

Maternal and Child Health Zika Capacity Assessment

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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- **Purpose of the data collection:** The purpose is to assess the organizational capacity of maternal and child health (MCH) programs within local health departments (LHDs) to monitor, track, and support mothers and their infants potentially affected by Zika virus.
- **Intended use of the resulting data:** Findings from this assessment will inform CDC's Zika Virus Response activities in support of state department of health (SDOH) and local health departments (LHDs). The information collected through this assessment will benefit the federal government by informing public health practice, expand the public health emergency response capacity investment to reach vulnerable city and county LHDs with potential of local transmission and/or high travel burden, help to inform the National Center on Birth Defects and Developmental Disability's (NCBDDD) long-standing activities with MCH programs across the United States, and help tailor resources and technical support to meet these needs.
- **Methods to be used to collect data:** This assessment will utilize an electronic, web-based data collection tool.
- **Respondent Universe:** The subpopulation to be studied: 690 local health officials serving as the local Zika response leader/coordinator (e.g., maternal and child health (MCH) leader, agency leadership, epidemiology/surveillance leader, or infectious/communicable diseases leader) from 690 LHDs in 10 states identified as high priority for the CDC Zika virus response: Alabama, Arizona, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, New York and Texas.
- **How data will be analyzed:** The data will be collected and analyzed using descriptive statistics. All data will be reported in aggregate.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from a total of 690 local health officials across 690 local health departments (LHDs) in 10 states: Alabama, Arizona, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, New York, and Texas. CDC has identified these states as high priority jurisdictions for assessing necessary support (**see Attachment A – Respondent Breakdown**). Designation as high priority jurisdiction is based on the presence of the *Aedes aegypti* and *Aedes albopictus* mosquitoes. These mosquitoes live in tropical, subtropical, and in some temperate climates which have disproportionately infected South America, Central America, and the Southern United States. The identified high priority states are identified in NACCHO's *Mosquito Surveillance and Control Assessment in Zika Virus Priority States* publication.¹ States were also included in the sampling universe if they had reported Zika virus in the community (travel-related, sexual transmission, or local Zika virus transmission).² In addition, identified states respondents acting in their official capacities include local health officials who serve as local Zika response leaders/coordinators (e.g., maternal and child health (MCH) leader, agency leadership, epidemiology/surveillance leader, or infectious/communicable diseases leader) at the LHD.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of (4) mobilizing community partnerships to identify and solve health problems when otherwise unavailable and (7) linking people to needed personal health services and assure the provision of health care.

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems

- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems³

This assessment is in support of CDC's Zika Virus Response. In January 2016, CDC activated its Emergency Operations Center (EOC) to respond to outbreaks of Zika virus occurring in the Americas and increased reports of birth defects and Guillain-Barré syndrome in areas affected by Zika. In February 2016, CDC elevated its EOC activation to a Level 1, the highest level of response reserved for critical emergencies. In April 2016, CDC concluded that Zika virus infection in pregnancy can cause microcephaly and other severe brain defects. To date, local mosquito-borne Zika virus transmission has been limited in the continental United States; however, cases of travel-associated Zika virus infection among pregnant women and infants have been reported across the United States.² CDC's emergency response activities include tracking the spread of Zika virus in the United States and globally, supporting investigations to identify and report possible cases of Zika virus infection, providing clinical guidance to healthcare providers evaluating pregnant women and infants with possible exposure to Zika virus, developing and conducting diagnostic tests, investigating the link between Zika virus infection and adverse health outcomes, and advising and educating the public about Zika virus infection and prevention strategies.

In collaboration with state departments of health (SDOHs) and LHDs, CDC's US Zika Pregnancy Registry seeks to track all pregnancies in the 50 United States and US Territories (excluding Puerto Rico) to estimate the risk of microcephaly and other birth defects associated with Zika virus infection during pregnancy.⁴ CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) has a long history of building and maintaining birth defects surveillance systems. Existing surveillance infrastructure developed and maintained by NCBDDD enabled states to rapidly identify infants born with birth defects possibly linked to prenatal Zika-virus infection and facilitate referral to specialized care and interventions.

LHDs play a critical role in responding to public health emergencies, including the current Zika virus outbreak. LHDs' position within the community, sharpened understanding of the unique needs of their community, and cultivated relationships with local organizations and healthcare providers makes them integral to the Zika virus response and future public health responses⁵. The governance, structure and funding levels of LHDs vary, therefore there is high variability in available resources and capacity of LHDs to conduct surveillance activities and respond to the current Zika virus outbreak based on the unique attributes of the populations they serve.³ To assist LHDs and the larger health care system in the Zika virus response, baseline information on the strengths and gaps in LHD capacity are needed to inform targeted resource allocation and technical assistance. Currently no data is available characterizing relationships between LHDs and internal and external partners in regards to Zika virus capacity. Unlike other emergency responses where infectious disease is central to supporting the response, MCH programs and clinical practitioners are the leaders in the Zika virus response because of the impact the virus has on women and infants.⁶ It is unknown how many LHDs have established formal and/or informal relationships with MCH providers and services in the community. It is important to assess the type of relationships between these groups to better serve women and children impacted by Zika virus.

NCBDDD has partnered with the National Association of County and City Health Officials (NACCHO) to facilitate this data collection effort. NCBDDD's mission includes addressing the causes of birth defects and helping children reach their potential. This aligns with NCBDDD vision in which babies are born healthy, children reach their potential and everyone thrives⁷. In the context of CDC Zika virus response, NCBDDD seeks to understand the capacity of maternal and child health (MCH) programs within local health departments (LHDs) to support mothers and their infants with possible Zika virus infection. Maternal child health programs link mothers and their infants to needed health services and assure the provision of health care when otherwise unavailable, enabling babies to be born healthy and to reach their potential. NACCHO was chosen to support development of and administer the assessment because their national membership includes over 1,250 LHDs and a registry of nearly 3,000 LHDs across the nation; NACCHO also has extensive experience collaborating with CDC to develop assessments to assess LHD capacity (e.g. the NACCHO Profile of Local Health Departments); and NACCHO has a trusted relationship with local health officials in data collection. With guidance from CDC, NACCHO will design the assessment questions and incorporate them into their existing web-

based assessment tools. CDC and NACCHO will collaborate to collect and analyze the data, in aggregate form, and publish the results to better inform public health practice at the local, state and national levels.

The possible dire and life-long consequences of the Zika virus infection increases the need for targeted and aggressive approaches to minimize the number of pregnant women infected with Zika virus and strengthening of strategies to link affected women, infants and families to vital services. The purpose of the assessment is to assess the organizational capacity of MCH programs within LHDs to monitor, track, and support mothers and their infants potentially affected by Zika virus.

Findings from this assessment will inform CDC's Zika Virus Response activities in support of state department of health (SDOH) and local health departments (LHDs). The information collected through this assessment data will benefit the federal government by informing public health practice, including LHDs' capacity to respond to the current Zika virus outbreak and future public health responses where mothers and children are identified as vulnerable populations. This assessment will also expand the public health emergency response capacity investment to reach vulnerable city and county LHDs with potential of local transmission and/or high travel burden. In addition, collected data will also help to inform the National Center on Birth Defects and Developmental Disability's (NCBDDD) long-standing activities with MCH programs across the United States, including tracking infants born with birth defects without a known cause, identifying children with autism spectrum disorder, and linking children and families to specialized care. Assessing and characterizing strengths and gaps in LHDs' MCH capacity will help CDC and NACCHO to tailor resources and technical support to meet these needs.

Overview of the Information Collection System

Data will be collected from 690 MCH leaders at LHDs in the 10 priority jurisdictions, via an electronic, web-based tool (**see Attachment B—LHD Zika Capacity Assessment (Web Version) and Attachment C—LHD Zika Capacity Assessment (Word version)**). The instrument will be used to gather information from the local Zika response leader/coordinator at the LHDs to assess the organizational capacity of MCH programs within LHDs to monitor, track, and support mothers and their infants potentially affected by Zika virus.

The information collection instrument was pilot tested by 7 public health professionals. Feedback from this group was used to refine questions, as needed; ensure accurate programming and skip patterns; and establish the estimated time required to complete the information collection instrument.

Items of Information to be Collected

The data collection instrument consists of 13 questions of various types, including multiple response and contingency questions. The instrument will collect data on the following four topics: (1) LHD internal partnerships, (2) LHD external partnerships, (3) LHD Zika response capacity, and (4) LHD community engagement and outreach connections to assess the organizational capacity of MCH programs within LHDs. Specifically, the assessment will collect data on the following:

- Topic 1: Local Health Department Internal Partnerships – one (1) question to collect information related to formal and/or informal notification processes within the local health department.
- Topic 2: Local Health Department External Partnerships – one (1) question to collect information related to formal and/or informal notification processes between the maternal and child health program and clinical practitioners.
- Topic 3: Local Health Department Zika Response Capacity – seven (7) questions to collect information about the LHD's level of engagement in Zika virus prevention and response, LHD role in collecting and reporting Zika virus lab results; and LHD role in reporting to birth defects registries and the US Zika Pregnancy Registry.
- Topic 4: Local Health Department Community Engagement and Outreach Connections – three (3) questions to identify services the LHD or partners provide in the jurisdiction as well as the how the LHD engages community providers to notify them of the services available to pregnant women and infants exposed to the Zika virus.

In addition to the topical question, the assessment has one (1) additional question for the respondent to identify their primary role at the LHD.

2. Purpose and Use of the Information Collection

The purpose of this data collection activity is to assess the organizational capacity of MCH programs within LHDs to monitor, track, and support mothers and their infants potentially affected by Zika virus.

Findings from this assessment will inform CDC's Zika Virus Response activities in support of state department of health (SDOH) and local health departments (LHDs). The information collected through this assessment data will benefit the federal government by informing public health practice, including LHDs' capacity to respond to the current Zika virus outbreak and future public health responses where mothers and children are identified as vulnerable populations. This assessment will also expand the public health emergency response capacity investment to reach vulnerable city and county LHDs with potential of local transmission and/or high travel burden. In addition, collected data will also help to inform the National Center on Birth Defects and Developmental Disability's (NCBDDD) long-standing activities with MCH programs across the United States, including tracking infants born with birth defects without a known cause, identifying children with autism spectrum disorder, and linking children and families to specialized care. Assessing and characterizing strengths and gaps in LHDs' MCH capacity will help CDC and NACCHO to tailor resources and technical support to meet these needs.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via an electronic, web-based tool. This method was chosen to reduce the overall burden on respondents by allowing them to take the assessment at their own convenience and by allowing them to skip irrelevant questions. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 13 questions).

4. Efforts to Identify Duplication and Use of Similar Information

CDC assessed current and past data collection efforts, and there are no efforts underway that assesses the organizational capacity of MCH programs within LHDs to monitor, track, and

support mothers and their infants potentially affected by Zika virus. CDC's inquiries about similar efforts included discussions with OSTLTS, the Joint Information Center in the Emergency Operations Center, the Division of Reproductive Health and within NCBDDD to explore if these organizational units had gathered information about maternal and child health programs in local health departments as part of the CDC Zika virus response. The respondents indicated no similar efforts have been conducted. NACCHO has conducted an assessment of overall LHD capacity to respond to Zika virus in the "2017 Forces of Change" assessment; however, this assessment was only sent to a sample of 948 LHDs, of which only a portion were in the priority jurisdictions. Therefore, there is not sufficient information on the high priority jurisdictions to determine the degree of LHD MCH program engagement in the national Zika response efforts. Also, the data and report will not be available for use or dissemination until September of 2017, which impacts CDC's ability to provide support prior to the 2017 mosquito season.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Identify gaps in LHD maternal and child health capacity and services to respond to the needs of pregnant women and infants exposed to Zika virus.
- Identify gaps in community-level services and engagement of health care providers treating/serving pregnant women and infants exposed to Zika virus.
- Effectively develop strategies to build LHD capacity ahead of the 2017 mosquito season.
- Inform CDC's LHD field support activities designed to increase capacity of LHDs to respond to Zika virus.

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

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on May 16, 2014, Vol. 79, No. 95; pp. 28513. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this data collection. STLT governmental staff and / or delegates will be speaking from their official roles.

This data collection is not research involving human subjects.

Although NACCHO will collect some individually identifiable information (IIF) related to the official roles of respondents, including the respondent's name and official role at the LHD, all information will be kept on secure, password protected servers accessible only to NACCHO project team members, CDC will not have access to any collected IIF. Data collected during the assessment will only be shared with CDC in aggregate form. CDC and NACCHO will also only report findings from this assessment in aggregate form, therefore no IIF will be distributed.

According to NACCHO’s record retention policy, data from this assessment will be destroyed by NACCHO after 7 years.

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

No information will be collected that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the data collection instrument by 7 of public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 5 minutes and 30 seconds (range: 4 - 9). For the purposes of estimating burden hours, the upper limit of this range (i.e., 9 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for General and Operations Managers in Local Government http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of \$47.76 is estimated for all 690 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Data collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
LHD MCH Zika Capacity Assessment	Local Zika Response Leader/Coordinator	690	1	9 / 60	104	\$47.76	\$4,967
	TOTALS	690	1		104		\$4,967

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

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only costs to the federal government would be the salary of CDC staff and the NACCHO contract to develop the data collection instrument, collect data, perform data analysis, and develop a report. The total estimated cost to the federal government is \$82,607.15. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Project Officer (1 FTE)	15	\$75.95/hour	\$1,139
Fellow (1 FTE)	90	\$16.31 /hour	\$1,468
Contractor – NACCHO (5 FTE)	500	Varies / hour	\$80,000
Estimated Total Cost of Information Collection			\$82,607

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Upon completion of the data collection period, data will be cleaned, de-identified, and coded using STATA and excel. Data analysis, for descriptive statistics and subgroup analysis, will also be performed using STATA and excel. CDC and NACCHO will develop a final report which will be shared with CDC senior leadership, as well as NACCHO members through various dissemination channels. Although NACCHO will collect some individually identifiable information (IIF) related to the official roles of respondents, including the respondent’s name and official role at the LHD, all information will be kept on secure, password protected servers accessible only to NACCHO project team members, CDC will not have access to any collected IIF. Data collected during the assessment will be shared with CDC only in aggregate form. CDC and

NACCHO will also only report findings from this assessment in aggregate form, therefore no IIF will be distributed.

Project Time Schedule

- ✓ Design instrument (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan (COMPLETE)
- ✓ Pilot test instrument (COMPLETE)
- ✓ Prepare OMB package (COMPLETE)
- ✓ Submit OMB package (COMPLETE)
- OMB approval (TBD)
- Conduct data collection 3-5 weeks
- Code data, conduct quality control, and analyze data..... 2 weeks
- Prepare summary report(s) 2 weeks
- Disseminate results/reports 1 weeks

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

- Attachment A – Respondent Breakdown
- Attachment B – LHD Zika Capacity Assessment (Web Version)
- Attachment C – LHD Zika Capacity Assessment (Word version)

REFERENCE LIST

1. National Association of County and City Health Officials (NACCHO). “Mosquito Surveillance and Control Assessment in Zika Virus Priority States.” Available at

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