CDC Emergency Operations Center: Zika Related Clinical Inquiries

Request for OMB Approval of a New Information Collection

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Supporting Statement A

Justification

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The goal of this information collection is to document and track clinical inquiries made to the CDC EOC call center related to Zika virus illness, as well as to systematically collect standardized clinical/demographic/epidemiologic information about suspected cases of Zika virus illness, so that clinical inquiries can inform future guidance and research.

The intended use of the EOC Clinical Inquiries Database is to provide guidance to State, Local, Tribal and Territorial (STLT) authorities and health facilities for Zika virus clinical inquiries and to carry out monitoring for the ongoing Zika virus outbreak. Data will provide accountability for services provided to callers and may provide feedback into call center operations, and it will also inform ongoing response activities.

STLT jurisdictions and healthcare providers call the CDC on their own volition. STLT health departments must follow their local requirements for privacy protections of individual cases, patients, and persons of interest (POIs) when providing patient information to CDC.

The respondents are the general public; clinicians, other providers, and workers from healthcare, laboratory, and environmental services; and at times the STLT authorities, themselves.

1. Circumstances making the Collection of Information Necessary

Zika virus is spread to people primarily through the bite of an infected Aedes species mosquito. The most common symptoms of Zika virus disease (or Zika) are fever, rash, joint pain, and conjunctivitis (red eyes). The illness is usually mild with symptoms lasting for several days to a week. There is no vaccine to prevent or medicine to treat Zika. Severe disease requiring hospitalization is uncommon and deaths are rare.

Mosquitoes that spread Zika virus are aggressive daytime biters, prefer to bite people, and live indoors and outdoors near people. The mosquitoes that spread Zika virus also spread dengue and chikungunya viruses.

Outbreaks of Zika have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and most recently in the Americas. Because the mosquitoes that spread Zika virus are found throughout the world, it is likely that the outbreak will continue to spread.

In May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed Zika virus infection in Brazil. The outbreak in Brazil led to reports of Guillain-Barré Syndrome (GBS) and pregnant women giving birth to babies with birth defects and other pregnancy problems.

“On January 22, 2016, CDC activated its Incident Management System and, working through the Emergency Operations Center (EOC), centralized its response to the outbreaks of Zika occurring in the Americas and increased reports of birth defects and Guillain-Barré syndrome in areas affected by Zika. On February 1, 2016, the World Health Organization declared a Public Health Emergency of International Concern (PHEIC) because of clusters of microcephaly and other neurological disorders in some areas affected by Zika. On February 8, 2016, CDC elevated its

response efforts to a Level 1 activation, the highest response level at the agency." (http://www.cdc.gov/zika/geo/index.html)

No local transmission of Zika virus been documented in the 50 US states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands, and American Samoa. Zika virus infections have also been reported in travelers returning to US states from areas with local transmission of Zika.

Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for Zika virus acquisition. With the ongoing outbreak in the Americas, the number of Zika virus disease cases among travelers returning to the United States likely will increase and local transmission in US states may occur.

In some Brazilian states where Zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses in women infected during pregnancy.

In response, CDC has issued travel notices for people traveling to regions and certain countries where Zika virus transmission is ongoing.

CDC has set up a call center to respond to inquiries on clinical care of persons potentially of interest for Zika virus infection. The EOC Clinical Inquiries Database information collection activities for the 2016 Zika Response are currently approved under OMB Control number 0920-1101 *CDC Emergency Operations Center Zika Related Clinical Inquiries and Surveillance* (exp. Date 08/31/2016). The CDC requests a three-year approval period for this new ICR that will replace the OMB control number 0920-1101, that was previously granted 6 months emergency clearance.

This information collection request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment A**).

2. Purpose and Use of Information Collection

This information collection is designed to allow CDC to provide support for State, Local, Tribal and Territorial (STLT) authorities and health facilities in responding to the ongoing Zika virus outbreak.

In the beginning of the 2016 Zika virus response, the CDC EOC Clinical Inquiries Database was quickly established when the arrival of Zika in the Americas was documented and demonstrated the risks posed by this and other exotic viruses. The CDC consultation service was set up to assist in the evaluation of persons thought to be at risk for Zika virus. The CDC will collect structured case-patient information from the inquirers using a web-based collection tool under the "ZIKA Clinical Inquiries Database" **(Attachment C)**.

Because clinical data are not systematically collected in the clinical inquiries database currently, information on certain variables might be incomplete, including whether testing occurred. As a result STLT health departments and health facilities will be called to collect that missing data

including: presence of symptoms, final diagnosis, whether testing was done, pregnancy status, or birth outcome.

The purpose of this project is to document and track clinical inquiries made to the CDC EOC call center related to Zika virus illness, as well as to systematically collect standardized clinical/demographic/epidemiologic information about suspected cases of Zika virus illness, so that clinical inquiries can inform future guidance and research. Data will provide accountability for services provided to callers and may provide feedback into call center operations, and it will also inform ongoing response activities.

STLT jurisdictions and healthcare providers call the CDC on their own volition. STLT health departments must follow their local requirements for privacy protections of individual cases, patients, and persons of interest (POIs) when providing patient information to CDC.

HIPAA's Privacy Rule establishes conditions under which covered entities (i.e., healthcare providers) may disclose a patient's protected health information (PHI) to a public health authority for public health purposes (including public health investigations) if a public health authority (i.e., CDC) is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability [45 CFR § 164.512(b)]. The Privacy Rule also establishes minimum Federal standards for protecting the privacy of individually identifiable health information and confers to individuals the right to access and amend their health information and to obtain a record of when and why their PHI has been sheared with others for certain purposes. In accordance with HIPAA's Privacy Rule, CDC will only be collecting necessary PHI from other public health authorities, and occasionally from covered entities (i.e., health care providers)—who voluntarily contact the EOC call center.

3. Use of Improved Information Technology and Burden Reduction

One-hundred percent of burden hours will be incurred by respondents using improved information technology.

The CDC EOC call center has developed an electronic data collection tool called the EOC Clinical Inquiries Database using a Microsoft SharePoint platform.

4. Efforts to Identify Duplication and Use of Similar Information

Telephone inquiries from STLT public health authorities and health facilities to the CDC EOC call center involve discussion about cases under treatment, contacts, and POIs for arboviral infection, flavivirus infection and other unforeseen emerging pathogens that may be of concern in the future. This information forms a convenience sample of case-, POI-, or patient-level data voluntarily provided and advantageously recorded during the telephone call or entered after the call from handwritten notes. Providing information for all fields is not required by the call center.

The CDC requires immediate information, often daily or weekly, during an emergency response, so even information conveniently collected by the CDC EOC call center can be a useful initial data source.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the small entities involved, the burden imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

6. Consequences of Collecting the Information Less Frequently

CDC activities regarding the domestic Zika virus response and other responses would be significantly hindered if it were not able to collect the information at the frequency necessary to prohibit the spread of this disease.

Collecting information less frequently than the CDC recommendations indicate will interfere with the public health actions required to contain and respond to Zika virus transmission and to do everything possible to limit, if not stop, deaths and birth defects due to this disease. Given the limited information available on Zika virus disease during pregnancy, information is needed to inform CDC recommendations.

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

This request fully complies with the guidelines in 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 Vo. 81, No. 84 was published May 2, 2016. (**Attachment B**) One comment (Attachment E) was received praising the efforts of CDC and the Agency responded to this comment.

B. There was no consultation outside of the Agency.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

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

CDC is collecting clinical information for the Zika Clinical Inquiries Database in identifiable form as a public health authority, defined in the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations, Standards for Privacy of Individually Identifiable Health Information (45 CFR § 164.501)] ("Privacy Rule").

Pursuant to 45 CFR § 164.512(b) of the Privacy Rule, covered entities such as healthcare providers may disclose, without individual authorization, protected health information to public health authorities "… authorized by law to collect or receive such information for the purpose of

preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions… ." CDC is requesting these records as a public health authority conducting a public health activity as described by 45 CFR § 164.512(b), and as authorized by section 301 of the Public Health Service Act. The information requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR § 164.514(d) of the Privacy Rule.

The Privacy Act is applicable. Records are covered under CDC Privacy Act System of Records Notice (SORN) No. 0920-0136 "Epidemiologic Studies and Surveillance of Disease Problems" and SORN No. 09-20-0113, "Epidemic Investigation Case Records Systems Notice."

Personally identifiable information will be collected by CDC from STTL authorities and healthcare providers and health facility staff. As respondents, domestic public health authorities and healthcare providers will respond as representatives of their agencies or facilities in their business roles. To protect case and POI identities, these entities will be reminded that release of identifiable personal information must be in accordance with the privacy requirements of their own jurisdictions. As an added measure, only de-identified data will be presented in case reports and in aggregated reports, and datasets with individual records will not be shared beyond the various partnerships, to the extent allowed by law. In addition, CDC will apply for an Assurance of Confidentiality, authorized under Section 308(d) of the Public Health Service Act, to protect the data collected under this request at the federal level. In accordance with Assurance requirements, all CDC registry staff will have the appropriate confidentiality training.

Privacy Impact Assessment

The following information in identifiable form (IIF) will be collected.

IIF CATEGORIES	
Name	X
Date of Birth /Death/Age	X
Address/GPS Coordinates	X
Date of Residence	
Phone Numbers	X
Date of Hospital Admission/Transfer/Discharge	X
Medical Information and Notes	X
Medical Records Numbers/Case ID	X
Biological Specimens	X
Email Address	X

Employment Status	X
Foreign Activities/Travel	X

Information owned by the STTL authority may be shared with CDC for assistance with data analysis and publications as agreed.

The CDC will not include information in aggregate datasets that may identify cases or patients, including geographic locations of Zika virus diagnosis, and specified dates directly related to the patient such as admission dates, dates of diagnosis or specific procedure dates.

Because the number of cases, patients, and POIs may be small in a given locality or facility, a breach in privacy is a concern. Suppression of data where small numbers occur is another technique to protect privacy. Variables constructed from potentially identifiable elements such as health facility name or location origin will be anonymized prior to data sharing.

Data will be aggregated to summarize the clinical information for individuals to understand resource needs and to assist in the public health response. No information that includes personally identifiable information will be released on individuals. Only de-identified data will be presented in case reports or in aggregate. 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.

The respondents' identities will be known to the CDC. Case, patient, POI, and other respondent data are treated in a private manner, unless otherwise compelled by law. Highly sensitive information is being collected and would affect individual privacy if there were a breach of confidentiality. CDC will make every effort to secure the information. In addition, an application for an Assurance of Confidentiality, authorized under Section 308(d) of the Public Health Service Act, to protect the EOC Clinical Inquiries Database information is in process. The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

STTL jurisdictions and healthcare providers contact the EOC Call Center at CDC on their own volition. They are also told that providing patient information to CDC must follow their local requirements for privacy protections of individual cases, patients, and POIs, and that information provided is stored securely in a certified Microsoft SharePoint site with limited access to only those who work on the team or manage the data (currently 20 people).

To collect information for the Zika Clinical Inquiries Database and the US Zika Pregnancy Registry, CDC will receive data from health care providers who call the Zika Pregnancy Hotline. In addition, basic case data reported to ArboNET and additional information specific to the registry provided to CDC by STTL health departments or health care providers will be received electronically or entered manually into a HIPAA-compliant REDCap database established for the registry.

Stringent safeguards are in place at CDC to ensure a respondent's privacy including restriction of access to authorized users, physical safeguards, and procedural safeguards.

Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters.

Procedural safeguards: Protections for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic media containing Privacy Act information. Finally, CDC and contractor employees who maintain and use records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. CDC employees and contractors are required to be trained on the Privacy Act and receive information security awareness training at least annually.

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

IRB Approval

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). (**Attachment D**)

If the forms are subsequently used for research activities, applicable IRB approvals and PRA clearances must be obtained for these new information collections.

Justification for Sensitive Questions

The forms are used to collect medical and laboratory data which is highly sensitive:

- Epidemiologic data such as clinical signs, symptoms, and laboratory diagnosis; history of illness, pregnancy, pregnancy and infant outcomes associated with Zika virus exposure and infection, and infant growth and development; and sexual practices to accurately determine a respondent's public health risk for Zika virus;
- Demographic data such as age, sex, ethnicity, and religious affiliation.

All of these data elements are essential to meeting the goals of these information collections.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State and Local Health Departments	Clinical Inquiries Database	420	1	15/60	105
Clinicians and Other Providers	Clinical Inquiries Database	800	1	15/60	200

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

Registered nurses are often the persons interviewed at hospitals, so their mean hourly wage ($33.55) is used to represent the hospital staff wages. The mean hourly wage for epidemiologists is $35.63. Information on mean wage rates is available at http://www.bls.gov/oes/current/oes_nat.htm.

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State/Local Health	Clinical Inquiries Database	105	$35.63	$3,741.15

Departments				
Health Facilities	Clinical Inquiries Database	200	$33.55	$6,710.00
Total				$10,451.15

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

There are no known capital and maintenance costs incurred by respondents or record keepers.

14. Cost to the Government

The cost to the federal government is estimated at $108,699.60. This estimate represents the amount of time for the CDC staff to respond to inquiries, follow protocols, procedures, and communication standard operating procedures (SOPs), enter data, and conduct descriptive statistical analyses, in addition to the time spent managing the response in the EOC. Hourly wage rates were used for step-1 FTEs for the Atlanta locality. These numbers are available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/ATL.pdf.

Project	**Grade**	**Hours**	**Hourly Wage**	**Total**
EOC call center	GS-11	240	$29.69	$7,125.60
	GS-13	2,400	$42.31	$101,544.00
Total				$108,669.60

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will occur on a continuous basis for which the timing of inquiries to the CDC EOC Clinical Inquiries Database will be determined by the frequency that cases, POIs in applicable risk categories, and contacts occur in a given STTL jurisdiction.

This new ICR will cover Zika-related inquiries reported to the EOC for three years. As information is reported voluntarily to the EOC by inquiring members of the general public and clinicians, and not all zika cases that occur domestically may necessarily result in a call to the EOC---this collection is not intended to result in generalizable conclusions or to directly inform

health policy. Outcomes from this collection may result in internal improvements to the EOC and Zika-related activities as well as inform future guidance and research on the Zika virus.

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

The display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

A. Authorizing Legislation
B. 60-day Federal Register Notice
C. Zika Clinical Inquiries Database
D. IRB Approval – EOC call center
E. 60-Day Federal Register Notice Public Comments