Emergency Zika Package V:
Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections

Request for OMB approval of an Emergency ICR

Supporting Statement B
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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

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The purpose of this project is not to make statistical generalizations beyond the particular respondents.

1. Respondent Universe and Sampling Methods

The two projects proposed use a mixed methods approach (project 1) and a case-control approach (project 2) that will assess the following interventions for pregnant women that have been implemented in Puerto Rico starting in March 2016:

1. Zika Education Sessions (at WIC clinics)
2. Zika Prevention Kits
3. Communication activities
4. Vector control services in and around the home of pregnant women (Indoor Residual Spraying, Outdoor Residual Spraying, and larviciding)

For project 1, the population will include pregnant women who are enrolled in the Women, Infants, and Children's (WIC) program and living in Puerto Rico. WIC participants were chosen for this project because the program serves over 90% of pregnant women in Puerto Rico, and WIC maintains a database of program participants and their phone numbers.

The desired sample size for the initial telephone interview is 1,800 participants. 1,800 pregnant WIC participants is a pragmatic sample that is large enough to get robust feedback on what pregnant women may or may not be receiving in terms of the interventions that are targeting them, but a small enough sample that does not divert resources from service delivery to evaluation efforts. Each month CDC will receive a list of approximately 13,500 women because at any point in time approximately 13,500 pregnant women are enrolled in WIC in Puerto Rico. Each month 2% of the women on the list (300 women total, 100 per trimester) will be randomly selected. Therefore, after six months approximately 1,800 women will have been interviewed. The team's discussions about the sampling frame (numbers of participants and duration of the information collection) are consistent with CDC's evaluation framework that describes "optimal evaluations" as focusing on answering three questions: (1) What is the best way to evaluate? (2) What are we learning from evaluation? And (3) How will we use the learning to make our efforts more effective? The team has also strived to balance costs, time, collecting information that is context-sensitive (e.g., about the interventions being offered AND the intended effects of the interventions) and non-punitive in a manner that is inclusive of all stakeholders involved so that the objectives of interventions are achieved—support for pregnant women in protecting

themselves (and their babies) from getting Zika virus infections during their pregnancy. We make no claims that the sample size will be representative of the whole WIC pregnant population, but we do believe the sample size will provide the team with insights about what may or may not be working in the delivery of interventions as well as insights about any intended or unintended effects of the interventions. The team believes that the sample size addresses core evaluation framework standards of utility, feasibility, propriety, and accuracy with the practical constraints of doing the evaluation activities themselves in terms of time and costs. Because we are proposing a monthly information collection that produces a monthly report which then is reviewed with the intent of improving service delivery, we believe that the sample proposed will be useful in offering insights AND feasible to gather, analyze, and act upon.

The desired sample size for the follow-up interviews in this project is 900 (150 interviews per month). Based on prior experience conducting similar assessments during the Ebola response, approximately half of initial participants agree to participate in follow-up telephone interviews. Therefore, a sample size of 900 participants is reasonable, especially since no incentives are being offered. The leader for this assessment led two evaluation endeavors that sought input from travelers from Ebola-affected countries coming to the U.S. regarding airport entry screening and active monitoring requirements. Both projects utilized Generic Information Collection Request control # 0920-0932. The first project entitled "A baseline evaluation of the Ebola CARE program" was approved on December 11, 2014 and the second project entitled "Evaluating the Effectiveness of Ebola CARE Plus Program" was approved on April 3, 2015. Both evaluation efforts employed follow-up telephone surveys after an initial information collection at the airport. In each scenario, an initial interview provided feedback on their experience of the entry screening process and/or educational encounter along with intentions to perform required performance and reporting behaviors (e.g., contact health department to report temperature and symptoms) which was followed up with a telephone interview within 3-5 days of the initial information collection to see if required behaviors had begun or whether obstacles had been encountered. For the baseline assessment, the response rate for the telephone follow-up was 64.9%%. For the evaluation of the CARE Plus program, the response rate for the first telephone follow up was 54.7%. Findings from the baseline evaluation led to major revisions of the Ebola CARE kit. Neither of the Ebola evaluations, as is proposed in this evaluation, offered incentives to participants, but relied on participants' willingness to provide feedback for improving services. What is different about what we are proposing from what was done with Ebola, is that we want the assessment to be done in a way that offers monthly feedback for interventions that are being delivered, so improvements can be made in real time, over time.

For project 2, we propose use of a case-control approach to rapidly assess risk factors among pregnant women with Zika infection or protective factors when compared with pregnant women with negative Zika virus test results. Case-control methods are frequently used in situations in which a condition or outcome (in this case, Zika virus infection during pregnancy) is relatively rare, in order to compare cases with controls and have sufficient power to identify statistically significant risk factors. Although other types of projects to assess risk factors will be available in upcoming years, the current outbreak necessitates rapid assessment of current prevention methods in an ongoing manner to direct public health prevention actions in a timely way. Using a matched case-control approach, we estimate to have a power of 80%, 1-alpha at 95%, and expected percent of controls with possible exposures (risk factors for mosquito exposure) at 30%, necessitating a sample size of 130 (33 cases and 97 controls). To account for refusals and missing or incorrect contact information, we will select up to 50 cases and 150 controls.

While this will primarily be a retrospective assessment, a prospective component might be incorporated to reach the optimal sample size.

Inclusion Criteria

For project 1:

1. Women enrolled in WIC in Puerto Rico
2. Pregnant at the time of the interview
3. 18 years of age or older

For project 2:

1. Women enrolled in WIC in Puerto Rico whose Zika virus lab test results are known
2. Pregnant at the time of specimen collection for Zika virus lab testing
3. 18 years of age or older

2. Procedures for the Collection of Information

For project 1, data from women will be collected during two telephone interviews that will be pre-programmed into an Epi-INFO database, a round of initial interviews, and follow-up interviews with the respondent pool from the initial interviews. The initial telephone interview (Attachment C) of approximately 1,800 women will take approximately 20 minutes and will offer a robust view of the services that pregnant women have been offered and/or received (or not) . The follow up telephone interview (Attachment D) of approximately 900 women will take approximately 15 minutes. This sample of pregnant women will allow a robust view of the actions of those who are at risk for having Zika-affected pregnancies as well as actions that pregnant women see their communities taking.

Many of the questions are similar to and follow-up from questions that were asked in March, 2016 (OMB Gen-IC No. 0920-0932 and OMB Gen-IC No. 0929-1071). The preliminary findings from the previous qualitative studies were used to develop the response options for closed-ended questions for the telephone interviews in this project. Most of the questions are multiple choice, but women will have the opportunity to provide answers not included as response options. Proposed questions are grounded in social science literature in their respective domains (e.g., motivation, self-efficacy, perceptions of threat, etc.). The project lead who designed this project has a long history of constructing orally-administered interviews both by in-person encounters and by telephone. The project lead has estimated that each of the instruments can be completed within the proposed time.

For Project 2, data will be collected in one telephone interview from a form that will be pre-programmed into an Epi-INFO database. This telephone interview of approximately 200 women is expected to take 20 minutes, and will capture information about Zika Prevention Kit receipt and use, insecticide use, behaviors, and household characteristics to assess protective factors for preventing Zika virus infection.

Questions were designed based on the telephone interviews in project one, which were developed from previous qualitative studies. One question was taken from a previously OMB-approved questionnaire regarding risk factors for mosquito exposure and chikungunya virus infection. The questions include a combination of open ended and closed-ended questions to facilitate data analysis.

For both projects, the telephone interviews with pregnant women will be collected by trained interviewers at the call center that is part of the Puerto Rico Emergency Operations Center.

Telephone interviews

For project 1, the initial telephone interview will take approximately 20 minutes (see Attachment C). The follow-up interview will take approximately 15 minutes (see Attachment D). Information will be collected by trained interviewers using these interview questions. Most of the questions are multiple choice but women will have the opportunity to provide answers not included as response options. At the conclusion of the initial interview, respondents will be asked if they are willing to participate in the follow-up telephone interview in the next month. If they agree, they will be called within 2 weeks of the initial phone call.

Two interview sessions are planned because the content of the surveys differs. The first survey focuses on receipt/exposure/experience with the Zika prevention services or products (interventions). The second interview focuses on the self-reported behaviors (personal) that those interventions are intended to influence. It also asks women to report any actions that their communities may be taking in response to Zika. As community engagement efforts are launched, we hope that pregnant women report more visible actions in their community. Asking about services and self-reported behaviors in the same interview session increases the likelihood of biased answers due to social desirability. Additionally, there are two interviews because of the total survey length. The first survey contains approximately 52 items and the second contains approximately 20 items. Two sessions will prevent participant fatigue.

For project 2, the telephone interview will take approximately 20 minutes (see Attachment E). Information will be collected by trained interviewers using these interview questions. Most of the questions are multiple choice, but women will have the opportunity to provide answers not included as response options.

Description of how the information will be shared and for what purposes

For project 1, the information collected through this assessment will be used to help refine interventions that are designed and targeted toward pregnant to prevent Zika related birth defects and morbidities. The plan is to conduct up to 300 initial interviews and up to 150 follow-up interviews each month for six months, analyze the data, and generate a report for leaders of the response to offer insights on the delivery of interventions to pregnant women. The information will be used to make recommendations for improving interventions. Information may also be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs of this sort.

The Epi-INFO system will store the name and telephone number for each participant from the first interview until the last interview is completed. Once all interviews (initial and follow-up) are completed, names and phone numbers will be deleted. Only members of the assessment team (staff who are conducting telephone interviews) will have access to contact information.

For project 2, the information will be used to directly assess the impact of Zika prevention activities and risk for Zika infection. The comparison of cases and controls will enable identification of factors that play a role in disease prevention. Information gathered will be analyzed and a summary shared with project stakeholders to provide recommendations for improving interventions. Information may also be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs. When the interview is complete, names and phone numbers will be deleted. Only members of the assessment team will have access to contact information.

For both projects, final reports, manuscripts, and presentations will contain no information regarding identities of the participants. All collected data will be destroyed within one year after the data collection is complete.

3. Methods to Maximize Response Rates and Deal with No Response

For both projects, five attempts will be made to contact each potential participant. However, if a participant is not reached after five attempts, their phone number will be removed from the sampling frame.

If the participant agrees to participate in the follow-up interview, they will be asked about the best time to call them and the phone number they prefer. The project staff will use this information to contact them for the follow-up telephone interview. As in the initial interview, five attempts will be made to contact each potential participant.

4. Tests of Procedures or Methods to be Undertaken

No pilot testing will be done.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Christine Prue
Associate Director for Behavioral Science, NCEZID, OD
404-735-6592
cep9@cdc.gov

Laura Adams

Epidemiologist, NCEZID, Dengue Branch
787-706-2249
ipb2@cdc.gov

Tyler Sharp
Health Scientist, NCEZID, Division Of Vector-Borne Diseases, Dengue Branch
787-706-2245
iyp4@cdc.gov

Jennifer Read
Chief, Epidemiology Section, NCEZID, Dengue Branch
787-706-2472
jlr6@cdc.gov

Dana Thomas
Operations Chief for Puerto Rico Zika Response
OPHPR, Division Of State And Local Readiness, Field Services Branch
787-765-2929
wii6@cdc.gov