since been associated with devastating birth defects, Guillain-Barre syndrome, and is the first arbovirus that can also be transmitted through sexual contact. In addition, the four viruses that cause dengue were introduced to the Americas over

the past several hundred years and have since become endemic, and yellow fever virus has recently caused large outbreaks in Brazil and there is risk of importation to other counties in the Americas.

In all of these cases, the public health response to the spread of these arboviruses throughout the tropics, where their mosquito vectors thrive, has been hampered by a lack of sustainable and effective interventions to prevent infection with any of these arboviruses at the community level. Additionally, the rapid speed with which new arboviruses spread does not often provide the time needed to plan and implement community-level interventions to decrease disease transmission. Although several candidate vaccines for chikungunya and Zika are currently in clinical development, none are yet available. A dengue vaccine has been licensed in several countries, but initial analyses have suggested that decades will be needed before it results in reduction in transmission of dengue virus.

In recent years, community based strategies for vector control have been studied and implemented in different countries as an alternative to vertical strategies (e.g. insecticide spraying delivered by government agencies). A new intervention has recently been demonstrated to reduce the rates of infection with common tropical arboviruses transmitted by Ae. aegypti mosquitos (i.e., dengue, chikungunya, and Zika viruses). The

Camino Verde approach utilizes community mobilization to motivate clean-up campaigns to reduce rates of dengue virus infections in Nicaragua and Mexico. However, the intervention occurred in small communities, and has not been evaluated in an urban setting. There is therefore a need to determine the effectiveness of such types of interventions in relatively large, urban communities.

Research suggests that vector control programs that have substantial community participation can have significant and lasting impacts on vector density, and are more cost-effective than vertically structured programs. In addition, these types of programs have been reported to readily integrate with other health or development programs, promote an enduring sense of pride in the home and community, and make use of politically viable vector control strategies.

The purpose of this study is to establish longitudinal follow-up of a community cohort and evaluate the impact of vector control interventions in 14 communities in southern Puerto Rico. The study investigators have prior experience working in these communities; however, there is minimal available information regarding the prevalence or incidence of infection with tropical arboviruses, density of Ae. aegypti mosquitos, or community members' knowledge, attitudes, and practices regarding behaviors intended to avoid mosquitos. Such

information will be needed to inform decision-making regarding the location, design, and content of interventions to be implemented and evaluated to reduce the burden of these pathogens.

The questionnaire section will vary depending on age and day of birth of each participant. A questionnaire with general household questions will be administered to one household representative in each home with one or more participants. This representative should be 21 years or older, or an emancipated minor. If all eligible household members are unemancipated minors, a household member over the age of 50 may act as household representative and complete this section of the survey only. A questionnaire on socio-demographic information will be administered to all participants. The assessment of knowledge, attitudes, and practices questionnaire will be administered to all participants seven years and older with questions adapted for ages: 7-11 (younger child), 12-13 (older child), 14-50 (adult). A vector control tools questionnaire will be administered to all participants 21 years or older born on an odd numbered day of the month. The questionnaire will be administered after written consent and verbal assent (when appropriate) from those present in the household at the time of the visit. The knowledge, attitudes, and practices questionnaire will be focused on vector control, healthcare-seeking behavior,

and disease occurrence. We will collect demographic information (e.g., age, sex, duration of time residing in Puerto Rico), travel history, and information on recent illnesses from all participants via household (and individual) questionnaires. Parents or guardians will serve as proxy respondents for children aged <7 years. The questionnaires will be administered after written consent and verbal assent (when appropriate) from those present in the household at the time of the visit. GPS coordinates will also be collected for each household visited to later assess for potential clustering of arboviral infections within communities. We will ask participants if they have been ill with arbovirus-like illness (i.e., fever, rash, joint pain, and conjunctivitis) in the past year. If so, we will collect details on the symptoms experienced during their illness. The questionnaires will be administered to all randomly selected residents of the 14 communities in Ponce. At the time of the questionnaire administration, ~15 mL of blood will be collected to conduct serological testing of arboviruses for a sero-survey. The sero-survey and socio-demographic questionnaire will be repeated every 12 months after the initial assessment, up to a period of five years. OMB clearance will be extended after three years. This project will allow the evaluation of a community based approach for vector control strategies in Ponce, Puerto Rico. The information obtained will inform decision making

regarding the location, design, and content of future interventions to be implemented and evaluated to reduce the burden of arboviral disease in Puerto Rico. Incidence and prevalence of arboviral disease will be estimated to guide control programs development and fill the current knowledge gaps.

There is no burden on respondents other than the time needed to participate. Estimated annual burden is 2,416 hours. Authorizing legislation comes from Section 301 of the Public Health Service Act.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Ponce residents	Household representative questionnaire	2,506	1	10/60
	Socio-demographic questionnaire	2,996	1	15/60
	Knowledge, attitudes, and practices individual questionnaire	2,996	1	15/60
	Vector control tools questionnaire	600	1	25/60
	Specimen collection	2,996	1	5/60

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