Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico, 2016

Request for OMB approval of an Emergency ICR

January 23, 2021

Supporting Statement A

Contact:
Lee Samuel
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: llj3@cdc.gov

Table of Contents

- **Goal of the study:** To collect scientifically valid, current information on various aspects of contraceptive use and related reproductive health topics from a representative sample of women of reproductive age throughout Puerto Rico.
- **Intended use of the resulting data:** To provide a basis on which to make decisions regarding the distribution of effective contraceptive methods among residents of the island who are at risk of pregnancy who do not wish to become pregnant, as well as other information valuable in formulating responses to the Zika virus outbreak.
- **Methods:** An island-wide, population-based telephone survey representative of all women of reproductive age in Puerto Rico.
- **The subpopulation to be studied**: A representative sample of women between 18 and 49 years of age living throughout the island of Puerto Rico.
- **How data will be analyzed:** The latest version of WinCATI, a telephone-based interviewing system, will be used for data entry and management. SAS or SPSS will be used for data analysis.

This is a request for emergency OMB approval of the information collection, "Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico, 2016." CDC requests six months of OMB clearance. Information collection is not expected to require more than six months. If more than six months are needed to complete this information collection, CDC will pursue a formal ICR.

Authorizing Legislation for this information collection comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment A).**

1. Circumstances Making the Collection of Information Necessary

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. The Puerto Rico Department of Health became the first U.S. jurisdiction to report autochthonous transmission on of Zika virus in December 2015. Puerto Rico has reported the highest number of Zika Virus cases in the U.S. and the number is expected to rise. From November 1, 2015 to April 14, 2016, there were 683 laboratory-confirmed cases of Zika virus infection in Puerto Rico. Of those, 65 were pregnant women.

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 for women who do not desire pregnancy now to use effective contraception. Few women in Puerto Rico are using the most highly effective contraceptive methods, and the reasons are unclear but may be associated with factors including availability and access. With neither a vaccine nor medication available to prevent Zika virus infection, increasing access to effective contraception should be considered a key countermeasure to prevent Zika virus-affected infants.

Even in the absence of disease outbreaks that can lead to increased incidence of birth defects and negative pregnancy outcomes, it is important that every woman/couple have access to safe, effective, and affordable contraceptive methods in order to be able to control the number and timing of their pregnancies. Because Puerto Rico is currently in the midst of an outbreak of Zika virus, which carries with it the risk of severe birth defects, it is even more important now that Puerto Rican women/couples have access to effective means to avoid pregnancy when they do not desire to become pregnant. There is a pressing need to provide comprehensive contraceptive services in Puerto Rico, including removing financial barriers, providing acceptable and effective contraceptive options, and providing patient education and provider training.

Understanding the extent to which various contraceptive methods are being used in Puerto Rico and the extent to which there is a need for methods to help women prevent pregnancy depends on the availability of recent and reliable information on the topic. "Unmet need" is the term used to describe the proportion of women or couples who are able to become pregnant, are sexually active, are not using a method of contraception, but state that they do not wish to become pregnant. Little scientifically valid information has been collected on most aspects of contraceptive use in recent years. Island-wide contraceptive prevalence and method mix were most recently measured in 2004 and the most recent comprehensive population-based Reproductive Health Survey took place in 1995-96. Since contraceptive use and needs are likely to have changed since those data collection efforts, there is a pressing need to have current information on contraception and pregnancy that is representative of all women of reproductive age in Puerto Rico.

2. Purpose and Use of Information Collection

The objective of this assessment is to collect scientifically valid, current information on various aspects of contraceptive use and related reproductive health topics from a representative sample of women of reproductive age throughout Puerto Rico. This information will provide the Puerto Rican government and CDC's emergency response team a basis on which to make decisions regarding the distribution of effective contraceptive methods among residents of the island who are in need of contraception, 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 contraceptive use, contraceptive needs, and pregnancy in Puerto Rico that will be useful in order to help minimize the risk of Zika-related birth defects among newborn. These questions include:

- What is the contraceptive prevalence rate among women/couples (overall and broken out by geographic, demographic, and socioeconomic characteristics)?
- What is the mix of contraceptive methods that is being used?
- What is the level of "unmet need for family planning methods", i.e., the percentage of women who are able to become pregnant, are sexually active, are not using a method of contraception, but state that they do not wish to become pregnant?
- What is the rate of pregnancy that was not desired by women and the proportion of pregnancies that are desired/not desired?
- What are the reasons that women who do not desire to become pregnant are not using contraception? (i.e., what are the main barriers to contraceptive use?)
- What do women know about the effects of Zika on births and pregnancy and how have their knowledge and opinions affected desires and behaviors related to pregnancy and contraception?

The questionnaire has been designed to provide information that is valuable for developing and implementing an emergency response to the Zika virus outbreak in Puerto Rico. All of the information

collected will serve an important purpose with regard to current contraceptive practices, pregnancy intentions, and the impact of Zika on Puerto Rican women's reproductive behaviors and intentions.

The questionnaire **(Attachment C)** consists of several groups of questions:

- Screening questions to determine whether the person answering the phone is eligible to be part of the sample. This includes information on age, sex, willingness to participate, and whether the person resides in Puerto Rico.
- Demographic and socioeconomic questions
- Sexual experience
- Current pregnancy intention
- Current contraceptive use
- Planning status for most recent pregnancy
- Zika-related attitudes and behaviors

Some of the key questions that the survey is designed to answer require combining information obtained from several questions. For instance, estimating the level of "unmet need" for family planning requires combining data from several question, including: whether women have recently been sexually active; whether women are physically able to become pregnant; whether women are currently using contraception; and their current desire to become pregnant.

With the exception of Zika-specific questions included in the assessment, all other questions have been drawn from other large surveys, including the National Survey of Family Growth (NSFG), the Pregnancy Risk Assessment Monitoring System (PRAMS), and the BRFSS module on reproductive health, being used in several states [OMB Control No. 0920-1061].

3. Use of Improved Information Technology and Burden Reduction

One-hundred percent of burden hours will be incurred by respondents over the phone.

The latest version of WinCATI, a telephone-based interviewing system, will be used for data entry and management. WinCATI is the system used by the Puerto Rico Department of Health for the routine, on-going BRFSS.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of any other systematic collection of the information described herein.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection to assess various aspects of contraceptive use and related reproductive health topics.

Collecting information less frequently than the CDC recommendations would interfere with the public health actions required to contain and respond to Zika virus transmission and to do everything possible to limit, if not stop, deaths and birth defects due to this disease.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A) Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. A 60-day Federal Register Notice was drafted **(Attachment B).**

B) There was no consultation outside of the Agency.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act is applicable. Records are covered under CDC Privacy Act System of Records Notice (SORN) No. 0920-0136 "Epidemiologic Studies and Surveillance of Disease Problems" and SORN No. 09-20-0113, "Epidemic Investigation Case Records Systems Notice."

No personal identifying information, such as names or addresses, will be collected during the interviews for the assessment. The telephone numbers used to reach respondents will not be included in the assessment's data files. No data, other than what is collected in the telephone interview, will be included in the assessment. The CDC will not include information in reports that may identify respondents. Information that could potentially be used to indirectly identify an individual will be suppressed; for example, aggregated data will not be stratified into subcategories that might allow for identification of individuals.

At the end of an introductory statement about the survey and the reason for its being conducted, potential respondents will be made aware that participation is purely voluntary and that no personal identifiers will be collected. The first question following this statement will ask the person if he/she is willing to participate in the survey. The response to this question will be recorded by the interviewer.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This protocol was submitted for Human Subjects Protection review on April 27, 2016 and received a non-research determination **(Attachment D).**

Justification for Sensitive Questions

Because many of the questions to be asked of respondents will deal with sensitive topics, including sexual activity, pregnancy, and contraception, all interviewers will be female. Sensitive questions are essential to meeting the goals of this information collection.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

A total of 2,500 women between the ages of 18 and 49 will be interviewed for this assessment. This will consist of 2,000 interviews of women between the ages of 22 and 49 and an oversample of 500 women between the ages of 18 and 21, since this is the age group where unintended pregnancies that are not desired are expected to be the most widespread.

The first eight questions asked by the interviewer will screen respondents for eligibility to participate. Those unwilling to participate, men, and women not between the ages of 18 and 49 will be thanked for their time and the interview will be terminated. The total burden on those who do not participate will not exceed one minute per person.

For those that do participate, it is expected that this questionnaire will take an average of about 10 minutes to administer, with a maximum time of no more than 15 minutes.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Women of reproductive age	Questionnaire	2,500	1	15/60*	625
Individuals who are not women of reproductive age	Screening questions	12,000	1	1/60	200**
Total					825

**Some completed interviews will likely exceed 15 minutes, but the average duration will be between 10 and 15 minutes*

***Estimate based on expected number of calls that will be made to individuals who are not women of childbearing age (WCA) or WCA who decline to be interviewed. Length of time for these contacts will vary, but will rarely last more than about 1 minute.*

B. Estimated Annualized Burden Costs

There will be no anticipated costs to respondents other than time.

The average annual response burden cost is estimated to be $14,518.75. The hourly wage estimates are based on the Bureau of Labor Statistics May 2015 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm). The mean hourly wage rate for all occupations ($23.23) was used.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Women of	Questionnaire	625	$23.23	$14,518.75

reproductive age				
Individuals who are not women of reproductive age	Screening questions	200	$23.23	$4,646.00
Total				$19,164.75

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

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

14. Annualized Cost to the Government

The total estimated cost to the government is $94,656.00. The table below breaks down how many CDC employees will be working on this project, what percentage of their time will be devoted to this project, and how much they will make during this time. Information collection is expected to last no more than two months, though preparation and analysis will take six months. Hourly wages were based on Step 1 employees for the Atlanta locality available here: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/ATL_h.pdf.

Grade	# of FTEs	Hourly Wage	% time devoted to project	Total Hours	Total
GS-14	1	$50.00	100	1,044	$52,200.00
GS-14	1	$50.00	100	348	$17,400.00
GS-13	1	$42.31	100	348	$14,723.88
GS-11	1	$29.69	100	348	$10,332.12
Total					$94,656.00

15. Explanation for Program Changes or Adjustments

This is a new information collection request, therefore program changes and adjustments do not apply at this time.

16. Plans for Tabulation and Publication and Project Time Schedule

The CDC Emergency Operations Center (EOC) will take responsibility for all data tabulations for this assessment. CDC's Division of Population Health, which coordinates all Behavioral Risk Factor Surveillance System (BRFSS) activities for the US, including Puerto Rico, will prepare the data files for analysis. This preparation will include final data cleaning and weighting. CDC epidemiologists and/demographers detailed to the EOC will develop an analysis plan and table shells during the data collection phase and will perform all data analysis immediately upon availability of final data files. A preliminary report, for internal use at the Puerto Rico Department of Health and CDC will be used to begin applying findings in Puerto Rico. Once final tabulations are available a final report will be published, as well as an MMWR article on key findings.

Project Time Schedule:

- May 1-27, 2016: Preparations for data collection in Puerto Rico, including: recruiting and hiring data collection staff, obtaining necessary space and computers, translation of questionnaire into Spanish, preparation of training materials, programming of questionnaire for data entry and editing, obtaining additional software licenses, etc.

    - Who: Puerto Rico Dept. of Health
- May 31-June 4: Training of interviewers
    - Who: Puerto Rico Dept. of Health and CDC Emergency Operations Center
- June 6-10: Piloting of data collection procedures and questionnaire
    - Who: Puerto Rico Dept. of Health and CDC Emergency Operations Center
- June 13-August 5: Interview of core sample of 2,000 respondents (representative sample of 18-49 year-old women)
    - Who: Puerto Rico Dept. of Health
- June 13-July 29: Development of data analysis plan
    - Who: CDC Emergency Operations Center
- August 6-September 16: Interview of oversample of 500 18-21 year-old women
    - Who: Puerto Rico Dept. of Health
- August 8-19: Weighting, final cleaning, and preparation of core sample data for analysis
    - Who: CDC Division of Population Health
- August 22-September 2: Analysis of core sample
    - Who: CDC Emergency Operations Center
- September 5-16: Preparation of preliminary assessment report in Spanish and English
    - Who: CDC Emergency Operations Center
- September 19-23: Weighting, final cleaning, and preparation of full sample data for analysis
    - Who: CDC Division of Population Health
- September 26-30: Analysis of full sample and special tabulations for 18-21 year-olds
    - Who: CDC Emergency Operations Center
- October 3-21: Preparation of final assessment report, including analysis of 18-21 year-old oversample, in English and Spanish
    - Who: CDC Emergency Operations Center

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

A. Public Health Service Act (42 USC 241)
B. Draft 60-Day FRN
C. Assessment of Contraceptive Use and Needs Questionnaire
D. IRB Non-Research Determination