

Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico

New Information Collection Request

Supporting Statement B

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LIST OF ATTACHMENTS

- A. Section 301 of the Public Health Service Act (42 USC 241)
- B-1.. 60-day FRN
- B-2. Public comment received
- C. Privacy Act determination
- D-1. CDC IRB approval letter
- D-2. UPR IRB approval letter
- E. Interim contacts with Z-CAN patients (English and Spanish)
- F. Invitation to Z-CAN patients to participate in online 18- and 30-month surveys (English and Spanish)
- G. Consent form for online surveys with Z-CAN patients (18- and 30-month surveys) (English and Spanish)
- H-1. Online 18-month follow-up survey for Z-CAN patients (English and Spanish)
- H-2. Online 30-month follow-up survey for Z-CAN patients who responded to the 18-month survey (English and Spanish)
- H-3. Online 30-month follow-up survey for Z-CAN patients who did not respond to the 18-month survey (English and Spanish)
- H-4. Screen shots of 18-month follow-up survey for Z-CAN patients (Spanish)
- H-5. Screen shots of 30-month follow-up survey for Z-CAN patients who responded to the 18-month survey (Spanish)
- H-6. Screen shots of 30-month follow-up survey for Z-CAN patients who did not respond to the 18-month survey (Spanish)
- I. Referenced articles

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

For online surveys with Z-CAN patients to be conducted at approximately 18 and 30 months after Z-CAN enrollment (**Attachments H-1, H-2 and H-3** for Spanish and English text of surveys to be administered in Spanish only; Spanish screenshots displayed in **Attachments H-4, H-5, H-6**), the respondent universe is Z-CAN patients aged 18 and older who completed a 2-week patient satisfaction survey conducted by the CDC Foundation as part of regular program improvement activities. At the time of their initial Z-CAN visit, Z-CAN patients were only notified about potential follow-up surveys through 12 months post-enrollment. To ensure that we do not contact women no longer wishing to participate in follow-up surveys, a thank you message will be sent approximately 1-2 months before the 18-month survey with information describing further follow-up contact planned and how patients can opt out of being contacted about these additional follow-up activities. Additionally, to help improve follow-up, short interim contact messages may be sent to women in between survey time points to maintain contact with women and request updated contact information, if any. The interim contacts, including the thank you message, survey pre-notification, and short interim messages will be sent via email or text message; these communications are included in **Attachment E** (English and Spanish).

All potential participants will receive invitations to complete the 30-month survey, regardless of whether or not they completed the 18-month survey, as long as they do not opt out. The 18-month survey is scheduled to be launched, on an ongoing basis, immediately upon OMB approval through January 2019. The 30-month survey is scheduled to be launched, on an ongoing basis, from April 2019 through January 2020.

2. Procedures for the Collection of Information

For the online surveys with Z-CAN patients, invitations to participate (**Attachment F**) will be sent via email or text message up to three times and will include an electronic link to the survey. Z-CAN patients must provide informed consent electronically to participate in the online surveys; the consent form for patients is included in **Attachment G**. Surveys will be self-administered electronically on personal devices (e.g., computers, smart phones). Data will be collected via a secure, web-based survey platform (i.e., HIPAA-compliant version of Survey Monkey). Each participant will be asked to provide consent electronically prior to beginning the electronic survey. The data collection contractors will regularly download the survey data and strip any identifying information other than the patient's unique Z-CAN identification number which will be used for linking purposes with programmatic data. Survey data transmitted to CDC at the end of the data collection period will not contain any information in identifiable form.

Quality Control. Surveys will be conducted using a secure, web-based survey platform, which will eliminate the need for data transcription, reducing data entry errors. The survey will be

programmed to limit out of range values and to reduce problems following skip patterns. All skip patterns will be verified prior to launching the surveys.

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

To determine the number of Z-CAN patients desired in our sample, we consulted with a statistician to assist with power calculations. Sample size estimates were generated assuming various levels of contraceptive method continuation at 12 months (a key outcome of interest) (i.e., 50-80%), various levels of attrition (none, 25%, 50%), and various levels of confidence interval widths (i.e., 0.05, 0.10, 0.15, and 0.20). Ultimately, we estimate approximately 60% of the 3,200 of patients sent invitations will consent to participate. Although approximately 50% of patients consented to participate in the 6-month survey, disruptions in data collection occurred because of Hurricanes Irma and Maria, and we are hopeful that with additional follow-up efforts, a higher response rate will be obtained. Although patients who choose to participate may differ from patients who decline to participate, we will be able to examine characteristics between respondents and non-respondents using programmatic data collected by the CDC Foundation, and adjust for potential differences, if needed. Data also may be weighted to correct for nonresponse to ensure representativeness of the entire Z-CAN patient population, which will be known using Z-CAN programmatic data.

The following procedures will be used to maximize cooperation and to achieve the desired participation rates:

- The survey instruments have been developed to minimize the time required for completion (no more than 10 minutes).
- Z-CAN patients are notified about the potential to be contacted to participate in follow-up online surveys at the time of their enrollment in Z-CAN (as part of regular Z-CAN programmatic activities) and 1-2 months before the 18-month survey.
- Z-CAN patients may receive short interim messages via email or text message in between survey time points to maintain interim contact and request updated contact information, if any.
- Approximately 1-2 weeks before the invitations to participate in the 18- and 30-month surveys are distributed, a pre-notification will be sent via email or text message.
- Multiple reminders (via email, text, and/or phone) will be sent to each participant to request participation in the survey (up to six).
- A token of appreciation will be provided to Z-CAN patients who participate to thank them for their time and effort in the study.
- Data may be weighted to correct for nonresponse to ensure representativeness of the entire Z-CAN patient population, which will be known using Z-CAN programmatic data.

4. Tests of Procedures or Methods to Be Undertaken

Survey instruments will be created in English and translated into Spanish, with specific focus on using appropriate Spanish for the local context in Puerto Rico. Materials will be reviewed by the University of Puerto Rico (UPR) to ensure cultural appropriateness and understanding of the issues addressed. Prior to implementing the online surveys, Centers for Disease Control and Prevention (CDC) staff and contractors will test the entire process of self-administering the

surveys to pilot test survey programming and logic. All instrumentation is new, but several items from the online surveys have been modified from other instruments such as the Pregnancy Risk Assessment Monitoring System and data collection surveys included as part of “Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics” (OMB Control No. 0920-0969; Expiration Date: 05/31/2014).

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

Individuals consulted on statistical aspects and/or contributed to the design of the data collection activities and/or will contribute to data analysis include, but are not limited to, the following:

Name	Organization	Role
Eva Lathrop, MD, MPH*# wuu7@cdc.gov , 770-833-1884	CDC/Emory University	CDC project lead
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Name	Organization	Role

*Contributed to design of the data collection activities.

#Will contribute to data analysis.

Several iterations of feedback on study design and data collection instruments were sought. All feedback received was fully considered as a collaborative group and incorporated, as appropriate.