DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–1254; Docket No. CDC–2021–0121]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project 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). The purpose of this study is to measure the incidence of arboviral infections in 38 communities in southern Puerto Rico.

DATES: CDC must receive written comments on or before January 21, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0121 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

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 Study)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The four viruses that cause dengue are transmitted by *Aedes* species mosquitoes and were introduced to the Americas over the past several hundred years where they have since become endemic. Puerto Rico, a Caribbean island and U.S. commonwealth, has the highest burden of dengue virus in the U.S., and recent years have seen the emergence of two epidemic arthropod-borne viruses (arboviruses) also transmitted by *Aedes* 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, the first arbovirus that can also be transmitted through sexual contact, was first detected in the Americas in 2014 and has been associated with devastating birth defects and Guillain-Barre syndrome. Yellow fever virus has recently caused large outbreaks in Brazil, and there is risk of importation to Puerto Rico and other counties in the Americas.

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. Moreover, 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 viruses are currently in clinical development, none are yet available. A dengue vaccine was recently recommended for children 9–16 years old with previous dengue infection and living in dengue-endemic parts of the United States. However, this will only benefit a small proportion of the population at risk for dengue infection.

The purpose of the Communities Organized to Prevent Arboviruses (COPA) project is to measure the incidence of arboviral infections and assess suitability, acceptability, and impact of community-level mosquito control interventions in 38 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 mosquito control interventions to be implemented, as well as to evaluate their effectiveness in reducing the arbovirus burden. Additionally, the COPA project can act as a research platform to assess acceptability of arbovirus vaccines and other individual level prevention measures in Puerto Rico and provide community-level data on emerging diseases, including novel coronavirus 2019 (COVID–19).

CDC plans to 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 written or verbal assent (for minors) 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- or COVID–19-like illness (*i.e.,* fever, rash, fever, cough, sore throat, difficulty breathing, diarrhea, body pain, or loss of taste/smell in the last week) in the past week and year. If so, we will collect details on the symptoms experienced during their illness. The questionnaires will be administered to Ponce residents from the 38 communities in Ponce, Puerto Rico. Being a resident is defined by having slept in the house for at least four of the past seven nights. At the time of the questionnaire administration, ~15 mL of blood will be collected to conduct serological testing of arboviruses for a sero-survey. If the participant has COVID–19-like symptoms, an anterior nasal swab will also be collected.

The questionnaire section will vary depending on the age of each participant. The Household questionnaire will be administered to one household representative in each home with one or more COPA participants. This representative should be 21 years or older or an emancipated minor. This information is key to understand the household composition, characteristics, and use of chemical insecticides and other preventive practices. 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.

The Individual questionnaire will be administered to all participants to collect individual-level socio-demographic information. This questionnaire will collect information on past illnesses and health seeking behaviors, identify the main healthcare facilities used in the area, and estimate costs associated with acute febrile illness. Questions related to COVID–19 vaccine uptake, illness, and diagnosis are also included to describe and estimate the number of previous SARS–CoV–2 infections and evaluate the success of ongoing COVID–19 vaccination efforts in these communities.

The Mobility questionnaire will be administered to all participants to assess general individual-level mobility patterns, including time spent in and outside of the home each week. We will ask participants about the location and characteristics of places where they spend more than five hours per week to assess potential arboviral exposures outside of the home.

The assessment of Knowledge, Attitudes, and Practices (KAP) questionnaire will be administered to participants 14–50 years old to collect information on knowledge, perceptions of risk and prevention measures, and past experience with dengue and COVID–19. Data will be used to understand how community members view arboviral diseases and COVID–19, and how these perceptions relate to experience and willingness to adopt individual and community-level prevention measures. Questions related to general perceptions and confidence in vaccines will be asked to see how these relate to intentions to vaccinate against dengue and COVID–19.

A Vector Control Tools questionnaire will be administered to all household representatives to evaluate knowledge and acceptability of several mosquito control methods. This information will be shared with local governments and vector control agencies to inform selection and implementation of potential mosquito control interventions in the region.

An Acute Illness Surveillance (AIS) project component is being implemented to better identify and assess the incidence of arboviral disease and COVID–19 among COPA participants. This additional weekly activity will use an automated text-messaging system to ask COPA household representatives and other household adults who consent to receive text messages if any COPA participants in the household have experienced fever or other COVID-like symptoms in the past seven days. Project staff will contact households in which one or more participants reported symptoms to schedule an appointment to collect samples for arbovirus and SARS–CoV–2 molecular testing and to administer a AIS questionnaire about symptoms, exposure and health seeking behaviors. From previous febrile surveillance studies, we expect approximately 40% of household adults will respond to text messages each week and 10% of COPA participants will report acute symptoms and agree to a sample collection visit each year.

Participants with a positive SARS–CoV–2 molecular test will be contacted by phone 2–4 weeks later for a COVID–19 Case Follow-up questionnaire on symptoms, health care seeking, potential exposures, and outcomes of SARS–CoV–2 infection. We are expecting that 20% of participant that report symptoms will have a positive COVID–19 result and respond to this follow-up questionnaire.

The central COPA questionnaires (Household, Individual, KAP, Mobility, Vector Control) will be repeated among approximately 3,800 participants every 12 months, up to a period of five years. The AIS and COVID–19 follow-up components will be renewed and modified annually as applicable according to research and funding priorities. This project will allow us to better understand the risk, perceptions, and burden of arboviral infections and COVID–19 and evaluate a community-based approach for vector control in 38 communities in Ponce, Puerto Rico. The information obtained will inform decision making regarding the location, design, content, and evaluation of future mosquito control interventions implemented in Puerto Rico. Data on incidence and perception of COVID–19 disease will also be used to inform local control programs and fill the current knowledge gaps.

There is no burden on respondents other than the time needed to participate. Estimated annual burden is 4,309 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Ponce residents from the 38 selected communities 21 years and older or emancipated minor.	Household Representative questionnaire.	2,700	1	10/60	450
Ponce residents from the 38 selected communities 1–50 years old.	Individual questionnaire	3,800	1	20/60	1,267
Ponce residents from the 38 selected communities 1–50 years old.	Specimen Collection	3,800	1	5/60	317
Ponce residents from the 38 selected communities 14–50 years old.	Knowledge, Attitudes, and Practices questionnaire.	3,090	1	15/60	773
Ponce residents from the 38 selected communities 1–50 years old.	Mobility	3,800	1	10/60	633
Ponce residents from the 38 selected communities 21 years and older.	Vector Control	2,500	1	10/60	417
Ponce residents from the 38 selected communities 21 years and older.	AIS text message	1,000	52	0.5/60	433
Ponce residents from the 38 selected communities with inclusion criteria.	AIS questionnaire	380	1	8/60	51
Ponce residents from the 38 selected communities with inclusion criteria that tested positive for SAR–CoV–2.	COVID–19 case follow-up questionnaire.	75	1	6/60	8
Total					4,309

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10515]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 21, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10515 Payment Collections Operations Contingency Plan

Under the 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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Payment Collections Operations Contingency Plan; *Use:* Under sections 1401, 1411, and 1412 of the Patient Protection and Affordable Care Act (PPACA) and 45 CFR part 155 subpart D, an Exchange