Supporting Statement: Part A

Information Collection Request: Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN)

Request for OMB approval of an Emergency ICR

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Abstract

The goal of the project is:	To monitor and evaluate the implementation of the Zika Contraception Access Network (Z-CAN), a program designed to increase access to reversible contraceptive methods among reproductive-aged women in Puerto Rico who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes, and assess patterns of contraceptive use and pregnancy rates after participating in Z-CAN. The specific objectives are to evaluate: (1) perceived facilitators and barriers to accessing reversible contraception in Puerto Rico among both Z-CAN and non-Z-CAN patients aged 18 years or older and able to conceive; (2) Z-CAN physician and clinic staff perceptions of potential areas for Z-CAN program improvement and sustainability that could better enhance patient access to contraception; and (3) contraceptive use patterns, contraceptive continuation rates, and pregnancy rates among Z-CAN patients at 6 and 12 months after receipt of Z-CAN services.
The intended use of the resulting data is:	To improve Z-CAN program implementation and services delivered to women in Puerto Rico. Information gathered will also be used to determine the program's appropriateness/potential for replication/adaptation in other jurisdictions that may be similarly affected by the Zika virus. The information gained will be put to *immediate use* to prevent adverse pregnancy and birth outcomes caused by Zika virus infection among women in Puerto Rico served by the Z-CAN program, and to help determine Zika prevention efforts in other jurisdictions in 2017.
Methods to be used to collect data:	Mixed methods approach, consisting of: (1) focus groups with women aged 18 years or older and able to conceive enrolled and not enrolled in the Z-CAN program; (2) semi-structured, individual interviews with Z-CAN physicians and clinic staff; (3) online surveys with Z-CAN physicians and clinic staff; and (4) online surveys of women who have received services through Z-CAN.
The subpopulation to be studied:	(1) Women aged 18 years or older and able to conceive living in Puerto Rico who are interested in delaying or avoiding pregnancy during the Zika virus outbreak; and (2) physicians and staff at private health clinics and community health centers in Puerto Rico who have been trained to provide client-centered contraceptive counseling and are delivering free contraceptive services to women in Puerto Rico as part of the Z-CAN program.
How the data will be analyzed:	Qualitative data from focus groups and semi-structured, individual interviews will be recorded, transcribed, and coded using qualitative analysis software; key themes will be summarized. Quantitative data from online surveys will be analyzed using a statistical software package, such as SAS, STATA, or equivalent. Analyses of factors associated with contraception continuation at 6 and 12 months will be explored using appropriate analytic methods (e.g., chi-square tests, multivariable logistic regression).

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Acronyms

CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FRN	Federal registry notice
ICR	Information collection request
IIF	Information in identifiable form
IRB	Institutional review board
IUD	Intrauterine device
LARC	Long-acting reversible contraception
OMB	Office of Management and Budget
PR DOH	Puerto Rico Obstetrics and Gynecology
PROGyn	Puerto Rico Obstetrics and Gynecology
SORN	System of Records Notice
TSI	Total Solutions, Inc.
UPR	University of Puerto Rico
USVI	United States Virgin Islands
Z-CAN	Zika Contraception Access Network

1. Circumstances Making the Collection of Information Necessary

This is a request for emergency OMB approval of the information collection, "Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN)." The length of this emergency information collection request (ICR) for Office of Management and Budget (OMB) approval is three months. As more than three months are needed to complete this information collection, the Centers for Disease Control and Prevention (CDC) will pursue a formal ICR to immediately follow this submission. Authorizing legislation for this ICR comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment A).**

Puerto Rico continues to report the highest number of Zika virus infections in the United States and its territories, including infections in pregnant women. Zika virus infection during pregnancy has been identified as a cause of microcephaly and other severe brain abnormalities, and has been linked to other problems such as miscarriage, stillbirth, defects of the eye, hearing deficits, limb abnormalities, and impaired growth.[1,2] These adverse pregnancy outcomes along with ongoing Zika virus transmission in Puerto Rico intensify the need to reduce high rates of unintended pregnancy by removing barriers and increasing contraception access for women who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes.

Historically, the proportion of unintended pregnancies in Puerto Rico is higher than in the U.S. overall (65% vs. 45% in 2010-2011).[3,4] In April 2016, CDC estimated that approximately 138,000 women in Puerto Rico may be at risk of unintended pregnancy and not using one of the highly effective or moderately effective methods of reversible contraception.[5] To date, access to contraception in Puerto Rico has been limited by reduced availability of the full range of reversible contraceptive methods, high out-of-pocket costs for patients, insurance reimbursement that does not cover the full cost of devices and services, logistical barriers that limit same-day provision, lack of patient education on the range of reversible contraception methods available and their effectiveness, and a shortage of physicians trained to insert and remove long-acting reversible contraception (LARC), i.e., intrauterine devices [IUDs] and implants). Several projects in settings without active Zika virus transmission have demonstrated the importance of removing barriers to access to the full-range of reversible contraceptive methods, including LARC, on increasing use of the most effective reversible methods and on reducing unintended pregnancies.[6-8]

In response to the Zika virus outbreak in Puerto Rico, the CDC Foundation, with technical assistance from the CDC, and in collaboration with the Puerto Rico Department of Health (PR DOH), Puerto Rico Obstetrics and Gynecology (PROGyn) and other partners, launched the Zika Contraception Access Network (Z-CAN) in April 2016 with the first provider training. Z-CAN is a program designed to develop a network of physicians at clinics across Puerto Rico trained to provide client-centered contraceptive counseling and same-day access to the full range of Food and Drug Administration (FDA)-approved, reversible contraceptive methods at no cost to women who choose to delay or avoid pregnancy during the Zika virus outbreak.

While the Z-CAN program started providing services to women in July 2016, Z-CAN providers were trained, approved, and began receiving donated contraceptive product on a rolling basis over several months. The majority of Z-CAN providers were approved to provide services by October 2016, and since then, patient enrollment in Z-CAN has been rapidly increasing. As of 1/13/2017, approximately 4,900 women have enrolled in the Z-CAN program, with approximately 500 newly enrolled women per week. To maximize program impact, address patient barriers to accessing reversible contraception in Puerto Rico, address Z-CAN physician and staff perceptions of potential areas for Z-CAN program improvement and sustainability, and assess suitability of the Z-CAN program for potential replication/adaptation in other jurisdictions that may be similarly affected by the Zika virus, it is urgent that we begin data collection as soon as possible. Due to the ongoing nature of enrollment, the exact dates for the 6 and 12 month follow up survey will vary by participant. However, potential participants will be drawn from the pool of patients who completed a 2-week patient satisfaction survey which was launched October 14, 2016 (that collection activity was funded by the CDC Foundation and was not directed by the federal government). As such, hundreds of Z-CAN participants are rapidly approaching the 6 month mark, increasing the urgency of collection of this data. A delayed start would mean collecting critical information to improve program implementation after the end of the program; too late to incorporate changes. A delayed start would also mean collecting critical information to determine the program's suitability for adaptation in other jurisdictions, potentially after the need for such a program. The information gained will be put to *immediate use* to prevent adverse pregnancy and birth outcomes caused by Zika virus infection among women in Puerto Rico served by the Z-CAN program, and to help determine Zika prevention efforts in other jurisdictions in 2017.

2. Purpose and Use of the Information Collection

The purpose of this ICR is to monitor and evaluate the implementation of the Z-CAN program and assess patterns of contraceptive use and pregnancy rates after participating in Z-CAN. The specific objectives are to evaluate:

1. perceived facilitators and barriers to accessing reversible contraception in Puerto Rico among both Z-CAN and non-Z-CAN patients aged 18 years or older and able to conceive to improve the Z-CAN program;
2. Z-CAN physician and clinic staff perceptions of potential areas for Z-CAN program improvement and sustainability that could better enhance patient access to contraception; and
3. contraceptive use patterns, contraceptive continuation rates, and pregnancy rates among Z-CAN patients at 6 and 12 months after receipt of Z-CAN services.

CDC proposes to conduct a mixed-method study to monitor and evaluate the Z-CAN program including focus groups with women aged 18 years or older and able to conceive; semi-structured, individual interviews with Z-CAN physicians and clinic staff; and online surveys with Z-CAN physicians, clinic staff, and patients aged 18 years or older.

Information collected as part of this ICR, in combination with Z-CAN programmatic data, will be used to monitor and evaluate the overall implementation of the program and to assess patterns

of contraceptive use and pregnancy rates at both the 6 and 12 month mark after participating in Z-CAN. Z-CAN programmatic data, which include data from initial visits, return visits, adverse event forms, and a 2-week patient satisfaction survey provide information on: contraceptive method use before Z-CAN visit, contraceptive method(s) received through Z-CAN, same day receipt of methods, whether methods and related services were provided free of charge, patient satisfaction with services, and implementation of client-centered counseling. The collection of Z-CAN programmatic data is funded by the CDC Foundation. By extending follow-up with Z-CAN patients to 6 and 12 months post-enrollment and expanding data collection to include assessments with women aged 18 years or older and able to conceive enrolled and not-enrolled in Z-CAN, as well as with Z-CAN physicians and staff, we will now be able to assess outcomes of interest over a longer period of time and general facilitators and barriers to contraception access in Puerto Rico. The *practical utility* of the information to be collected as part of this ICR is to improve program implementation and services delivered to women in Puerto Rico, understand changes in outcomes of interest over a longer period of time, and determine the Z-CAN program's appropriateness/potential for replication/adaptation in other jurisdictions that may be similarly affected by the Zika virus. The information gained will be put to *immediate use* to prevent adverse pregnancy and birth outcomes caused by Zika virus infection among women in Puerto Rico served by the Z-CAN program, and to help determine Zika prevention efforts in other jurisdictions in 2017.

The *negative consequences* of not having the information would be potential underperformance of the program, not knowing anything about changes in outcomes over a longer period of time, and the inability to determine the program's potential for replication/adaptation in other jurisdictions interested in improving contraception access for reproductive-aged women in the context of a complex emergency response.

The data will primarily be used by CDC and the CDC Foundation, in collaboration with the PR DOH, Total Solutions, Inc. (TSI), PROGyn, and the University of Puerto Rico (UPR), and may be used on an ongoing basis (i.e., not limited to a given frequency). Others entities (e.g., jurisdictional departments of health and human services) may also be interested in using the data to inform potential replication/adaptation of the program for their communities.

3. Use of Improved Information Technology and Burden Reduction

This ICR consists of three types of data collection activities: focus groups; semi-structured, individual interviews; and online surveys. All data collection tools (i.e., focus group discussion guides, semi-structured interview guides, online surveys) have been designed to collect the minimum amount of information necessary to meet the study objectives.

The focus groups with women aged 18 years or older and able to conceive will be conducted in-person. Focus groups will be digitally audio-recorded to capture all information and assist with analysis and preparation of reports. No additional technology will be used for the focus groups. All information collected will be from people talking and engaging with the focus group facilitator and other members of the focus groups.

The semi-structured, individual interviews with physicians and clinic staff may be conducted either in-person, by telephone, or through an online communication platform (e.g., Skype, videoconferencing, etc.). In all cases, the interviews will be conducted in private spaces to ensure confidentiality. In case of technical difficulties, a back-up mode for communication will be identified (e.g., alternate phone number or software application). Interviews will be digitally audio-recorded to capture all information and assist with analysis and preparation of reports.

The online surveys with Z-CAN patients, physicians, and staff will be self-administered electronically on personal devices (e.g., computers, smart phones). Use of online surveys has several advantages. They are less expensive to deploy, reduce the need for data entry thereby eliminating transcription errors, allow respondents to respond at a time that is most convenient to them, and reduce respondent burden by allowing respondents to automatically skip questions that are not applicable based on an answer to a previous question. All skip patterns will be verified prior to launching the surveys.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of any systematic collection of the information described in this ICR. Although CDC received emergency OMB approval for the ICR "Emergency Zika Package IV: Assessment of Contraceptive Use and Needs, Puerto Rico, 2016" (OMB Control No. 0920-1114), that data collection effort largely occurred prior to the launch of the Z-CAN program and therefore does not include a significant number of Z-CAN participants (if any). Also, that data collection effort was cross-sectional and did not assess contraceptive continuation rates or pregnancy rates over time, nor did it collect information on barriers and facilitators to accessing contraception in Puerto Rico among women enrolled and not enrolled in Z-CAN, nor Z-CAN physician and staff perceptions on potential areas for program improvement and sustainability.

CDC also received emergency OMB approval for several ICRs that involved data collection with pregnant or immediately postpartum women including "Formative Evaluation of Zika Prevention Kits for Pregnant Women in Puerto Rico" (OMB Control No. 0920-1071), "Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika Virus Infections" (OMB Control No. 9020-1118), and "Emergency Zika Package: Zika Postpartum Emergency Response Survey, Puerto Rico, 2016" (OMB Control No. 0920-1127). None of these ICRs collected information that could be used to improve Z-CAN program implementation or determine its suitability for replication/adaptation in other jurisdictions.

Further, CDC received emergency OMB approval for the ICR "Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika" (OMB Control No. 0920-1148). Although this ICR collected information on barriers and facilitators to accessing contraception among women of reproductive age in USVI, the findings are not generalizable to the experiences of women in Puerto Rico given the very different contexts between USVI and Puerto Rico.

No other similar data collections have been conducted or are underway, as confirmed via literature searches of electronic databases and discussions with stakeholders and federal partners.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small businesses or other small entities. However, some respondents may represent small businesses or other small entities. The data collection elements are the absolute minimum required for the intended use of the data. The burden of participation in the data collection activities will not affect the normal functioning of the entities in which they work.

6. Consequences of Collecting the Information Less Frequently

For the focus group discussions with women aged 18 years or older and able to conceive in Puerto Rico enrolled and not enrolled in Z-CAN, women will participate only once in a single focus group. For the semi-structured, individual interviews with Z-CAN physicians and clinic staff, Z-CAN physicians and clinic staff will participate only once in a single interview approximately 3 months after beginning to provide Z-CAN services. For the online surveys, the frequency of data collection varies by respondent type. For Z-CAN patients, women will be asked to respond to online surveys approximately 6 and 12 months after their initial Z-CAN visit. For Z-CAN physicians and staff, physicians and staff will be asked to respond only once to a single survey approximately 6 months after beginning to provide Z-CAN services.

The data collection frequency is minimal for most data collection activities. The only data collection activity that involves more than a single data collection time point is the online surveys with Z-CAN patients approximately 6 and 12 months after their initial Z-CAN visit. Since women's satisfaction with their contraceptive method and continued use of that method may vary over time,[9-12] it is important to monitor these outcomes, as well as pregnancy rates, over a longer period of time to monitor potential changes. Longitudinal data collection is also important to ensure patients do not incur costs associated with their contraceptive method over time, a key component of the program, to help assess fidelity of implementation. Collecting this information from Z-CAN patients less frequently will preclude this assessment.

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. A 60-day notice will be published in the Federal Register to make the public aware of this proposed information collection (**Attachment B**). However, because this is a request for an emergency clearance, CDC requests OMB review without waiting for the 60-day comment period to expire. As more than six months are needed to complete this information collection, CDC will pursue a formal ICR as soon as emergency approval is granted. For this formal, non-emergency ICR, a new 60-day notice will be published in the Federal Register inviting public comment, followed by a 30-day notice and ICR application for three years of OMB clearance.

B. Local collaborators, including PROGyn, a medical non-profit organization, and UPR, have been involved in discussions since early September 2016 regarding the design of the overarching monitoring and evaluation strategy to ensure cultural appropriateness and community relevance in all aspects of data collection, including recruitment efforts, instruments, and consent processes. CDC is currently working closely with UPR colleagues to align English and Spanish versions of the consent forms to meet both CDC and UPR requirements. There are no unresolved problems with outside collaborators.

9. Explanation of Any Payment or Gift to Respondents

This ICR consists of three types of data collection activities: focus groups, semi-structured interviews, and online/web-based surveys. Furthermore, three different groups will be engaged in these activities: women aged 18 years or older and able to conceive, physicians providing contraceptive counseling and services through Z-CAN, and staff working at participating Z-CAN clinics. In collaboration with local partners with training and experience conducting research within Puerto Rico with similar populations, we have tailored recruitment and engagement tactics based on the data collection activity and the population to be engaged. To encourage participation in these data collection activities, tokens of appreciation will be provided to some participants, as outlined below:

Data Collection Activity	Population Engaged	Token of Appreciation
Focus group discussions (1-1.5 hours)	Women aged 18 years or older and able to conceive	Gift card valued at $50
Semi-structured interviews (45-60 minutes)	Z-CAN physicians	None
	Z-CAN staff	Gift card valued at $20
Online/web-based surveys (10-15 minutes)	Z-CAN patients aged 18 years or older	Gift card valued at $5
	Z-CAN physicians	None
	Z-CAN staff	None

Providing tokens of appreciation will aid in ensuring adequate participation from hard to reach populations critical for this ICR. Inability to recruit adequate participation would result in reduced sample sizes which would compromise our ability to use the information collected from respondents. The token of appreciation amounts were determined through discussions with local collaborators with expertise in conducting data collection activities with the study populations. Removing the tokens of appreciation would incur significant costs for extended recruitment and timeline delays which could threaten our ability to assess the effectiveness of the Z-CAN program and promptly address any potential challenges or issues identified for program improvement.

Focus group discussions. Women will be travelling from an hour or so to attend the focus group discussions. It is estimated that the duration of each focus group will be 1.0-1.5 hours. Women participating in focus group discussions will be provided with a one-time gift card valued at $50 as a token of appreciation. This amount is similar to amounts given in other studies conducted in Puerto Rico during the Zika emergency response.

Semi-structured interviews. Z-CAN physicians and staff will be invited to participate in semi-structured interviews. The anticipated length of the interviews is approximately 45-60 minutes. Z-CAN physicians will not be provided an incentive for participation in the interviews, since all Z-CAN physicians have agreed to participate in general monitoring and evaluation activities as part of their contractual responsibilities as a Z-CAN provider. Z-CAN clinic staff participating in the semi-structured interviews will be provided with a one-time gift card valued at $20 as a token of appreciation.

Online/web-based surveys. Women who receive services through the Z-CAN program will receive invitations to complete 6- and 12-month online surveys. Each survey should take approximately 10 minutes to complete. Z-CAN patients participating in the surveys will be provided with a gift card valued at $5 for each of the two surveys completed, as a token of appreciation.

Z-CAN physicians and staff will also be invited to participate in online surveys. The surveys should take approximately 15 minutes to complete. No incentives will be provided to Z-CAN physicians and staff for participation.

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

The Chief Privacy Officer for CDC has determined that the Privacy Act does apply to this data collection (**Attachment C**). CDC will not be given information in identifiable form (IFF) such as name, e-mail or phone number. However, each participant will have a unique identifier that will be used to identify and retrieve records across various project components. The System of Records Notice (SORN) being used for this data collection is: 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems (https://www.cdc.gov/SORNnotice/09-20-0136.htm). Given the applicability of the Privacy Act, all appropriate security controls and rules of behavior will be incorporated to protect the confidentiality of information obtained. All individuals involved in any data collection activity will be trained concerning procedures and practices to ensure privacy of data. The sections below describe the protections in place to preserve privacy and confidentiality.

Focus groups and semi-structured, individual interviews. At the beginning of each focus group discussion and semi-structured interview, the facilitator will explain his/her role and the purpose of the data collection activity using informal language and casual style to put the participants at ease. For focus groups, the facilitator will encourage women to choose a pseudonym to use throughout the focus group to avoid using real names to identify themselves. For interviews with Z-CAN physicians and staff, after recruitment, participants will only be identified using their unique Z-CAN identification number. Participants will be given time to read the consent forms and ask questions. The consent forms will communicate that all study findings will be reported in

summary form so that participants cannot be individually identified. Information from focus groups and interviews will be digitally audio-recorded by the interviewer. No data will be collected other than what is collected during the focus groups and interviews. Once data are transcribed and prepared for analysis, any identifying information, including Z-CAN identification number for Z-CAN physicians and staff, will be removed. No identifying information will be retained in the transcripts for data analysis and reporting. All notes, consent forms, other written materials, and audio-recordings will be kept securely on a password-protected computer and/or in a locked facility at the University of Puerto Rico and only shared with research staff members who are authorized to access the information. Audio-recordings will be destroyed immediately after transcription and translation has been completed and verified.

Online surveys. Z-CAN patients, physicians, and clinics have been assigned a unique identification number by the Z-CAN program (i.e., Z-CAN identification number). PROGyn, the Z-CAN implementation partner in Puerto Rico, maintains a list of all Z-CAN physicians and clinic staff and their contact information, as well as a list of Z-CAN patients who completed the 2-week patient satisfaction survey that occurred after the initial Z-CAN visit (as part of Z-CAN programmatic monitoring activities and not as part of this ICR) and their contact information. PROGyn will provide the data collection contractor a file containing the Z-CAN identification numbers, names, and emails of those to be surveyed. A password-protected electronic file will be used to transmit the information to the contractor. The password to unlock the file will be provided to the contractor via telephone and not in written form (technical control). Z-CAN identification numbers will be used to track responses.

Data will be collected via a secure, web-based survey platform (i.e., HIPPA-compliant version of Survey Monkey) with security features to help protect the data, including automatic logoff after 30 minutes of inactivity and logging of account access and modifications to survey data, including account logins/failures, account password and username requests, survey response exports, sharing, and deletions; and transferring surveys to other accounts. The platform also implements administrative, physical, and technical safeguards to protect the confidentiality and integrity of the data, such as regular risk assessments of systems, backup data plans, disaster recovery plants, and regular system monitoring, updating, and patching.

Each participant will be asked to provide consent electronically prior to beginning the electronic survey. For the online surveys with Z-CAN patients, the surveys will be described as “patient satisfaction surveys.” The Z-CAN program will not be mentioned by name in the invitation link. This description is vague enough to prevent someone who may have access to the invitation (who is not the intended participant) from immediately knowing the purpose of the survey. This is an added layer of privacy protection for Z-CAN patients.

All electronic files will have restricted access and will be password protected. Back-up files of data will be password protected and securely stored. The contractors will download the survey data and strip names, emails, and phone numbers from the dataset before saving as a secure password-protected file. The datasets will contain the Z-CAN identification numbers of respondents for tracking and linking purposes. Data will be reported in aggregate to prevent identification of individuals. Information that could potentially be used to indirectly identify

an individual will be suppressed in reports; for example, aggregated data will not be stratified into subcategories that might allow for identification of individuals. Survey data transmitted to CDC at the end of the data collection period will not contain any IIF; instead, only de-identified data will be provided. The data collection contractor will work closely with CDC's National Center for Chronic Disease Prevention and Health Promotion's Office of Informatics and Information Resources to ensure that technical and security standards, processes, and procedures are followed (administrative control).

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

IRB Approval

The protocol was submitted and received CDC IRB approval on December 23, 2016 (**Attachment D-1**). The IRB determined the study to be not greater than minimal risk to subjects.

The protocol was also submitted to UPR's IRB as two separate protocols. The protocol containing the qualitative data collection activities was approved on December 20, 2016 (**Attachment D-2**). The IRB determined the study to be not greater than minimal risk to subjects. The protocol containing the quantitative data collection activities was submitted in December, 2016 and is pending.

Justification for Sensitive Questions

Some topics covered in the data collection activities may be sensitive for some participants (e.g., contraception, occurrence of pregnancy). However, these questions are essential to meeting the goals of the information collection. During the informed consent process, participants will be notified of the types of the questions that will be asked and also notified that they may decline to discuss any of the topics or decline to answer any question without penalty. Steps to protect the privacy of information provided by respondents is included in Section 10.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Focus groups with approximately 240 women aged 18 years or older and able to conceive (120 who are enrolled in Z-CAN and 120 who are not) will be conducted to better understand facilitators and barriers to accessing reversible contraception in Puerto Rico. A range of recruitment strategies will be utilized to recruit participants. Recruitment flyers posted at Z-CAN clinics will be used to recruit women who have received Z-CAN services. The same flyer will also be posted in community settings and businesses frequented by women of reproductive age (e.g., grocery stores, shopping areas), principally to recruit women who have not accessed Z-CAN services. The recruitment flyer will contain a brief description of the purpose of the focus group, who is eligible to participate, what is expected of the participant, the token of appreciation for participation, and how to register if they are interested in participating. The recruitment flyer is included in **Attachment E-1** (English) and **Attachment E-2** (Spanish). In addition, advertisements will be posted through media outlets (e.g., radio, newspaper, and internet) to

ensure a diverse sample of participants. Potential focus group participants will be screened in person or online and will be accepted based on participant eligibility criteria until established quotas are met for the following characteristics: participation or non-participation in the Z-CAN program and age group (18-24 years vs. 25+ years). We estimate the need to screen approximately 300 women to identify 240 that meet eligibility criteria. The screener form is included in **Attachment F-1** (English) and **Attachment F-2** (Spanish); screen shots for the online version of the screener form are included in **Attachment F-3** (Spanish)**.** Women must provide informed consent to participate in the focus groups (**Attachment G**). The focus group guide for women enrolled in Z-CAN is included in **Attachment H-1** (English) and **Attachment H-2** (Spanish). The focus group guide for women not enrolled in Z-CAN is included in **Attachment H-3** (English) and **Attachment H-4** (Spanish).

Semi-structured, individual interviews with Z-CAN physicians and clinic staff will be conducted to identify potential areas for Z-CAN program improvement and sustainability that could better enhance patient access to contraception. Approximately 25 physicians and 25 clinic staff will be purposively selected to participate in individual interviews approximately 3 months after beginning to provide Z-CAN services. Each physician and clinic staff member selected to participate in the individual interviews will receive an invitation to participate via email or phone. The invitation to participate in the physician interview is included in **Attachment I-1** (English) and **Attachment I-2** (Spanish). The invitation to participate in the staff interview is included in **Attachment I-3** (English) and **Attachment I-4** (Spanish)**.** Z-CAN physicians and staff must provide informed consent to participate in the individual interviews; the consent form for physicians is included in **Attachment J-1** and the consent form for staff is included is **Attachment J-2**. The interview guide for physicians is included in **Attachment J-1** (English) and **Attachment K-2** (Spanish). The interview guide for staff is included in **Attachment K-3** (English) and **Attachment K-4** (Spanish).

Online surveys. All Z-CAN physicians (n=163) and one randomly selected Z-CAN staff member from each clinic that provides Z-CAN services (n=150) will be invited to complete an online survey six months after beginning to provide Z-CAN services. The invitation to participate will be sent via email or text message and will include an electronic link to the survey. The invitation to participate in the online physician survey is included in **Attachment L-1** (English) and **Attachment L-2** (Spanish). The invitation to participate in the online staff survey is included in **Attachment L-3** (English) and **Attachment L-4** (Spanish)**.** Z-CAN physicians and staff must provide informed consent electronically to participate in the online surveys; the consent form for physicians is included in **Attachment M-1** and the consent form for staff is included in **Attachment M-2**. The Z-CAN physician survey is included in **Attachment N-1** (English); the screen shots are included in **Attachment N-2** (Spanish). The Z-CAN staff survey is included in **Attachment N-3** (English); the screen shots are included in **Attachment N-4** (Spanish). It is possible that the Z-CAN physician and staff member surveys may be modified slightly based on results from the semi-structured, individual interviews; if modifications are made, a change request will be submitted.

Online surveys will also be conducted with approximately 3,200 Z-CAN patients aged 18 years or older and able to conceive to assess contraceptive use patterns, contraceptive continuation rates, and self-reported pregnancy rates 6 and 12 months following their enrollment in Z-CAN.

Potential participants for the online follow-up surveys with Z-CAN patients will be derived from the list of Z-CAN patients who completed a 2-week patient satisfaction survey, an effort determined to be part of regular Z-CAN program activities that received a non-research determination from CDC in August 2016 (**Attachment O-1**), with a revision approved in October, 2016 (**Attachment O-2**). To maintain interim contact with Z-CAN patients who completed the 2-week survey, a thank you message will be sent approximately two months after completion of the 2-week survey. Also, approximately 1-2 weeks before the invitations to participate in the 6-month and 12-month surveys are distributed, a pre-notification will be sent. The interim thank you message and pre-notification will be sent via email or text message; these communications are included in **Attachment P-1** (English) and **Attachment P-2** (Spanish). The invitation to participate in the 6-month and 12-month surveys will also be sent via email or text message and will include an electronic link to the survey; the invitation is included in **Attachment P-3** (English) and **Attachment P-4** (Spanish). Women must provide informed consent electronically to participate in the online surveys (**Attachment Q**). Since it is possible that Z-CAN patients may respond to the 12-month survey who did not participate in the 6-month survey, there are two different versions of the 12-month survey – one for Z-CAN patients who responded to the 6-month survey (version A) and one for Z-CAN patients who did not respond to the 6-month survey (version B). The survey content will be identical for the 6-month survey and the 12-month survey version A; that survey is included in **Attachment R-1** (English) and the screen shots are included in **Attachment R-2** (Spanish). The content for the 12-month survey version B will be identical except that women will be asked about contraceptive use patterns, contraceptive continuation rates, and self-reported pregnancy rates in the past 12 months versus 6 months; that survey is included in **Attachment R-3** (English) and the screen shots are included in **Attachment R-4** (Spanish).

Some of the data collection activities will occur within a single year and others will span across multiple years (see table below).

Data Collection Activity	**Time Frame**
• A total of 24 focus groups with women aged 18 years or older and able to conceive enrolled and not enrolled in Z-CAN (each with a maximum of 10 participants); we anticipate needing to screen 300 women to identify 240 eligible participants.	Begins immediately upon approval and occurs within a single year
• A maximum of 25 semi-structured, individual interviews with Z-CAN physicians.	Begins immediately upon approval and occurs within a single year*
• A maximum of 25 semi-structured, individual interviews with Z-CAN clinic staff.	Begins immediately upon approval and occurs within a single year*
• An online survey with an estimated 163 Z-CAN physicians.	Begins late March 2017 and occurs within a single year*
• An online survey with an estimated 150 Z-CAN clinic staff	Begins mid-April 2017 and occurs within a single year*
• An online survey at two different time points (6 and 12 months) with approximately 3,200 women (aged 18 years or older) who have received services through the Z-CAN program. Power calculations determined	Begins mid-April 2017 and may span across 3 years, since Z-CAN patients enroll on an ongoing basis and data collection activity involves 6- and 12-

Data Collection Activity	Time Frame
that a total of 3,200 patients should be invited to participate to estimate the contraceptive method continuation rate at 12 months, assuming 50% attrition by 12 months (see supporting statement B for more information).	month follow-up.** To estimate annualized burden hours for the 6-month and 12-month surveys, separately, the total number of estimated respondents (assuming 25% attrition by 6 months and 50% attrition by 12 months) will be divided by 3.

* Z-CAN trainings for physicians and staff were completed September 23, 2016.
**Z-CAN patients who complete the 2-week patient satisfaction survey will serve as potential participants. The Z-CAN 2-week survey was launched October 14, 2017. Z-CAN services are expected to cease July 30, 2017, but may be extended if funding and contraceptive products are available.

The total number of annualized burden hours in this ICR is estimated to be 736.

Type of Respondents	**Form Name**	**Total No. of Respondents**	**Annualized No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Annualized Burden Hours**
Women aged 18 years or older and able to conceive	Focus group screener form (**Attachment F-2 or F-3**)	300	300*	1	5/60	25
Women aged 18 years or older and able to conceive	Focus groups (**Attachment H-2 and H-4**)	240	240*	1	1.5	360
Z-CAN physicians	Semi-structured, individual interviews (**Attachment K-2**)	25	25*	1	1	25
Z-CAN staff	Semi-structured, individual interviews (**Attachment K-4**)	25	25*	1	1	25
Z-CAN physicians	Online surveys (**Attachment N-2**)	163	163*	1	15/60	41
Z-CAN staff	Online surveys (**Attachment N-4**)	150	150*	1	15/60	38

Type of Respondents	Form Name	Total No. of Respondents	Annualized No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Annualized Burden Hours
Z-CAN patients aged 18 years or older	Online surveys (6-month follow-up) (**Attachment R-2**)	2400**	800[#]	1	10/60	133
Z-CAN patients aged 18 years or older	Online surveys (12-month follow-up) (**Attachment R-2 or R-4**)	1600**	534[#]	1	10/60	89
TOTAL						736

*Data collection occurs within a single year.
**Assuming 25% attrition by 6 months and 50% attrition by 12 months, among the 3,200 invitations sent.
[#]Data collection spans across 3 years.

B. Estimated Annualized Burden Costs

For women aged 18 years or older and able to conceive included in this ICR, we do not know what the wage rate category will be for the selected participants. Therefore, we used the minimum wage rate for Puerto Rico ($7.25 per hour) (available at https://www.dol.gov/whd/minwage/america.htm#PuertoRico).

In calculating annualized burden costs to Z-CAN physicians, we used $107.10 per hour as an estimate of the mean hourly wage rate. To establish this amount, we used the mean hourly wage for physicians and surgeons released by the United States Department of Labor, Bureau of Labor Statistics (May 2015; available at http://www.bls.gov/oes/current/naics4_621100.htm). For Z-CAN clinic staff, we used $58.32 per hour, which is the mean hourly wage rate for health care practitioners and technical occupations released by the United States Department of Labor, Bureau of Labor Statistics. Actual hourly wage rates will vary by credentials (e.g., wage rates for nurses may be higher than wage rates for health educators). For both Z-CAN physicians and Z-CAN clinic staff, these costs were based on estimates for the United States, as regional wage estimates were not available. The estimated annual response burden cost to participants for this ICR will be $15,179.76.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Women aged 18 years or older able and to conceive	Focus group screener form (**Attachment F-2 or F-3**)	25	$7.25	$181.25
Women aged 18	Focus groups	360	$7.25	$2,610.00

years or older and able to conceive	(**Attachment H-2 and H-4**)			
Z-CAN physicians	Semi-structured, individual interviews (**Attachment K-2**)	25	$107.10	$2,677.50
Z-CAN staff	Semi-structured, individual interviews (**Attachment K-4**)	25	$58.32	$1,458.00
Z-CAN physicians	Online surveys (**Attachment N-2**)	41	$107.10	$4,391.10
Z-CAN staff	Online surveys (**Attachment N-4**)	38	$58.32	$2,216.16
Z-CAN patients aged 18 years or older	Online surveys (6-month follow-up) (**Attachment R-2**)	133	$7.25	$964.25
Z-CAN patients aged ≥18 years	Online surveys (12-month follow-up) (**Attachment R-2 or R-4**)	89	$7.25	$645.25
TOTAL				$15,143.51

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

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

14. Annualized Cost to the Federal Government

The total estimated cost to the federal government is $902,969.41. This amount is based on the contractor's costs for carrying out the data collection activities and reporting and CDC personnel time for obtaining CDC approvals, providing project oversight, and participating in analysis and dissemination of the results. The table summarizes expenses to the federal government. Salary estimates were obtained from the US Office of Personnel Management salary scale and were based on Step 1 employees for the Atlanta locality (available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/ATL.pdf). This project will be executed as part of Contract No. 200-2016-91591.

Expense Type	Expense Explanation	Annual Costs (dollars)
Contract	Contract No. 200-2016-91591 (Total Solutions, Inc.)	$752,055.01
	Subtotal, Contract Costs	***$752,055.01***
CDC Personnel	Behavioral Scientist GS-14, 30% of FTE	$31,304.70
	Health Scientist GS-14, 30% of FTE	$31,304.70

	Health Scientist GS-13, 50% of FTE	$44,152.50
	Statistician GS-13, 50% of FTE	$44,152.50
	Subtotal, CDC Personnel	***$150,914.40***
	TOTAL COST TO THE GOVERNMENT	**$902,969.41**

15. Explanation for Program Changes or Adjustments

This is a new ICR, therefore program changes or adjustments do not apply at this time.

16. Plans for Tabulation and Publication and Project Time Schedule

For qualitative data collection activities (i.e., focus groups and semi-structured, individual interviews), *a priori* codebooks will be developed for each round of data collection based on the key objectives of this study, as well relevant theoretical frameworks and scientific findings. These codebooks will be used to code transcripts. Once the coding process begins, the codebooks will be refined to reflect any emerging themes. As codes are added and/or revised, previously coded transcripts will be reviewed to ensure that they align with the updated codebooks. Transcripts will be coded using a qualitative analysis software (e.g., MAXQDA, ATLAS.ti, or Nvivo) by reading the data line-by-line to assist in identifying concepts within each statement. Each section of data will be labelled according to the concept(s) in the transcript with a brief code and used to create a new tree node. When the same idea appears again, this will be coded to the same node, creating a list of repeating ideas. As coding develops and themes emerge, nodes will be arranged in groups under a parent node labelled with the theme. Beyond this, themes may be collated into broader groups. All transcripts will be read and coded independently by two analysts. Transcripts will then be checked for inter-coder reliability.

For quantitative data collection activities (i.e., online surveys with Z-CAN physicians, staff, and patients), data analysis will be conducted using a statistical software package (e.g., SAS, STATA, SUDAAN). Descriptive statistics will be examined, and appropriate analytic tests (e.g., chi-square tests, multivariable logistic regression) will be applied to examine research questions (e.g., factors associated with Z-CAN patient contraceptive continuation rates at 6 and 12 months).

Below are key activities and target dates for this ICR:

Activity	**Time Schedule***
Activity 1: Focus groups with women aged 18 years or older and able to conceive enrolled and not enrolled in Z-CAN	
Recruitment strategy for focus groups finalized and implemented	Beginning immediately after OMB approval
Focus group discussions scheduled and conducted	1-2 months after OMB approval
Focus group discussions transcribed and	1-2 months after OMB approval

Activity	Time Schedule*
translated	
Focus group data are entered into qualitative software and are accessible to the CDC	1-2 months after OMB approval
Focus group data are analyzed	3-4 months after OMB approval
Findings from the focus group discussions are disseminated	5-6 months after OMB approval
Focus group findings are used to improve Z-CAN program implementation	5-6 months after OMB approval
Manuscripts are developed and submitted for publication	6-11 months after OMB approval
Activity 2: Semi-structured, individual interviews with Z-CAN physicians and clinic staff three months after beginning to provide Z-CAN services	
Interviews are scheduled and conducted	Beginning immediately after OMB approval
Interview sessions are transcribed and translated	Beginning 1 months after OMB approval
Interview data are entered into qualitative software and is accessible to the CDC	Beginning 1 months after OMB approval
Interview data are analyzed	Beginning 2 months after OMB approval
Findings from semi-structured interviews are disseminated	Beginning 3 months after OMB approval
Interview findings are used to improve Z-CAN program implementation	Beginning 3 months after OMB approval
Manuscripts are developed and submitted for publication	Beginning 6 months after OMB approval
Activity 3: Online surveys with Z-CAN physicians and clinic staff six months after beginning to provide Z-CAN services	
Surveys may be modified based on results from semi-structured, individual interviews (Activity 2); modifications (if any) will not affect burden time estimates	Beginning immediately after completion of interview
Web-based survey platform is built	Currently under development
Send web-based link for Z-CAN physician and staff surveys on rolling basis to Z-CAN physicians and staff	Beginning mid-April 2017
Data are converted to analytic dataset and sent to the CDC	Beginning mid-May 2017
Survey data are analyzed	Beginning mid-May 2017
Findings are disseminated	Beginning mid-May 2017
Survey findings are used to improve Z-CAN program implementation	Beginning mid-May 2017
Manuscripts are developed and submitted for publication	2-3 months after end of data collection
Activity 4: Online surveys with Z-CAN patients ≥18 years at six and twelve months	

Activity	Time Schedule*
post-enrollment	
Web-based survey platform is built	Currently under development
Obtain contact information of potential respondents from PROGyn	Beginning mid-March 2017
Send web-based link for Z-CAN patient 6-month survey on rolling basis to Z-CAN patients based on Z-CAN enrollment date)	Beginning mid-April 2017
Send web-based link for Z-CAN patient 12-month surveys on rolling basis to Z-CAN patients based on Z-CAN enrollment date)	Beginning mid-March 2018
Data are converted to analytic dataset and sent to the CDC	Beginning mid-May 2017
Survey data are analyzed	Beginning mid-May 2017
Findings are disseminated	Beginning mid-May 2017
Manuscripts are developed and submitted for publication	2-3 months after end of data collection

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

The OMB expiration date will be displayed on necessary materials and documents.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

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