

Zika Reproductive Health and Emergency Response Call-Back Survey, 2018

New Information Collection Request

Supporting Statement A

January 21, 2021

Contact:

Karen Pazol
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (770) 488-6305
Email: kpazol@cdc.gov

Table of Contents

| | | |
|-----|---|----|
| 1. | Circumstances Making the Collection of Information Necessary..... | 4 |
| 2. | Purpose and Use of Information Collection..... | 6 |
| 3. | Use of Improved Information Technology and Burden Reduction..... | 7 |
| 4. | Efforts to Identify Duplication and Use of Similar Information..... | 8 |
| 5. | Impact on Small Businesses or Other Small Entities..... | 11 |
| 6. | Consequences of Collecting the Information Less Frequently..... | 11 |
| 7. | Special Circumstances Relating to the Guidelines of 5 CFR 1320.5..... | 12 |
| 8. | Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency | 12 |
| 9. | Explanation of Any Payment or Gift to Respondents..... | 12 |
| 10. | Protection of the Privacy and Confidentiality of Information Provided by Respondents..... | 12 |
| 11. | Institutional Review Board (IRB) and Justification for Sensitive Questions..... | 13 |
| 12. | Estimates of Annualized Burden Hours and Costs..... | 13 |
| 13. | Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers..... | 17 |
| 14. | Annualized Cost to the Government..... | 18 |
| 15. | Explanation for Program Changes or Adjustments..... | 18 |
| 16. | Plans for Tabulation and Publication and Project Time Schedule..... | 18 |
| 17. | Reason(s) Display of OMB Expiration Date is Inappropriate..... | 19 |
| 18. | Exceptions to Certification for Paperwork Reduction Act Submissions..... | 19 |
| | Attachments..... | |
| 1. | Public Health Service Act (42 USC 241) | |
| 2. | (a) 60-Day FRN, and (b) Public Comment Received | |
| 3. | Question source and history of use | |
| 4. | Recruitment Script | |
| 5. | Call-back Survey and Consent | |
| 6. | Non-research Determination, Call-back Survey | |

- **Goal of the study:** To assess the extent to which women of reproductive age (18-49 years): are being screened for potential travel related exposure to Zika and other infectious diseases, are knowledgeable about recommendations for pregnancy timing in regards to Zika exposure, and are prepared for public health emergencies, including natural disasters such as the recent hurricanes along the Gulf Coast and Caribbean.
- **Intended use of the resulting data:** Information collected will be used to help states improve their response planning for women of reproductive age as a specific sub-

nse
from
this
80,
ty

notice was subsequently published in the Federal Register on September 20, 2017, Vol. 82, No. 181, pp 43990-1 under the title “Zika Reproductive Health Call-Back Survey (ZRHCS), Puerto Rico, 2017” to obtain approval for information collection in Puerto Rico (OMB Control No. 0920-1188). The current request seeks approval to collect this information from women of reproductive age (18-49 years) in the remaining US states and territories included in the original 60-day FRN. Additionally, because the recent hurricanes in the Gulf of Mexico and Caribbean have highlighted the need for states to develop response plans for a wider range of public health emergencies, CDC has adjusted its information collection instrument to address these circumstances.

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} Since 2015, when the Zika virus first began circulating in the Western Hemisphere, 37,076 symptomatic Zika virus disease cases have been reported in US territories, and 5,577 have been documented in the Continental US and Hawaii.³ Local vector-borne transmission has predominated in the US territories, but within the Continental US travel-related cases have predominated, with some localized transmission observed in Florida and Texas.⁴

Given the adverse pregnancy and birth outcomes associated with Zika virus infection during pregnancy, CDC recommends that healthcare providers discuss travel plans with women and couples and screen them for possible exposure⁵ to Zika virus as a part of preconception counseling.⁶ For couples desiring pregnancy, CDC recommends providers discuss appropriate time from exposure or symptom onset for couples to wait to attempt to conceive; for couples who do not want to become pregnant, CDC recommends providers discuss strategies to prevent unintended pregnancy.⁶

¹ Meaney-Delman D, Rasmussen SA, Staples JE, et al. Zika Virus and Pregnancy: What Obstetric Health Care Providers Need to Know. *Obstetrics and Gynecology*. 2016;127(4):642-8: <https://www.ncbi.nlm.nih.gov/pubmed/26889662>.

² Rasmussen SA, Jamieson DJ, Honein MA, Petersen LR. Zika Virus and Birth Defects--Reviewing the Evidence for Causality. *NEJM*. 2016;19;374(20):1981-7: <https://www.ncbi.nlm.nih.gov/pubmed/27074377>.

³ <https://www.cdc.gov/zika/reporting/case-counts.html>.

⁴ <https://www.cdc.gov/zika/geo/index.html>.

⁵ Possible exposure includes travel to or residence in an area with risk for mosquito-borne Zika virus transmission or sex with a partner who has traveled to or resides in an area with risk for mosquito-borne Zika virus transmission.

⁶ Petersen EE, Meaney-Delman D, Neblett-Fanfair R, et al. Update: Interim Guidance for Preconception Counseling and Prevention of Sexual Transmission of Zika Virus for Persons with Possible Zika Virus Exposure - United States, September 2016. <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6539e1.pdf>.

As part of its emergency response efforts, CDC has conducted a survey of women of reproductive age (18-49 years) in Puerto Rico as the US territory with highest number of reported Zika virus cases and widespread local transmission (OMB Control No. 0920-1188; 0920-1114).⁷ However, there is a continuing risk for Zika transmission in parts of the Americas and other areas of the world,⁸ and isolated outbreaks continue to occur.⁹ Hence there is a continuing need to screen women living in other US jurisdictions for potential exposure, particularly related to travel, which may put them at risk for additional infectious diseases that affect pregnancy.^{10,11}

Similar to the Zika virus outbreak, other public health emergencies, such as natural disasters and other infectious disease outbreaks, have highlighted the need to develop response plans specifically targeted to women of reproductive age (i.e., women aged 18-49 years). Natural disasters have been associated with a wide range of needs specific to women and children, including access to schools, WIC¹² services and childcare.¹³ Additionally, several studies have shown that women may have difficulty accessing contraception during and after a public health emergency;^{14,15,16,17,18} this has led to lapses in contraceptive use and increases in unintended pregnancy.^{13,14} The consequences of having an unintended pregnancy can be exacerbated during a public health emergency, given that natural disasters^{19,20} and infectious disease outbreaks have been associated with adverse maternal and infant outcomes.²¹ For example, during the 2009 H1N1 influenza pandemic, pregnant women with 2009 H1N1 influenza were at increased risk of hospitalization or death compared to the general population, and their infants were at increased risk for adverse outcomes such as preterm birth.²²

⁷ <https://www.cdc.gov/zika/intheus/maps-zika-us.html>.

⁸ <https://wwwnc.cdc.gov/travel/page/zika-information>.

⁹ For recent localized cases in Mexico, see: <https://www.gob.mx/salud/documentos/casos-confirmados-de-infeccion-por-virus-zika-2017>.

¹⁰ <https://wwwnc.cdc.gov/travel/page/pregnant-travelers>.

¹¹ <https://wwwnc.cdc.gov/travel/yellowbook/2018/advising-travelers-with-specific-needs/pregnant-travelers>.

¹² Special Supplemental Nutrition Program for Women, Infants and Children.

¹³ Centers for Disease C, Prevention. Illness surveillance and rapid needs assessment among Hurricane Katrina evacuees--Colorado, September 1-23, 2005. MMWR Morb Mortal Wkly Rep. 2006;55(9):244-7: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5509a7.htm>.

¹⁴ Behrman JA, Weitzman A. Effects of the 2010 Haiti earthquake on women's reproductive health. Stud Fam Plann. 2016;47(1):3-17: <https://www.ncbi.nlm.nih.gov/pubmed/27027990>.

¹⁵ Hapsari ED, Widayawati, Nisman WA, Lusmilasari L, Siswishanto R, Matsuo H. Change in contraceptive methods following the Yogyakarta earthquake and its association with the prevalence of unplanned pregnancy. Contraception. 2009;79(4):316-22: <https://www.ncbi.nlm.nih.gov/pubmed/19272502>.

¹⁶ Kissinger P, Schmidt N, Sanders C, Liddon N. The effect of the hurricane Katrina disaster on sexual behavior and access to reproductive care for young women in New Orleans. Sex Transm Dis. 2007;34(11):883-6: <https://www.ncbi.nlm.nih.gov/pubmed/17579338>.

¹⁷ Leyser-Whalen O, Rahman M, Berenson AB. Natural and social disasters: racial inequality in access to contraceptives after Hurricane Ike. J Womens Health (Larchmt). 2011;20(12):1861-6: <https://www.ncbi.nlm.nih.gov/pubmed/21942865>.

¹⁸ Ellington SR, Kourtis AP, Curtis KM, Tepper N, Gorman S, Jamieson DJ, et al. Contraceptive availability during an emergency response in the United States. J Womens Health (Larchmt). 2013;22(3):189-93: <https://www.ncbi.nlm.nih.gov/pubmed/23421580>.

¹⁹ Zotti ME, Ellington SR, Perez M. CDC Online course: reproductive health in emergency preparedness and response. J Womens Health (Larchmt). 2016;25(9):861-4: <https://www.ncbi.nlm.nih.gov/pubmed/27631300>.

²⁰ Callaghan WM, Rasmussen SA, Jamieson DJ, Ventura SJ, Farr SL, Sutton PD, et al. Health concerns of women and infants in times of natural disasters: lessons learned from Hurricane Katrina. Matern Child Health J. 2007;11(4):307-11: <https://www.ncbi.nlm.nih.gov/pubmed/17253147>.

²¹ Watson AK, Ellington S, Nelson C, Treadwell T, Jamieson DJ, Meaney-Delman DM. Preparing for biological threats: addressing the needs of pregnant women. Birth Defects Res. 2017;109(5):391-8: <https://www.ncbi.nlm.nih.gov/pubmed/28398677>.

²² Rasmussen SA, Jamieson DJ. 2009 H1N1 influenza and pregnancy--5 years later. N Engl J Med. 2014;371(15):1373-5: <https://www.ncbi.nlm.nih.gov/pubmed/25295498>.

Given the consequences of Zika virus and other infections during pregnancy, there is an ongoing need for healthcare workers to screen women for potential exposures, particularly related to travel, and to provide preconception counseling and care as appropriate. Additionally, the impact of recent hurricanes on a large number of US jurisdictions^{23,24} has highlighted the need for states to be prepared to meet the unique needs of women of reproductive age during a range of public health emergencies, including natural disasters as well as infectious disease outbreaks. Because of the unique needs of women of reproductive age and potential impact on pregnancy outcomes, the objectives of this information collection are to assess the extent to which women in this group: 1) are being screened for potential travel related exposures and are knowledgeable about recommendations for pregnancy timing in regards to Zika exposure; and 2) are prepared for natural disasters and other types of public health emergencies. Because of the potential impact of public health emergencies on pregnancy outcomes and services for women and children, women's receipt of preconception care and current plans for achieving or avoiding pregnancy and responsibility for children will also be assessed.

2. Purpose and Use of Information Collection

This information collection is designed to answer several important questions specific to women of reproductive age (18-49 years) about their knowledge and preparedness in relation to Zika virus infection and other public health emergencies. Information will be collected by states and territories and used by them to improve their response planning for women of reproductive age as a specific sub-population particularly susceptible to negative impacts of public health emergencies, including adverse pregnancy outcomes.

Given the profound consequences of Zika virus infection during pregnancy and the need for women of reproductive age to avoid Zika virus affected pregnancies, CDC's Emergency Operations Center, Pregnancy and Birth Defects Task Force recently provided funding through the Behavioral Risk Factor Surveillance System (BRFSS) for a limited number of states and territories to assess the knowledge and use of prevention strategies among women in this age group. Funding was provided through the BRFSS to allow states and territories to obtain their own state- and territory-specific, population-representative information for a number of reasons: the need to inform state, territory, and local readiness plans;²⁵ the wide variation across states and territories in the number of women affected by Zika virus;²⁶ and the variation in state and territorial programs and policies for providing access to contraception.²⁷ All states and territories were eligible to apply for funding, although funds were awarded preferentially to states and territories with local Zika virus transmission or a disproportionate number of travel-related cases.²⁸

²³ CDC. Hurricane season public health preparedness, response, and recovery guidance for health care providers, response and recovery workers, and affected communities - CDC, 2017. MMWR Morb Mortal Wkly Rep. 2017; 66(37):995-8: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6637e1.htm#suggestedcitation>.

²⁴ Wang A, Issa A, Bayleyegn T, Noe RS, Mullarkey C, Casani J, et al. Notes from the field: mortality associated with Hurricane Matthew - United States, October 2016. MMWR Morb Mortal Wkly Rep. 2017 ;66(5):145-6: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6605a3.htm>.

²⁵ <https://www.cdc.gov/phpr/readiness/index.htm>.

²⁶ <https://www.cdc.gov/zika/reporting/2016-case-counts.html>

²⁷ <https://www.cdc.gov/sixteen/pregnancy/index.htm>; and <http://www.astho.org/Programs/Maternal-and-Child-Health/Long-Acting-Reversible-Contraception-LARC/>

²⁸ Alabama, Arizona, District of Columbia, Florida, Georgia, Louisiana, Maryland, Mississippi, New Mexico, New York, Texas, Guam, and the US Virgin Islands.

Many of the jurisdictions that applied for and received these funds were also affected by recent hurricanes requiring emergency response efforts.^{29,30}

This survey will assess the extent to which providers have continued to discuss Zika virus as a part of preconception counseling and screen women of reproductive age for potential exposure to infectious diseases in general through travel. In light of the emergence of new public health emergencies in 2017 that can also affect pregnancy outcomes and create the need for emergency response efforts that are unique to women of reproductive age, this survey will also assess whether women of reproductive age have received certain relevant preconception health services and are prepared in general for potential public health emergencies.

Specific domains of information to be collected related to Zika and other public health emergencies will include:

- Healthcare workers screening for travel-related exposure to Zika and other infectious diseases
- Women’s knowledge about recommendations for pregnancy timing in relation to Zika virus exposure
- Women’s general preparedness, including:
 - perceived level of preparedness
 - plans for water, food, power and emergency contacts
 - supplies of prescription medicine
 - responsibility for children and whether emergency plans have been discussed with household members
 - knowledge of emergency plans within schools for dependent children

Additionally, to help states and territories assess current utilization of preconception care and contraceptive services so as to inform their programs and policies and the potential for increased need in the case of a public health emergency, the following information will be collected:

- Women’s plans and intentions for having children
- Women’s use of and access to contraception
- Women’s access to and receipt of healthcare for promoting their own health and the health of their pregnancies

3. Use of Improved Information Technology and Burden Reduction

This survey will be implemented via telephone using the data collection infrastructure and methodology established for the Behavioral Risk Factor Surveillance System (BRFSS; OMB Control No. 0920-1061) to collect information from a population-based sample of women of reproductive age. For the purposes

²⁹ CDC. Hurricane season public health preparedness, response, and recovery guidance for health care providers, response and recovery workers, and affected communities - CDC, 2017. MMWR Morb Mortal Wkly Rep. 2017; 66(37):995-8: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6637e1.htm#suggestedcitation>.

³⁰ Wang A, Issa A, Bayleyegn T, Noe RS, Mullarkey C, Casani J, et al. Notes from the field: mortality associated with Hurricane Matthew - United States, October 2016. MMWR Morb Mortal Wkly Rep. 2017 ;66(5):145-6: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6605a3.htm>.

of the ZRHER Call-Back Survey, women aged 18-49 years who complete the main BRFSS will be read a recruitment message at the end of the survey to ask if they are willing to be re-contacted. Combining this survey with the main BRFSS will increase efficiency by eliminating the need to re-sample eligible participants and will reduce respondent burden by avoiding replication in screening questions.

The use of a telephone survey system also offers a cost effective method of data collection. Interviewers will use Computer Assisted Telephone Interview (CATI) software to enter data directly into a database. Use of CATI software promotes efficiency in two ways: skip patterns can be programmed to route respondents only to questions that they are eligible to answer, and real-time quality control checks can be used to eliminate some errors that may otherwise be caused by manual data entry procedures.

The use of the CATI system to reduce burden and enhance data quality will be further improved through the use of a field test in a single state, selected on the basis of staff availability and concurrent field testing for the main BRFSS at the time this information collection is approved. Field-testing will be used to identify problems with instrument documentation or instructions, problems with conditional logic (e.g., skip patterns), software errors or other implementation and usability issues. A change request will be submitted for any necessary changes in questionnaire content that are identified.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of any other recent or ongoing systematic collection of the information described herein with a specific focus on women of reproductive age that can inform adherence to guidelines on preconception counseling and care and preparedness for public health emergencies. Information collected previously through CDC's Pregnancy and Birth Defects Task Force for the Zika Response found that among women aged 18-49 years in Puerto Rico, adherence to Zika prevention behaviors was low even at the peak of the outbreak in 2016.³¹ These findings suggest the need to reinforce adherence to central prevention strategies that remain relevant as the Zika outbreak wanes and captures less public attention. Additional information collected through the Pregnancy and Birth Defects Task Force among recently postpartum women in Puerto Rico has found that women consider their healthcare provider as the best source of information on Zika.³² The current information collection request has thus been targeted based on these prior results to: 1) focus on whether healthcare providers are screening women for potential exposure and offering appropriate counseling; 2) obtain information for US jurisdictions in addition to Puerto Rico and where travel related cases have predominated.

Another CDC information collection has been implemented to assess the effect of a Domestic Zika Readiness Initiative.³³ This information collection is being implemented in three phases to assess the effect of the campaign over time. However, in addition to focusing on community versus provider messages, this collection is limited to four geographic areas (Puerto Rico, Miami, Houston and

³¹ Assessment of Contraceptive Use and Needs, Puerto Rico, 2016" (CAPRZ; OMB Control No. 0920-1114). This survey found only 22% of women used mosquito repellent every day and 8% wore long sleeves and pants; among women who were sexually active and capable of pregnancy, only 13% used a most or moderately effective method and 14% used no contraceptive method.

³² Zika Postpartum Emergency Response Survey, Puerto Rico, 2016 (ZPER; OMB No. 0920-1127)
<https://www.cdc.gov/mmwr/volumes/66/wr/mm6622a2.htm>

³³ Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease ([OMB control numbers 0920-1197 0920-1136])

Mississippi), and is not directly relevant for other jurisdictions wishing to assess their preparedness. Moreover, the target population for this information collection is the general adult population – with a total sample of 600 individuals across all four areas this will have a limited numbers of women of reproductive age for each jurisdiction. Similarly, other surveys identified to assess more general emergency response preparedness³⁴ include the general US population, rather than focusing on women of reproductive age, and provide only national estimates or estimates for select local high-risk areas that cannot be used by the targeted jurisdictions in this information collection.

Below is a complete list of related projects that have been identified from the Zika Emergency Operations Center, through discussion with collaborators throughout the CDC, and by searching for related information collections within RegInfo. For each information collection, we describe how the data collected for the Zika Reproductive Health and Emergency Response (ZRHER) Call-Back Survey, 2018 differs and will fill gaps in existing efforts.

Table A.4-1: Recent and ongoing projects and how the Zika Reproductive Health and Emergency Response Call-Back Survey fills gaps not addressed by these existing efforts:

| Project | Objectives and Population | Contribution added by ZRHER |
|--|---|---|
| Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease (0920-1197) | Determine knowledge, attitudes, and practices (KAPs) related to a Domestic Readiness Initiative on Zika Virus Disease. This information collection assesses: awareness of campaign activities; how people perceive Zika virus as a health risk in general and in relation to pregnancy status, intentions and travel history; and uptake of recommended health behaviors, such as applying insect repellent, using condoms, and wearing long-sleeves. The target population is adults aged ≥18 years who are residents of Puerto Rico; Miami, FL; Houston, TX; and Mississippi. | ZRHER targets a larger geographic area, including states and territories that are not a part of the Domestic Readiness Initiative, and obtains a sample that is representative of the population of women of reproductive age for the entire state/territory. In addition, ZRHER assesses emergency response preparedness, in general, including preparedness for natural disasters and infectious diseases, other than and in addition to Zika virus. For information related to Zika virus, prior work has shown that women consider their healthcare provider as the best source of information. ³⁵ Therefore, in asking questions about pregnancy timing in relation to potential exposure, ZRHER specifically asks women if they received information from their healthcare providers. The information from ZRHER with therefore allow for an assessment of whether women are receiving recommended preconception counseling from their healthcare providers. ³⁶ Additionally, information from ZRHER related to contraceptive use allows for an assessment of whether women have received care appropriate for their pregnancy plans in relation to their potential exposure to Zika virus and other infectious diseases. |
| Assessment of Contraceptive Use and Needs, Puerto | These surveys assessed utilization of Zika virus prevention strategies targeted at women of reproductive | ZRHER also targets women of reproductive age and assesses contraceptive use, but there is no overlap in geographic area. Additionally, ZRHER focuses on |

³⁴ Community Preparedness and Participation Survey (OMB Control No. 1660-0105).

³⁵ <https://www.cdc.gov/mmwr/volumes/66/wr/mm6622a2.htm>

³⁶ https://www.cdc.gov/mmwr/volumes/65/wr/mm6539e1.htm?s_cid=mm6539e1_w

| Project | Objectives and Population | Contribution added by ZRHER |
|---|--|--|
| Rico, 2016 (CAPRZ) (0920-1114) and the Zika Reproductive Health Call-Back Survey (ZRHCS), Puerto Rico, 2017 (0920-1188) | age (18-49 years) in Puerto Rico during the first and then the second season of the Zika virus outbreak. Topics included use of and barriers to accessing contraception among women wishing to avoid or delay pregnancies, along with other Zika virus prevention strategies. | general preparedness for public health emergencies, such as natural disasters and infectious disease outbreaks other than and in addition to Zika virus. |
| Zika Postpartum Emergency Response Survey, Puerto Rico, 2016 (ZPER) (0920-1127), and 2017 (ZPER) (0920-1199) | The ZPER study population includes women who recently gave birth in Puerto Rico, and is intended to inform decision-making regarding promotion of protective behaviors against Zika virus exposure during pregnancy and the immediate postpartum period. | The focus of ZRHER is on assessing preconception counseling and pregnancy planning among women of reproductive age who are not currently pregnant. At any given point in time only a small proportion of women of reproductive age are expected to be pregnant (just 2% of women in CAPRZ (0920-1114) were pregnant). Therefore, ZRHER will focus on a distinct population from ZPER, and by taking a population-representative sample of women, it is anticipated to include a very small number of pregnant women. |
| Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika (0920-1148) | The objective of this information collection was to conduct a formative/qualitative assessment of knowledge, attitudes, and beliefs regarding contraceptive use, in general, and related to Zika virus exposure, in particular. It explored perceived barriers to accessing contraception and effective ways to provide messages about contraception and services. | ZRHER will collect information on a much larger, population-representative sample of women of reproductive age and will produce quantitative data on contraceptive use versus qualitative information on perceived barriers. |
| Behavioral Risk Factor Surveillance System (BRFSS) (0920-1061) | BRFSS surveys adults in participating jurisdictions, on a variety of health conditions, indicators, and behaviors. | <p>ZRHER uses the main BRFSS platform to sample respondents via a recruitment script administered to women aged 18-49 years at the end of the BRFSS survey.</p> <p>Although BRFSS has included optional modules in the past on preparedness and contraception, these modules are not included in the 2018 BRFSS survey.</p> <p>The ZRHER questions on contraceptive use, and preferences in the absence of costs constraints, will be important to align with information on health insurance. The single core BRFSS question on healthcare access (yes/no insurance) included on ZRHER will serve as a lead in to the optional question on health insurance type, and on the ZRHER will serve as a marker of fluctuation in coverage, given that use of preventive services may</p> |

| Project | Objectives and Population | Contribution added by ZRHER |
|---|--|---|
| | | <p>vary with the stability of health insurance.³⁷</p> <p>A second optional BRFSS question on Tdap vaccination will be included on ZRHER to align with questions on pregnancy intentions, given the recommendation that pregnant women be current on this vaccination.</p> |
| National Health Interview Survey (0920-0214) | The National Health Interview Survey (NHIS) is a nationally representative survey of noninstitutionalized civilians in the United States. It collects data on a range of health topics, including the prevalence, distribution, and effects of illness and the services rendered for or because of such conditions. The adult sample includes women and men aged 18 and older. | ZRHER, like the NHIS, will collect information on receipt of routine health care examinations and certain health services that are important for healthy pregnancies. However, ZRHER, unlike the NHIS, will sample women of reproductive age exclusively and provide direct population-representative state- and territory-level estimates that are not modeled and can be used by states and territories for emergency planning. Additionally, ZRHER will provide important information on contraceptive use and preparedness for public health emergencies that can be matched with data on healthcare utilization. |
| National Survey of Family Growth (0920-0314) | The National Survey of Family Growth (NSFG) collects information on fertility, sexual activity, contraceptive use, reproductive health care, family formation, and child care, among the household population of reproductive age women and men (15-49 years) in the United States. | ZRHER, like the NSFG, will collect information on contraceptive use and pregnancy intentions. However, ZRHER, unlike the NSFG, will provide direct population-representative state- and territory-level estimates that are not modeled and can be used by states and territories for emergency planning. Additionally, ZRHER will provide important information about preconception counseling on the risk of infectious disease exposure that can be matched with contraceptive use data, as well as information specific to contraceptive supplies for emergency response preparedness. |
| Community Preparedness and Participation Survey (1660-0105) | The Community Preparedness and Participation Survey collects information to track changes in knowledge, attitudes and behaviors related to preparedness in the general public, and to track the outcomes of the national campaigns and programs in motivating behavior change for preparedness in the general public. | ZRHER, like the Community Preparedness and Participation Survey, will collect information on household preparedness. However, the Community Preparedness and Participation Survey provides only national estimates and estimates for select local high-risk areas that do not represent the jurisdictions included in ZRHER. ZRHER will sample women of reproductive age exclusively and provide direct population-representative state- and territory-level estimates that are not modeled and can be used by states and territories for emergency planning. Additionally, ZRHER will provide important information about pregnancy intentions and preconception counseling on the risk of infectious disease exposure that is not on the Community Preparedness and Participation Survey and can be matched with contraceptive use data. Finally, |

³⁷ <https://www.cdc.gov/mmwr/volumes/66/ss/pdfs/ss6620.pdf>.

| Project | Objectives and Population | Contribution added by ZRHER |
|---------|---------------------------|--|
| | | ZRHER will also collect information specific to contraceptive supplies for emergency response preparedness that is not on the Community Preparedness and Participation Survey. |

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small business.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection. Respondents who have completed the main BRFSS will be re-contacted and asked to respond in detail to topics not included on the main BRFSS.

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 was published in the *Federal Register* on April 27, 2017, Vol. 82, No. 80, pp 19370-19371 to make the public aware of this proposed information collection (**Attachment 2a**). One non-substantive comment was received (**Attachment 2b**).

B) CDC has collaborated internally across the agency with experts in reproductive health, Zika virus, and emergency response preparedness. Feedback has been incorporated into the survey from:

- The National Center for Emerging and Zoonotic Infections Diseases;
- The National Center for Chronic Disease Prevention and Health Promotion;
 - o Division of Population Health (for BRFSS);
 - o Division of Reproductive Health (for contraceptive use measurement and emergency response preparedness among women of reproductive age);
- The Office of Public Health Preparedness and Response (OPHPR); and
- The National Center for Health Statistics, Reproductive Statistics Branch (for the National Survey of Family Growth, NSFG).

These consultations have included suggestions on adapting the wording of similar questions from existing surveys to provide state-specific estimates among women of reproductive age (**Attachment 3**).

Additionally, CDC has consulted with the BRFSS coordinators for each of the participating jurisdictions to ensure that content of the survey will meet their information needs (**Supporting Statement B.5**).

Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

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

This survey will be implemented using the data collection infrastructure and methodology established for the Behavioral Risk Factor Surveillance System (BRFSS; OMB Control No. 0920-1061). Previously for the BRFSS, it has been determined that the Privacy Act does not apply. BRFSS datasets delivered to CDC will not include any identifying information. Additional details on the data collection are described in the BRFSS Data User Guide, available at http://www.cdc.gov/brfss/data_documentation/pdf/userguidejune2013.pdf.

At CDC, access to data will be limited to CDC contractors and staff who conduct weighting and data cleaning procedures. Security measures for protecting the data will include: 1) Physical controls: CDC facilities are secure, ID accessed buildings. Data will not be stored in hard copy formats; and 2) Technical controls: All electronic data are stored on secured servers protected with firewalls and passwords. All employees are trained on data security measures by taking appropriate Health and Human Health Services (HHS) courses online. All data collection and records management practices and systems adhere to HHS and CDC IT policies and procedures.

Women aged 18-49 years participating in the main BRFSS survey will be asked if they agree to be contacted once more to answer additional questions. Participants will be informed that all information they provide will be kept secure and that they may refuse to participate in the future if they do agree at the time to be called back (**Attachment 4**). Respondents who are re-contacted will be informed again that their participation is purely voluntary, that they may skip or refuse to answer any question, that they will not be asked for any personal information, and that their responses will be kept confidential (**Attachment 5**).

The CDC will not include information in reports that may identify respondents. Information that could potentially be used to indirectly identify an individual will be suppressed; for example, aggregated data will not be stratified into subcategories that might allow for identification of individuals.

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

IRB Approval

This protocol was submitted for Human Subjects Protection review on February 28, 2017, and received a non-research determination, given that responses will be used to inform state and territory-specific emergency response plans rather than generalizable information (**Attachment 6**).

Justification for Sensitive Questions

Sensitive questions are essential to meeting the goals of this information collection. During the informed consent process, participants will be notified that they may decline to discuss any of the topics or decline to answer any question. Participants will be reminded during the survey that they can refuse to answer any question and still participate in the survey. Because many of the questions to be asked of respondents will deal with sensitive topics, including sexual activity, pregnancy, and contraception, jurisdictions will be advised to consider using female interviewers.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Eligible participants will be women aged 18-49 years who complete the main BRFSS. Field testing to identify problems with instrument documentation or instructions, conditional logic (e.g., skip patterns), software errors or other implementation and usability issues will involve 100 women in a single state, selected on the basis of staff availability and concurrent field testing for the main BRFSS at the time this information collection is approved. Upon approval of change request for any changes in the questionnaire content that are identified as necessary, a sample size of 800 women will be targeted in every state; a sample size of 400 women will be targeted in each of the two included territories (Guam and the US Virgin Islands). Eligible women will be read a recruitment script once they have completed the main BRFSS to ask if they are willing to be re-contacted.

Based on prior experience using the BRFSS survey to recruit respondents for a call-back survey, only a certain percentage of respondents will agree to be called back, and of those who agree to be called back, only a certain percentage will complete the survey. The following table shows estimated percentages of respondents in each of the states and territories from the main BRFSS survey who are expected to agree to be called back and then actually complete the survey.³⁸ Based on this information, we calculated the percent of all women aged 18-49 completing the main BRFSS who we anticipate will complete the ZRHER Call-Back Survey, and the number of respondents from the main BRFSS survey who will needed to be read the recruitment script to reach our target sample size for each participating state and territory.

Table A.12-1. Anticipated Response Rates by State/Territory

³⁸ https://www.cdc.gov/brfss/acbs/2014/pdf/ACBS_DataQualReport_14_REVISEDp112017CLEARED.pdf. Percentages are based on the adult landline and cell phone sample, unless only the adult landline sample was available, given the similar proportions of individual agreeing to be called back for the two samples. For states and territories without data on callback completion rates, the average for the remaining states and territories, respectively, was used.

| State/Territory | % Agreeing to participate in ZRHER Call-Back – among women age 18-49 years completing the main BRFSS | % Completing ZRHER Call-Back – among respondents agreeing to be called back | % Completing ZRHER Call-Back – among all women 18-49 years completing the main BRFSS | # Needed to be read the recruitment script to reach target sample |
|----------------------|--|---|--|---|
| Alabama | 78% | 52% | 41% | 1972 |
| Arizona | 73% | 54% | 39% | 2029 |
| District of Columbia | 69% | 47% | 32% | 2467 |
| Florida | 78% | 54% | 42% | 1899 |
| Georgia | 81% | 60% | 49% | 1646 |
| Louisiana | 71% | 48% | 34% | 2347 |
| Maryland | 75% | 40% | 30% | 2667 |
| Mississippi | 75% | 54% | 41% | 1975 |
| New Mexico | 72% | 42% | 30% | 2646 |
| New York | 75% | 52% | 39% | 2051 |
| Texas | 74% | 58% | 43% | 1864 |
| Guam | 88% | 62% | 55% | 733 |
| US Virgin Islands | 88% | 62% | 55% | 733 |

The average time burden time to complete the Recruitment Script (**Attachment 4**) is estimated at 1 minute, for a total among all respondents in all states and territories of 416 hours. Based on the time needed to complete the largely similar survey conducted in Puerto Rico in 2016 (OMB Control number 0920-1114) the average burden time to complete the Survey and Consent (**Attachment 5**) is estimated at 10 minutes, for a total among all respondents in all states and territories of 1,614 hours.

In addition to the burden during the main data collection period, immediately following OMB approval, a field test of the Survey and Consent (**Attachment 5**) will be conducted by a single state, to be determined, under the oversight of CDC. The field test will implement among 100 respondents for an additional burden of 17 hours. In total, the estimated burden for this information collection is **2,030** hours.

Table A.12-1. Estimated Annualized Burden to Respondents

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hrs.) | Total Burden Hours | |
|--|----------------------|--------------------------|---------------------------------|---------------------------------------|--------------------|----|
| Women aged 18-49 years who completed the main BRFSS survey in: | Alabama | Att 4 Recruitment script | 1972 | 1 | 1/60 | 33 |
| | Arizona | Att 4 Recruitment script | 2029 | 1 | 1/60 | 34 |
| | District of Columbia | Att 4 Recruitment script | 2467 | 1 | 1/60 | 41 |
| | Florida | Att 4 Recruitment script | 1899 | 1 | 1/60 | 32 |
| | Georgia | Att 4 Recruitment script | 1646 | 1 | 1/60 | 27 |

| | | | | | | |
|---|----------------------|--------------------------|------|---|-------|--------------|
| | | | | | | |
| | Louisiana | Att 4 Recruitment script | 2347 | 1 | 1/60 | 39 |
| | Maryland | Att 4 Recruitment script | 2667 | 1 | 1/60 | 44 |
| | Mississippi | Att 4 Recruitment script | 1975 | 1 | 1/60 | 33 |
| | New Mexico | Att 4 Recruitment script | 2646 | 1 | 1/60 | 44 |
| | New York | Att 4 Recruitment script | 2051 | 1 | 1/60 | 34 |
| | Texas | Att 4 Recruitment script | 1864 | 1 | 1/60 | 31 |
| | Guam | Att 4 Recruitment script | 733 | 1 | 1/60 | 12 |
| | US Virgin Islands | Att 4 Recruitment script | 733 | 1 | 1/60 | 12 |
| Women aged 18-49 years who agree to participate in the call-back survey in: | Pilot State | Att 5 Survey & Consent | 100 | 1 | 10/60 | 17 |
| | Alabama | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Arizona | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | District of Columbia | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Florida | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Georgia | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Louisiana | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Maryland | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Mississippi | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | New Mexico | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | New York | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Texas | Att 5 Survey & Consent | 800 | 1 | 10/60 | 133 |
| | Guam | Att 5 Survey & Consent | 400 | 1 | 10/60 | 67 |
| | US Virgin Islands | Att 5 Survey & Consent | 400 | 1 | 10/60 | 67 |
| Total | | | | | | 2,030 |

B. Estimated Annualized Burden Costs

Annualized burden costs are summarized in the table below. The hourly wage estimates are based on the Bureau of Labor Statistics May 2016 National Occupational Employment and Wage Estimates. The mean hourly wage rate for all occupations in each state was used: <https://www.bls.gov/oes/tables.htm>. The average of the included states was used for the pilot state testing.

Table A.12-2. Estimated Annualized Cost to Respondents

| Type of Respondents | Form Name | Number of Respondents | Total Burden Hours | Average Hourly Wage Rate | Total Respondent Costs | |
|---|----------------------|--------------------------|--------------------|--------------------------|------------------------|------------|
| Women aged 18-49 years who completed the main BRFSS survey in: | Alabama | Att 4 Recruitment script | 1972 | 33 | \$20.44 | \$674.52 |
| | Arizona | Att 4 Recruitment script | 2029 | 34 | \$22.26 | \$756.84 |
| | District of Columbia | Att 4 Recruitment script | 2467 | 41 | \$39.88 | \$1,635.08 |
| | Florida | Att 4 Recruitment script | 1899 | 32 | \$21.18 | \$677.76 |
| | Georgia | Att 4 Recruitment script | 1646 | 27 | \$23.86 | \$644.22 |
| | Louisiana | Att 4 Recruitment script | 2347 | 39 | \$23.86 | \$930.54 |
| | Maryland | Att 4 Recruitment script | 2667 | 44 | \$22.38 | \$984.72 |
| | Mississippi | Att 4 Recruitment script | 1975 | 33 | \$18.41 | \$607.53 |
| | New Mexico | Att 4 Recruitment script | 2646 | 44 | \$21.23 | \$934.12 |
| | New York | Att 4 Recruitment script | 2051 | 34 | \$28.32 | \$962.88 |
| | Texas | Att 4 Recruitment script | 1864 | 31 | \$22.97 | \$712.07 |
| | Guam | Att 4 Recruitment script | 733 | 12 | \$16.73 | \$200.76 |
| | US Virgin Islands | Att 4 Recruitment script | 733 | 12 | \$18.10 | \$217.20 |
| Women aged 18-49 years who agree to participate in the call-back survey in: | Pilot state | Att 5 Survey & Consent | 100 | 17 | \$24.07 | \$409.22 |
| | Alabama | Att 5 Survey & Consent | 800 | 133 | \$20.44 | \$2,718.52 |
| | Arizona | Att 5 Survey & Consent | 800 | 133 | \$22.26 | \$2,960.58 |
| | District of Columbia | Att 5 Survey & Consent | 800 | 133 | \$39.88 | \$5,304.04 |
| | Florida | Att 5 Survey & Consent | 800 | 133 | \$21.18 | \$2,816.94 |
| | Georgia | Att 5 Survey & Consent | 800 | 133 | \$23.86 | \$3,173.38 |
| | Louisiana | Att 5 Survey & Consent | 800 | 133 | \$23.86 | \$3,173.38 |

| | | | | | | |
|--------------|-------------------|------------------------|-----|-----|---------|-------------|
| | | | | | | |
| | Maryland | Att 5 Survey & Consent | 800 | 133 | \$22.38 | \$2,976.54 |
| | Mississippi | Att 5 Survey & Consent | 800 | 133 | \$18.41 | \$2,448.53 |
| | New Mexico | Att 5 Survey & Consent | 800 | 133 | \$21.23 | \$2,823.59 |
| | New York | Att 5 Survey & Consent | 800 | 133 | \$28.32 | \$3,766.56 |
| | Texas | Att 5 Survey & Consent | 800 | 133 | \$22.97 | \$3,055.01 |
| | Guam | Att 5 Survey & Consent | 400 | 67 | \$16.73 | \$1,120.91 |
| | US Virgin Islands | Att 5 Survey & Consent | 400 | 67 | \$18.10 | \$1,212.70 |
| Total | | | | | | \$47,898.14 |

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 annualized estimated cost to the government is \$23,426. 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 how much they will make during this time. Annual wages are based on Step 1 employees for the Atlanta locality <https://www.federalpay.org/gs/locality/atlanta>.

| Grade | # of FTEs | Annual Wage | % time devoted to project | Total Hours | Total |
|--------------|-----------|-------------|---------------------------|-------------|----------|
| GS-14 | 1 | \$106,380 | 10 | 208 | \$10,638 |
| GS-13 | 1 | \$90,023 | 10 | 208 | \$9,002 |
| GS-12 | 1 | \$75,705 | 5 | 104 | \$3,785 |
| Total | | | | | \$23,426 |

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

CDC's National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health, which coordinates all Behavioral Risk Factor Surveillance System (BRFSS) activities for the US, will prepare the data files for analysis. This preparation will include final data cleaning and weighting. CDC's National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health will take responsibility for all data tabulations for this assessment. Once final tabulations are available, a final report will be published, as well as an MMWR article on key findings.

Project Time Schedule:

- Immediately upon OMB approval: Recruitment of eligible women through the Recruitment Script at the end of the main BRFSS.
- Month 1: CATI programming of the approved survey.
- Month 2: Pilot testing of the ZRHER Call-Back Survey among 100 participants.
- Month 3: Submission of a change to OMB, as needed, based on feedback from pilot testing.
- Month 3: Final preparations for data collection, including any needed programming changes.
- Month 4-12: Full implementation of the Consent and Call-back survey until targeted sample sizes are reached within each jurisdiction.
- Month 13-18: Cleaning and weighting of final data sets.
- Month 19-24: Analysis, final report, publication of MMWR article.

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.