Information Collection Request:
Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika

Request for OMB approval of an Emergency ICR

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Supporting Statement A

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- **Goal of the study:** To conduct a formative assessment to explore current knowledge, attitudes, and beliefs regarding contraception use, in general, and related to Zika virus exposure, in particular, among women of reproductive age (WRA; 18-44 years) and men of reproductive age (MRA; 18-44 years) in the U.S. Virgin Islands (USVI).
- **Intended use of the resulting data:** To provide data to inform the development of messages and materials designed to increase knowledge and awareness of the range of available contraceptive methods and to promote utilization of contraceptive services among WRA living in USVI who want to delay or avoid pregnancy during the Zika virus outbreak.
- **Methods:** Focus groups
- **The subpopulation to be studied:** (1) Women between the ages of 18 and 44 years living in the USVI who are currently not pregnant and interested in delaying or avoiding pregnancy during the Zika virus outbreak; and (2) men between the ages of 18 and 44 years living in the USVI who are interested in delaying or avoiding pregnancy during the Zika virus outbreak.

  How data will be analyzed: Descriptive and thematic analyses will be conducted manually and/or using a qualitative software package

1. Circumstances Making the Collection of Information Necessary

This is a request for emergency OMB approval of the information collection, "Formative assessment regarding contraception use in the U.S. Virgin Islands (USVI) in the context of Zika." CDC requests three (3) months of OMB clearance; information collection is not expected to require more than three months. Authorizing Legislation for this information collection comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment A).**

As of October 11, 2016, the U.S. Virgin Islands (USVI) Department of Health reported 1,320 reported cases, and 524 confirmed Zika cases. Ongoing Zika virus transmission in the USVI intensifies the urgent public health need to increase contraceptive access for women who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes. In addition to microcephaly, other problems have been linked to pregnancies and among fetuses and infants infected with Zika virus before birth, such as miscarriage, stillbirth, absent or poorly developed brain structures, defects of the eye, hearing deficits, limb abnormalities, and impaired growth (Meaney-Delman et al., 2016; Rasmussen et al., 2016). These adverse pregnancy outcomes highlight the critical need to facilitate pregnancy planning among women of reproductive age and address the high rates of unintended pregnancy by increasing access to contraception.

There are an estimated 21,000 women of reproductive age (WRA; 18-44 years) in the U.S. Virgin Islands (USVI), approximately 12,000 of whom are at risk of unintended pregnancy (women of reproductive age who are sexually active and fertile, and not currently desiring a pregnancy). Among women at risk of unintended pregnancy, 5,300 are not using highly or moderately effective contraception (long acting reversible methods [LARCs], including intrauterine devices [IUDs] and implants, or hormonal methods). Access to contraception in USVI is limited by reduced availability of the full range of contraceptive methods. Anecdotal evidence suggests women in the USVI encounter multiple barriers accessing contraceptive services, including health educator and provider shortages, stocking difficulties within clinics, and prohibitive out-of-pocket costs to patients. Conversations with healthcare providers in the USVI suggest that the lack of effective health communication messaging about contraception is another significant obstacle (J. Krashin, personal communication, October 4, 2016). Particularly vulnerable populations are those who lack insurance, are undocumented, and/or have low literacy and educational levels.

In response to the continued impact of the Zika virus in the USVI, CDC is proposing to develop a comprehensive communication strategy, including culturally-appropriate messages and materials, to raise awareness that pregnancy prevention in women who choose to delay or avoid pregnancy is a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes, the contraceptive methods and services available on the islands, and to provide information about each of the methods. To inform this communication approach, CDC plans to conduct a formative assessment with the target audiences of women of reproductive age (WRA; 18-44 years) and men of reproductive age (MRA; 18-44 years) in the USVI.

2. Purpose and Use of Information Collection

The purpose of this formative assessment is to learn about current knowledge, attitudes, and beliefs regarding contraception use, in general, and related to Zika virus exposure, in particular, among WRA and MRA in the USVI. We will explore perceived barriers to accessing contraception and effective ways

to provide messages about the contraceptive methods and services available on the islands. As the primary users of contraception, WRA are the primary audience for the proposed data collection activities. However, MRA are also targeted for participation because of their important role as key influencers who may affect decision-making around reproductive health issues and contraception use. Efforts will be made to recruit participants from vulnerable populations (e.g., those who lack insurance, are undocumented, and/or have low literacy and educational levels). A screener has been developed to ensure the recruitment and engagement of individuals who meet the eligibility criteria for this data collection (i.e., non-pregnant women between the ages of 18 and 44 who would like to avoid or prevent pregnancy, men between the ages of 18 and 44 who would like to avoid or prevent pregnancy; **Attachment B**)The feedback received will provide important insights into the facilitators and barriers individuals face when trying to access contraception and sustain use of contraceptives. Additionally, we will seek information on acceptable messaging strategies, including message content and related imagery, effective channels for message dissemination, and appropriate spokespersons and partners. This information will facilitate the development of a comprehensive communication strategy about the availability and benefits of contraception during the Zika virus outbreak and beyond. This data will support the creation of messages and materials that are clear and compelling while minimizing misinterpretation and unintended effects. The intended outcome is increased awareness of that pregnancy prevention in women who choose to delay or avoid pregnancy is a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes. The intended outcome is also increased awareness of contraceptive methods and services available on the islands methods. Consequently, increased use of these contraceptive methods will prevent additional births of infants affected by Zika among women who choose to delay or avoid a pregnancy during the outbreak.

The Focus Group Instruments **(Attachment C** and **Attachment D)** consists of different groups of questions on:

- Knowledge of different birth control methods and their availability in USVI;
- Questions regarding attitudes, beliefs and access to contraceptive options in USVI; and
- Questions related to messages developed.

3. Use of Improved Information Technology and Burden Reduction

Our data collection requires that we employ qualitative assessment methods through the use of focus groups conducted in person. The responses from the participants are as important as the interviewers' observation of the participants and the overall data collection. Where possible and upon consent from the participant, we will digitally audio-record the data collection to capture all information and assist with preparation of reports. No additional technology will be used for information collection. All information collected will be from people talking and engaging with the focus group facilitator and other members of the focus groups. One-hundred percent of burden hours will be incurred by respondents during their participation in the focus groups.

4. Efforts to Identify Duplication and Use of Similar Information

The current outbreak of Zika virus in the USVI is the first outbreak of this disease. This data collection activity is unique in that it designed to qualitatively inform the development of messages and materials to raise awareness of preventing vertical transmission of Zika virus through contraception through the collection of focus group data.

A related emergency response ICR (Assessment of Zika Prevention Strategies in the U.S. Virgin Islands, 0920-17CR) will be conducted in the USVI during the same period of time. The goal of this other ICR is to assess knowledge, attitudes, and behaviors related to a variety of Zika prevention activities, particularly around vector control in the USVI through individual interviews. While the findings of this other ICR will be utilized to inform health promotion and communication activities, contraceptive-related information is not within the scope of that investigation. Further details on the differences between ICR in this package, and 0920-17CR, are detailed in **Attachment E**.

Two other emergency response ICRs (Assessment of Contraceptive Use and Needs, Puerto Rico, 2016, 0920-1114 and Zika Postpartum Emergency Response Survey (ZPER), Puerto Rico, 0920-1127) similarly target women of reproductive age and explore contraceptive use in the context of the Zika virus outbreak. However, these data collection activities involve residents of Puerto Rico. The current project builds on the work previously done in Puerto Rico by using the data collection instruments to inform the content areas and domains of the focus group guides, particularly around awareness and knowledge about Zika virus and related prevention behaviors. As limited research has been conducted in the USVI regarding the Zika virus, focus group methodologies will be applied to allow for exploration of community understanding and awareness, which will inform future intervention strategies.

New data collection activities are required for the USVI, as the data collected in Puerto Rico are not considered to be directly relevant to USVI populations for multiple reasons. Research has established that contraceptive use is shaped by sociocultural factors (Higgins & Smith, 2016; Institute of Medicine, 1995; Wolifan et al., 2015). The sociocultural landscape in Puerto Rico are inherently different from the USVI, as the language, religious influences, history, and traditions differ significantly. Furthermore, anecdotal information from health care providers have underscored the differences in the health infrastructure and systems that influence access and availability of health services, including contraception, between these island territories. Consequently, findings from data collected in Puerto Rico are not transferrable and/or applicable to the development of messaging and communication strategies within the USVI.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not involve small businesses or small entities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection to assess knowledge of contraceptive options to inform the development of messages and materials for the USVI. Without this formative assessment, we would not be able to gather information about the target audiences for our proposed communication activities that would needed to develop culturally-appropriate and relevant messages and materials before they are widely distributed.

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

- Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived.
- The USVI Department of Health has been consulted.

9. Explanation of Any Payment or Gift to Respondents

It is estimated that the focus groups will take approximately two (2) hours to complete. Participants will be offered a token of appreciation for their participation in the form of a $25 gift card. The token is intended to recognize the time burden placed on participants and to convey appreciation for their contributions. The token of appreciation amounts were determined through discussions with local collaborators with extensive experience engaging the study population (i.e., women and men residing in the USVI). Incorporating modest incentives to aid in recruitment is considered justifiable in order to boost response rates and defray the cost of participation (e.g., transportation and childcare). Furthermore, numerous empirical studies have shown that honoraria can significantly increase response rates (Abreu & Winters, 1999; Kreuger, 1994; Shettle & Mooney, 1999).

Recent experiences in conducting evaluations in Puerto Rico (OMB control #0920-1118, "Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika Virus Infections") have shown that offering incentives has been extremely helpful in recruiting participants for information collections with very short turn-around times and has conveyed value to participants, who are most vulnerable to the adverse effects of Zika and who feel most threatened by it. Using incentives may improve the response rate and will demonstrate respect and appreciation for participants' participation in this important study.

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

The CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Associate Director of Science Office has determined that the Privacy Act is not applicable. All information collected shall be held in confidence to the extent allowed by law. All individuals involved in data collection shall be trained concerning procedures and practices to ensure privacy of data and will be required to undergo ethics and protection of human subjects training through an accredited course (e.g., CITI). No personal identifying information, such as names, addresses, or phone numbers, will be collected during the focus groups or maintained in any data files.

The focus groups will be digitally audio-recorded by the interviewer, and a note taker will be present to observe and document the focus groups. No data will be collected other than what is collected during the focus groups. All audio-recordings will be destroyed after notes have been verified. The applicable SORN is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

Prior to data collection, participants will be given time to read the consent (**Attachment E**) and ask questions. They will be given two copies of the informed consent: one to keep and one to sign to indicate consent and return. During the introduction to the focus group, the moderator will go over key parts of the informed consent, which will include informing participants of the following:

- The focus group is voluntary; participants may choose not to answer any question and end participation at any time.

- The moderator will report findings in summary form so that participants cannot be identified and any identifiable information will be kept secure and separate from the interview notes and audio-recordings.

The CDC will summarize the information from the focus groups for use in developing future messages and materials. If a description of focus group findings is published, CDC will report results in aggregate and will not include information that may be used identify respondents directly or indirectly.

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

IRB Approval

This protocol has been reviewed by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Human Subjects Protection contact. This data collection activity will receive a non-research determination (**Attachment F**). Documentation will be forwarded upon notification.

Justification for Sensitive Questions

Many of the questions to be asked of respondents will deal with sensitive topics, including sexual activity, pregnancy, and contraception, as well as cultural, historical, and social factors that influence contraceptive use and access. Therefore, CDC will identify staff who are skilled and trained in facilitating group discussions in a culturally-appropriate manner with the target audiences. Sensitive questions are essential to meeting the goals of this information collection. Steps to protect the privacy and confidentiality of information provided by respondents is included in Section 10.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Not more than 60 women and 12 men between the ages of 18 and 44 years will be interviewed for this data collection. The project will consist of 6 focus groups (each with a no more than 12 participants).

All respondents will be recruited by CDC and the USVI Department of Health partner. For those who consent to participate, it is expected that the focus groups will take between 90-120 minutes. The total number of burden hours is 144.

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	Semi-structured qualitative focus group interview—females (Attachment B)	60	1	2	120
Men of reproductive age	Semi-structured qualitative focus group interview—males (Attachment C)	12	1	2	24

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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 $1,044.00. The hourly wage estimates are based on the U.S. Department of Labor's Minimum Wage Laws by state and territory (https://www.dol.gov/whd/minwage/america.htm#VirginIslands). The minimum hourly wage ($7.25) was used.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Women of reproductive age	Semi-structured qualitative focus group interview--females	120	$7.25	$870.00
Men of reproductive age	Semi-structured qualitative focus group interview--males	24	$7.25	$174.00
Total				$1,044.00

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 for a three month project is $16,824.69. 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 costs related to salaries, as well as contract costs. Information collection and analysis is expected to last no more than one month.

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC – Personnel Health Communications Specialist 14 (1) 30% for one month $2,181.58 Health Communications Specialist 13 (1) 40% for one month: $2,461.53 Behavioral Scientist 14 (1) 30% for one month $2,181.58	$ 6,824.69
Contractor And Other Expenses	Facility Rental and Recruitment (will be donated in-kind from Department of Health)	-0-

	Travel for staff	$10,000
	TOTAL COST TO THE GOVERNMENT	$16,824.69

Salary estimates were obtained from the US Office of Personnel Management salary scale at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2016/general-schedule/.

The personnel related to the data collection include a Health Communications Specialist at the GS-13 level, one Health Communications Specialist at the GS-14 level, and one Behavioral Scientist at the GS-14 level. Travel is related to conducting focus groups.

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

Data will be analyzed manually and/or using a qualitative software package by members of the Pregnancy and Birth Defects Task Force/Contraception Access Team, CDC Zika Response. A thematic analysis approach will be used to determine common themes related to the categories addressed in the discussion guides. Codes will be developed based on themes and applied to the text, and the data will be synthesized. These formative assessment findings are primarily intended for use by CDC investigators and partners to develop messages during the Zika outbreak. In the future, publication of findings from this formative assessment will be considered for documentation of the public health response to the Zika outbreak.

Projected time frame for the project

Below are key activities and target dates for this project

Activity	Time Schedule*
Recruitment	Start immediately after OMB approval, continue for two weeks
Information/Data Collection	Start immediately after recruitment, continue for 2 weeks
Complete field work	4 weeks after OMB approval
Analyses	1-2 months after OMB approval

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.

References

Abreu, D. A. & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. Proceedings of the Survey Research Methods Section of the American Statistical Association.

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Institute of Medicine. (1995). The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. Washington, DC: The National Academies Press. doi: 10.17226/4903.

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Meaney-Delman D, Rasmussen SA, Staples JE, et al. Zika virus and pregnancy: what obstetric health care providers need to know. Obstet Gynecol 2016;127:642–8. DOI:10.1097/AOG.0000000000001378

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Unger, J.B. & Molina, G.B. (2000). Acculturation and attitudes about contraceptive use among Latina women. Health Care Women Int. 21, 235–249. doi:10.1080/073993300245285

Wulifan, J.K., Brenner, S., Jahn, A., & De Allegri, M. (2015). A scoping review on determinants of unmet need for family planning among women of reproductive age in low and middle income countries. BMC Womens Health, 16:2. doi: 10.1186/s12905-015-0281-3.

Attachments

A. Public Health Service Act (42 USC 241)
B. Focus Group Eligibility Screener Form
C. Focus Group Discussion Guide – Women of Reproductive Age
D. Focus Group Discussion Guide – Men of Reproductive Age
E. Explanation of differences between two Zika-related USVI Projects

F. Focus Group Consent Form
G. IRB Non-Research Determination