

# Assessment of Zika Care Connect Program

## Request for OMB approval of a GenIC (OMB Control No. 0920-1154)

January 21, 2021

### **Supporting Statement A**

**Contact:**

Catlin Green  
Epidemiologist  
National Center on Birth Defects & Developmental Disabilities  
Centers for Disease Control and Prevention  
4770 Buford Hwy.  
Mailstop E86  
Atlanta, GA 30341  
Phone 404-498-1462

## Table of Contents

1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of Information Collection.....	5
3. Use of Improved Information Technology and Burden Reduction.....	5
4. Efforts to Identify Duplication and Use of Similar Information.....	5
5. Impact on Small Businesses or Other Small Entities.....	6
6. Consequences of Collecting the Information Less Frequently.....	6
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	6
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.	6
9. Explanation of Any Payment or Gift to Respondents.....	6
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	6
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	7
12. Estimates of Annualized Burden Hours and Costs.....	7
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	8
14. Annualized Cost to the Government.....	8
15. Explanation for Program Changes or Adjustments.....	9
16. Plans for Tabulation and Publication and Project Time Schedule.....	9
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	9
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	9
Attachments.....	`

## Attachments

- Attachment 1 - Authorizing Legislation - Public Health Service Act (42 U.S.C. 241)
- Attachment 2 - Authorizing Legislation - Zika Response and Preparedness Act
- Attachment 3 - IRB Determination Letter
- Attachment 4 - Information Collection Instrument - Survey of Healthcare Professionals
- Attachment 5 - Information Collection Instrument - Survey of Website Users
- Attachment 6 - Email and Reminder Email - Survey of Healthcare Professionals

- **Goal of the study:** The purpose of this project is to assess the implementation and outcomes of a public health program, Zika Care Connect (ZCC).
- **Intended use of the resulting data:** This assessment will aid in understanding the program components that were most beneficial for patients and healthcare professionals, gaps in program components, and impact of the program to increase access to specialty healthcare services for the management of Zika virus in twenty jurisdictions. The findings will also aid in determining whether this public health approach is appropriate for replication/adaptation in other jurisdictions that may be similarly affected by the Zika virus or for other emerging diseases requiring specialty healthcare services in the future.
- **Methods to be used to collect:** Two surveys will be conducted, one with ZCC website users and the other with healthcare professionals enrolled in the ZCC Network; program metrics (e.g., website and HelpLine usage, ZCC Network enrollment) will also be analyzed.
- **The subpopulation to be studied:** Healthcare professionals enrolled in the ZCC Network and website users will be included in the data collection.
- **How data will be analyzed:** Descriptive statistics will be analyzed for the overall participants as well as stratified by location, type of specialty care, and frequency of caring for patients affected by Zika virus. Exploratory statistical analyses will be conducted to explore differences between specialties and/or location.

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new GenIC (OMB Control No. 0920-1154) titled the “Assessment of Zika Care Connect Program”.

Clinical management of Zika virus infection during pregnancy and the provision of specialized medical care for infants with congenital exposure to Zika virus can be complicated and may necessitate specialized health services. Because Zika virus infection is associated with a spectrum of infant outcomes, an interdisciplinary team of medical specialties may be needed to manage care for pregnant women with Zika virus infection and infants with congenital Zika virus syndrome<sup>1</sup>. Access to clinical services for all pregnant women and infants affected by Zika virus has the potential to improve birth outcomes, facilitate early intervention, and diminish the long-term developmental and psychosocial impact of Zika virus on children and families. However, several barriers exist that affect access to specialty Zika-related care, including availability of coordinated care and linkage between maternal and pediatric services.

Increased access to appropriate health services – including appropriate diagnostic testing, specialized clinical care, and early intervention and developmental services – may potentially lessen the overall impact of Zika virus infection in pregnancy and improve long-term outcomes for children affected by

<sup>1</sup> Bill G. Kapogiannis, Nahida Chakhtoura, Rohan Hazra, Catherine Y. Spong. Bridging Knowledge Gaps to Understand How Zika Virus Exposure and Infection Affect Child Development. *JAMA Pediatr.* 2017;171(5):478–485. doi:10.1001/jamapediatrics.2017.0002

Zika. Improved access to care can help quickly identify developmental delays in infants and children, potentially reduce the long-term effects of Zika on children and families, and give children the best chance to reach their full potential. To facilitate coordination of care for families and help improve access to necessary services, CDC and McKing Consulting Corporation (McKing) collaborated on the development of Zika Care Connect (ZCC). ZCC is a website that contains resources for women and families affected by Zika including educational resources (e.g. fact sheets, charts, checklists, and other documents about Zika), a HelpLine, and a healthcare professional network (the ZCC Network). The target population for this program includes women infected with Zika during pregnancy and families of infants born to mothers with laboratory evidence of Zika.

ZCC targets the barriers to care that are both important and feasible to address, as identified by maternal and pediatric care experts (e.g. linkage between maternal and pediatric care, availability of health care professionals). The ZCC Network can connect families to specialists who can provide Zika-related care. The ZCC Network is a directory of healthcare professionals who are knowledgeable about and able to provide healthcare services aligned with CDC's clinical guidance recommendations for pregnant women and infants affected by Zika. The ZCC Network can be accessed by patients and providers through the ZCC website and HelpLine, which assists families in finding specialty healthcare services and offers information about the practice to ensure it meets their needs such as location, language, or insurance.

This protocol describes activities designed to assess the ZCC program, including its impact and the effectiveness of the program's ability to meet its intended objectives.

The overall goals of the ZCC program are to:

1. Improve access to care for pregnant women with Zika virus and parents and families of infants with Zika.
2. Serve as an informational resource for patients and providers seeking information about accessing clinical services for the management of Zika virus.

The specific ZCC program objectives are:

1. By December 2018, enroll 1200 healthcare professionals into the Zika Care Connect Healthcare Professional Network.
2. By April 2017, establish and maintain a toll-free HelpLine for patients and healthcare professionals to access information about accessing care for Zika virus where all contacts are responded to within one business day.
3. By April 2017, establish and maintain a web-based link to information, resources, and services for pregnant women and families impacted by Zika virus accessible by members of all 20 ZCC jurisdictions.

ZCC is the first program designed to address barriers to accessing care for the management of Zika virus. This assessment will aid in understanding the program components that were most beneficial for patients and healthcare professionals, identifying any gaps in program components, and assessing the

impact of the program to increase access to specialty healthcare services for the management of Zika virus in twenty jurisdictions.

Authorizing legislation for this ICR comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1) and the Zika Response and Preparedness Act (Attachment 2).

## **2. Purpose and Use of Information Collection**

The purpose of this project is to assess the implementation and outcomes of a public health program, Zika Care Connect (ZCC). ZCC aims to improve access to specialty healthcare services for the management of Zika virus infection during pregnancy and outcomes in infants caused by Zika. The program targets the most important and removable barriers to care, as identified by maternal and pediatric care experts. ZCC focuses on women infected with Zika during pregnancy, as well as infants born to mothers with laboratory evidence of Zika. Central to the ZCC program is a healthcare professional network, accessible through the ZCC website and HelpLine, which helps connect pregnant women and families to specialists who can provide care.

This assessment aims to answer the following questions regarding the ZCC program:

- 1) Did Zika Care Connect achieve its program objectives?
- 2) How can Zika Care Connect be improved?
- 3) How did ZCC contribute to improving access to Zika-related clinical services?

To answer these questions two surveys will be conducted, one with ZCC website users and the other with healthcare professionals enrolled in the ZCC Network, and program metrics (e.g., website and HelpLine usage, ZCC Network enrollment) will be analyzed.

This assessment will aid in understanding the program components that were most beneficial for patients and healthcare professionals, gaps in program components, and impact of the program to increase access to specialty healthcare services for the management of Zika virus in twenty jurisdictions. Further, the findings will aid in determining whether this public health approach is appropriate for replication/adaptation in other jurisdictions that may be similarly affected by the Zika virus or for other emerging diseases requiring specialty healthcare services in the future.

## **3. Use of Improved Information Technology and Burden Reduction**

All responses (100%) will be collected through electronic submission of responses. Online web information collection was adopted as the method of data collection to streamline the process and ease for respondents. The information collected will be used to assess the ZCC program. The questions have been held to the absolute minimum required for the intended use of the data.

## **4. Efforts to Identify Duplication and Use of Similar Information**

CDC has engaged and discussed the ZCC Network with representatives from each of the twenty jurisdictions involved in this project as well as the professional organizations affiliated with the ZCC

specialties. While these entities have collaborated with ZCC, CDC is not aware of the any efforts to assess the ZCC program. Further, CDC has checked with HRSA, funders of Title V programs, to ensure there is no duplication of effort.

## **5. Impact on Small Businesses or Other Small Entities**

Every effort will be made to minimize the burden on small businesses. Some of providers who choose to self-enroll in the Network may be considered small businesses or small entities. According to the Survey of American Physician estimates in 2012<sup>2</sup> and 2014<sup>3</sup>, approximately 33% of physicians practice in a small business; therefore approximately 80 burden hours will be placed on small businesses annually (33% of the burden hours allotted to the specialty healthcare professionals). The questions have been held to the absolute minimum required for the intended use of the data.

## **6. Consequences of Collecting the Information Less Frequently**

This is a one-time information collection.

## **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. A 60-day Federal Register Notice has already been published for the Generic Clearance. No Federal Register Notice is required for this GenIC submission.

## **9. Explanation of Any Payment or Gift to Respondents**

There is no incentive provided to respondents who participate in the Assessment of Zika Care Connect.

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

CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. No personally identifiable information will be collected. Data will be secured in password-protected computer files, accessible by only members of the assessment team.

---

<sup>2</sup>2012 Survey of American Physicians. Survey conducted on behalf of The Physicians Foundation by Merritt Hawkins | Completed September, 2012. Copyright 2012, The Physicians Foundation.

<sup>3</sup> 2014 Survey of American Physicians. Survey conducted on behalf of The Physicians Foundation by Merritt Hawkins | Completed September, 2014. Copyright 2014, The Physicians Foundation. Accessed from:  
[http://www.physiciansfoundation.org/uploads/default/2014\\_Physicians\\_Foundation\\_Biennial\\_Physician\\_Survey\\_Report.pdf](http://www.physiciansfoundation.org/uploads/default/2014_Physicians_Foundation_Biennial_Physician_Survey_Report.pdf)

All findings will be reported in aggregate form, individual data will not be shared. Information will be used internally by CDC and project findings may be shared with the scientific community through scientific manuscripts of conference presentations.

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

### Institutional Review Board (IRB)

NCBDDD’s Human Subjects Advisor has determined that this information collection is public health practice not research involving human subjects. IRB approval was not required. (Attachment 4)

### Justification for Sensitive Questions

There are no planned sensitive questions.

## 12. Estimates of Annualized Burden Hours and Costs

### A. Estimated Annualized Burden Hours

Burden hours are included in Table 1. During the one-year project period, approximately 1200 healthcare professionals will be asked to complete the survey, and approximately 600 website users will visit the ZCC website and be asked to complete the ZCC website survey. Each enrolled healthcare professional will receive an email and two reminder emails to access the survey (Attachment 7). We anticipate 80% of all enrolled healthcare professionals will complete the survey as these individuals are part of the ZCC Network and thus have accountability and investment into the Network, increasing the likelihood of response. We anticipate 20% of all website users will complete the website survey based on typical online survey response rates.

Total burden hours are 260.

Table 1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Specialty Care Healthcare Professional	Email to access survey of enrolled HCPs	1,200	1	2/60	40
Specialty Care Healthcare Professional	Email of reminder to access survey of enrolled HCPs	1,200	2	1/60	40
Specialty Care Healthcare Professional	Survey of enrolled HCPs	960	1	10/60	160
Website User	Invitation to	600	1	1/60	10

	participate in survey of Website User				
Website User	Survey of Website User	120	1	5/60	10
<b>Total</b>					260

### B. Estimated Annualized Burden Costs

Burden costs are included in Table 2. The hourly wage rate of \$98.83 for healthcare professionals is based on the US Department of Labor, Bureau of Labor Statistics 2016 National Occupation Employment and Wage Estimates using category 29-1069 Physicians and Surgeons, All Others, since not all specialties are listed separately. (<http://www.bls.gov/oes/current/oes291069.htm>). The hourly wage rate of \$23.86 for website users is based on the US Department of Labor, Bureau of Labor Statistics 2016 National Occupation Employment and Wage Estimates using category 00-0000 All occupations. ([https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)).

Table 2. Estimated Annualized Burden Cost

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Specialty Care Healthcare Professional	Email to access survey of enrolled HCPs	40	\$98.83	\$3,953.20
Specialty Care Healthcare Professional	Email of reminder to access survey of enrolled HCPs	40	\$98.83	\$3,953.20
Specialty Care Healthcare Professional	Survey of enrolled HCPs	160	\$98.83	\$15,812.80
Website User	Invitation to participate in survey of Website User	10	\$23.86	\$238.60
Website User	Survey of Website User	10	\$23.86	\$238.60
<b>Total</b>				\$24,196.40

### 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 annualized government costs for this project consists of the McKing contract costs plus the personnel costs of federal employees involved in oversight. Contract costs include time to program the



website, audit the data entered, and manage the program components. Federal government involvement includes oversight of this project. The total cost of this project to the Federal government is \$20,260.48 and the project will last one year thus resulting in the annualized cost of \$127,239.14.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Contract	\$107,178.66
Direct Cost to Federal Government (CDC Project Officer)	\$20,060.48
Total	\$127,239.14

**15. Explanation for Program Changes or Adjustments**

This is a new GenIC to assess the Zika Care Connect program.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Data from the surveys will be analyzed with the statistical software package, SPSS version 22. Descriptive statistics will be analyzed for the overall participants as well as stratified by location, type of specialty care, and frequency of caring for patients affected by Zika virus. Exploratory statistical analyses will be conducted to explore differences between specialties and/or location. Categories will be collapsed, if needed, to increase the sample size of each group and thus improve the power of the analysis and ability to statistically detect differences among the groups. The below timeline outlines the anticipated start date for each data collection activity. Results of the assessment will be presented in a final report. Findings from these activities will be disseminated to CDC, project collaborators, external partners, and the scientific community (e.g., through presentations and published manuscripts).

Activity	Frequency	Date
Retrospective analysis of program metrics	Quarterly	January 2018, April 2018, July 2018, October 2018
Survey of members of the ZCC Healthcare Professional Network (Attachment 5)	Annual	September 2018
Survey of Website Users (Attachment 6)	Annual	September 2018

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

The display of the OMB Expiration date is appropriate. Knowledge that the form is OMB approved will not deter participants, therefore the display of OMB expiration may be included.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.