

Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections

Request for OMB approval of an existing information collection in use without an OMB control number

Supporting Statement B
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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

This project uses a mixed methods approach to assess the following interventions for pregnant women that have been implemented in Puerto Rico starting in March 2016:

1. Zika Education Sessions (at Women, Infants, and Children [WIC] clinics)
2. Zika Prevention Kits
3. Zika testing
4. Communications activities
5. Partnership engagement to mobilize community members
6. Vector control services in and around the home of pregnant women
7. Vector control activities in the community (traps, larviciding, community clean-up campaigns, etc.)
8. Mobilization of mental health services for pregnant women

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 (Attachment C) is 1,200 participants. 1,200 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. Every other month (February, April, June, and August 2017), 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 information collection month, the database manager from the Women, Infants, and Children (WIC) program randomly selects approximately 300 pregnant women in each pregnancy trimester who are 18 years old or greater from their database of 15,000 pregnant women. So, in all about 900 names are provided (in an excel spreadsheet) which are stratified by pregnancy trimester (300 in each). He provides a WIC

identification number, name, and phone number for each person which is reviewed by the behavioral science team deputy who removes pregnant women who have already been interviewed from previous waves of telephone calls. Once the list is finalized, call sheets are distributed to callers to track call attempts, refusals, and completed interviews. Interviews stop as soon as we complete 300 interviews (100 with pregnant women in each pregnancy trimester). After four waves of interviews, approximately 1,200 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 an every other month information collection that produces a 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 (Attachment D) in this project is 600 (150 interviews per month during February, April, June, and August). Based on experience conducting this assessment from July – December 2016, almost all pregnant women agree to participate in follow-up telephone interviews. Therefore, a sample size of 600 participants is reasonable, especially since incentives are not being offered to each participant (only a chance to win one of three raffle prizes).

Inclusion Criteria

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

2. Procedures for the Collection of Information

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 1,200 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 600 women will take approximately 10 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. 0920-0572 and OMB Gen-IC No. 0929-1071) and that have evolved with non-substantive change requests submitted in 2016, which mostly reflected the addition of response options that emerged from coding of open-ended questions. 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 and the on-going thematic analysis done in the previous information collections has expanded the number of response options. 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 proposed times are based on the average times resulting from the 1,800 initial interviews and 900 follow-up interviews conducted in 2016 as part of OMB Control No. 0920-1118.

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

The initial telephone interview will take approximately 20 minutes (see Attachment C). The follow-up interview will take approximately 10 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 interview 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 in order to prevent participant fatigue and to optimize completion of each interview by keeping each interview as brief as possible.

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

The information collected through this assessment will be used to help refine interventions that are designed and targeted toward pregnant women 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 every other month starting in February 2017 (February, April, June, and August), 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.

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

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

If the participant agrees to participate in the follow-up interview, she will be asked about the best time to call and the phone number she prefers. The project staff will use this information to contact her 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. However, the experience of conducting these interviews as part of OMB Control No. 0920-1118 has greatly informed this ICR and the procedures for collecting information.

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

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