

**Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback”
(OMB Control Number: 0920-1026)**

TITLE OF INFORMATION COLLECTION:

Management of Fever in Travelers from Ebola Affected and Ebola Non-affected Malaria Endemic Countries

PURPOSE:

According to the World Health Organization (WHO) and Ministries of Health update on January 4, 2015 (1), over 20,700 Ebola cases have been reported in West Africa, primarily from Guinea, Liberia, and Sierra Leone where transmission is widespread and intense. Guinea, Liberia, and Sierra Leone are also countries with high year-round malaria transmission. Each year, approximately 1,500 cases of malaria are diagnosed in the United States; almost all are acquired overseas. More than three quarters of these cases are imported from Africa, and two-thirds of those are typically acquired in West Africa.

On July 9, 2014, CDC activated its Emergency Operations Center (EOC) for the Ebola outbreak response. As a part of the response, the EOC formalized a consultation service designed to assist state and local public health officials and health care providers who must evaluate persons in the United States thought to be at risk for Ebola (2). From July 9–December 31, 2014, CDC EOC responded to 780 clinical inquiries from public health officials and health care providers from 49 states and the District of Columbia regarding persons thought to be at risk for Ebola. In a recent Morbidity and Mortality Weekly Report (MMWR) describing the clinical inquiries received by CDC, the most common alternate diagnosis was malaria (2). Additionally, anecdotal reports from these health departments and health care providers have noted that efforts to establish alternative diagnoses were hampered or delayed because of infection control concerns related to Ebola. For example, laboratory tests to guide diagnosis or management (e.g., malaria tests, complete blood counts, liver function tests, and serum chemistries) were reportedly deferred in the evaluation of some persons with fever and malaise until there were assurances of a negative Ebola virus test result (2).

This is important because the initial symptoms, fever and malaise, of Ebola and malaria are clinically indistinguishable and immediate laboratory testing for malaria is critical for the initiation of appropriate treatment. Malaria is a medical emergency, and if diagnosis and treatment is delayed, patients can suffer severe outcomes, including death. Current CDC guidance recommends immediate testing by blood smear for malaria parasites on all patients with fever and history of travel to a country with malaria regardless of other associated symptoms. If the current practices, due to concern about infection control related to Ebola, noted by health departments and healthcare provider are accurate, excess patient morbidity and mortality is likely, and if confirmed, immediate intervention is required.

CDC seeks a one-time collection of data on the presentation, course, and management of patients with fever returning to the United States from Ebola affected and Ebola non-affected malaria endemic countries in order to determine if the claims of delay in malaria testing and diagnosis in the United States are accurate. The data collected will allow CDC to validate these anecdotal reports and if confirmed make the necessary and timely changes to current CDC recommendations and guidance including public health communications.

Currently, CDC has OMB coverage for domestic malaria cases under The National Malaria Surveillance System (NMSS), National Notifiable Diseases Surveillance System (NNDSS),¹ OMB Control No. 0920-0728, expiration date 01/31/2017, however, those case reports do not collect information on dates and times of testing, results and treatment to determine whether delayed diagnosis or treatment has/is occurring. The Clinical Inquiries Database² contains patient-level information collected during caller inquiries. This database is used to record the caller’s identity in addition to information about the person or patient

¹ The National Malaria Surveillance System (NMSS) played a historic role in tracking malaria elimination efforts in the United States and has been in existence since the early 1950s. Until recently, data collection for NMSS was approved under OMB Control No. 0920-0009 with several other infectious disease surveillance activities. Beginning in 2014, all of the nationally notifiable conditions have been included as part of the National Notifiable Diseases Surveillance System (NNDSS) OMB package for data collection.

² The Clinical Inquiries Database was identified as an information collection in use without an OMB Control Number. CDC is currently undertaking the necessary steps to obtain appropriate OMB Paperwork Reduction Act clearance.

potentially at risk for Ebola, such as travel history or other risk factors, clinical presentation, and subsequent Ebola test results. Because complete clinical data are not systematically collected in the domestic Clinical Inquiries Database, information on certain variables might be incomplete, specifically whether malaria testing occurred. In sum, the Clinical Inquiries Database and the NMSS may include information needed for this data collection effort. To avoid duplication, CDC has dedicated staff who will review each record prior to contacting this respondent pool in order to identify already collected information via NMSS or the Clinical Inquiries Database. If information is identified, only the missing information will be requested.

Staff from the Malaria Branch and the Domestic Inquiries Team will call state/local health departments and health facilities associated with the patient (identified through the Clinical Inquiries Database), and record the data onto the data collection form. The CDC will collect the missing information by calling respondents and recording answers on a paper questionnaire. All hard copy materials submitted to CDC are stored in locked cabinets in restricted access areas in buildings that require card key access. The databases will be housed on secure servers with access restricted to only those individuals who are involved in this data collection effort.

Burden to the health department will be greater than the health facilities. All respondents will be called using a telephone script (Attachment C). The health department will be contacted first as it is expected that the health department will be able to provide the majority of the answers to the questionnaire. The Ebola-Malaria Assessment Form for Health Departments (Attachment A) questionnaire is estimated to take 10 minutes. If the Health Department is not able to provide answers for all the questions, the Health Facility will be contacted next and asked to complete the remainder of the questionnaire (Attachment B).

DESCRIPTION OF RESPONDENTS:

The respondents include the state/local health department in 43 jurisdictions including Washington D.C. and New York City, and health facilities (one health facility per patient=221). Data collection will involve contacting the state/local health departments and health facilities with the goal of contacting 100% of eligible health departments and health facilities to obtain information on the identified patients.

TYPE OF COLLECTION: (Check one)

- | | |
|--|---|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group |
| <input type="checkbox"/> Focus Group | <input checked="" type="checkbox"/> Other |

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

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To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? Yes No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? Yes No
3. If Applicable, has a System or Records Notice been published? Yes No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?
 Yes No

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/Local Health Departments	Ebola/Malaria Assessment Data Collection Tool	43	6	10/60	43
Health facilities	Ebola/Malaria Assessment Data Collection Tool	221	1	5/60	18
Total					61

FEDERAL COST: The estimated annual cost to the Federal government is:
 The anticipated cost to the Federal Government is approximately \$2309.70. These costs are comprised of:

Atlanta-based Support Hourly Wage			
Design of methods	1 FTE 10 hours	GS14 \$55.41	\$554.10
	1 FTE 10 hours	GS13 \$48.06	\$480.60
Data extraction from Clinical Inquiries Database	1 FTE 5 hours	GS13 \$48.06	\$240.30
Data aggregation and summary	1 FTE 10 hours	GS14 \$55.41	\$554.10
	1 FTE 10 hours	GS13 \$48.06	\$480.60
Total salary costs			\$2309.70
http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/ATL_h.pdf			

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? Yes No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

As seen in Attachment D, during July 9–December 31, 2014, CDC EOC responded to 780 clinical inquiries from public health officials and health care providers from 49 states and the District of Columbia regarding persons thought to be at risk for Ebola. Not all inquiries concerned travel to Ebola affected countries. For this collection, CDC aims to collect data on all patients in the database who had a fever and traveled to a malaria endemic country. Of the 780 inquiries, 108 had fever and reported travel to an Ebola affected country. Additionally, there were 113 inquiries for patients with fever and travel to an Ebola unaffected country that is endemic for malaria. In total, these 221 patients were reported by 43 state/local health departments.

The respondent pool includes two inquiry groups related to these patients: 1) the state/local health departments of the jurisdiction where these patients were treated; and if necessary 2) the health facilities who provided care for these patients.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

Web-based or other forms of Social Media

Telephone

In-person

Mail

Other, Explain

2. Will interviewers or facilitators be used? Yes No

Attachments

Attachment A, Ebola-Malaria Assessment Form for Health Departments

Attachment B, Ebola-Malaria Assessment Form for Health Facilities

Attachment C, Telephone Script for Health Departments and Health Facilities

Attachment D, Ebola-Malaria Flow Diagram for Population of Interest