

**Ebola Virus Disease in the United States:  
CDC Support for Case and Contact Investigation**

**Request for OMB Approval for a  
New Information Collection Request**

**January 23, 2015**

**Supporting Statement B  
Collections of Information Employing Statistical Methods**

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Emergency Information Collection Request**

**B. Collections of Information Employing Statistical Methods**

**1. Respondent Universe and Sampling Methods**

No statistical sampling methods are used in this data collection; however, the Centers for Disease Control and Prevention (CDC) will be generating statistical analyses with these data.

The method used for confirmed case and contact tracing is a case series study design.<sup>1</sup> The annualized burden table in Section A.12 outlines respondent groups as: general public [confirmed cases, persons under investigation (PUI), and contacts of cases], healthcare workers, laboratory personnel, environmental services personnel, and state, territorial, and local (STL) public health authorities. Each of these respondent groups will not be statistical samples, but rather included as soon as their required involvement in active monitoring is identified.

The CDC “Interim Guidance for Monitoring and Movement of Persons with Potential Ebola Virus” provides STL public health authorities and other partners with a framework for determining appropriate public health actions based on risk factors and clinical presentation (7). As of November 16, 2014, this interim guidance recommends public health actions based on high, some, low (but not zero), and no identifiable risk exposure categories; and adds recommendations for specific groups and settings.<sup>2</sup>

For those persons who are identified as being at high risk, some risk, or who are healthcare workers treating EVD patients in the U.S. STL public health authorities are responsible for ensuring that a public health authority (or delegate for healthcare workers) conducts direct active monitoring (DAM) by directly observing each person at least once daily to review the presence of symptoms consistent with EVD (including severe headache, fatigue, muscle pain, weakness, diarrhea, vomiting, abdominal pain, or unexplained hemorrhage); monitoring of temperature; and discussing plans to work, travel, take public conveyances, or be present in congregate locations.

For non-healthcare workers assessed as being at low, but not zero, risk, STL public health authorities are responsible for conducting active monitoring (AM) -- receiving daily reports of temperature monitored with a Food and Drug Administration (FDA)-cleared thermometer and presence/absence of symptoms.

Respondents will also include any contacts identified through the case investigation process, and for reporting purposes, STL public health authorities and their delegates; in this case, all affected states will be asked to report to the CDC.

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<sup>1</sup> See <http://www.cdc.gov/vhf/ebola/hcp/case-definition.html> for definition of Person Under Investigation (PUI) and Confirmed Case.

<sup>2</sup> Periodically updated, it is available at <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>.

## **2. Procedures for the Collection of Information**

In the field, the data needed to complete the forms may be collected by CDC staff (in-person, fax, email or phone) from persons under investigation, confirmed EVD cases, and contacts of Ebola cases on behalf of the STL public health authorities. While in the field, the CDC staff can provide daily reports to the CDC Emergency Operations Center (EOC), not imposing burden on the STL health authorities. When CDC is not in the field, the STL authorities collect their own case and control investigation data as non-federally sponsored collections; however, they incur burden when they provide daily reports back to the CDC.

The CDC does not have a sense of how many states have developed their own forms; however, it is clear from our communications with the states that they are looking to CDC for these forms. They are not primarily developing their own, but some are making minor modifications to ours that are relevant to their states.

As stated in Section A.10.1, if CDC is requested to use STL-customized forms by the requesting public health authorities, the forms will be submitted to OMB for PRA clearance as a change request. Burden tables will be adjusted to subtract hours from the standard EVD Toolkit requested herein and accounted for by the use of the STL-customized forms.

## **3. Methods to Maximize Response Rates and Deal with Nonresponse**

Due to the critical need to identify new Ebola cases as quickly as possible to prevent transmission to new cases, all contacts of the Ebola case are actively monitored – at a minimum they measure their temperature twice a day and report to STL at least once a day. All community members who are household contacts of the Ebola cases and all health care personnel who have contact with the Ebola case during patient care will have DAM for 21 days after last exposure. DAM includes one face-to-face meeting and one phone call each day during the 21 day monitoring period. All contacts will be educated so they understand the need for such close monitoring.

## **4. Tests of Procedures or Methods to be Undertaken**

CDC currently collected this type of data under a previously approved emergency data collection. The electronic systems used for this data collection are continually updated and improved for quality of data collection and ease of use for the public, industry and CDC program administrators.

Previously, the CDC deployed teams of public health experts to Texas and Ohio and plans to assist additional STL public health authorities that request CDC assistance with active surveillance of persons under investigation for EVD. A domestic Epi-Aid OMB generic information collection (GenIC) was approved under 0920-1011 “Emergency Epidemic Investigation Data Collections” for Texas and Ohio<sup>3</sup> that used an Ebola Case Investigation Form

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<sup>3</sup> Information collected under a 90-day Office of Management and Budget (OMB) approval titled “Emergency Epidemic Investigation Data Collections - Expedited Reviews” (OMB Control No. 0920-1011; expiration date: December 30, 2014).

and an Ebola Virus Disease Case Contact Questionnaire. These forms were used as models for the forms developed for the current EVD Toolkit. A significant effort was made to limit questions the number of questions.

## **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

CDC has activated its EOC to help coordinate technical assistance and control activities with partners. Although statistical methods are not employed in a case series design, the CDC tracks and reports summary surveillance statistics to the U.S. Department of Health and Human Services (HHS) and the White House on a daily basis.

Where CDC is not deployed to the field, CDC is requesting daily STL active monitoring reports from jurisdictions conducting their own case and contact investigations. Therefore, it is desired that 100% the persons under investigation are monitored and tracked for EVD until the 21 day monitoring period expires or a case is identified for treatment. Therefore, the CDC is not relying on statistical sampling methods to complete this information collection in the U.S.

## References

1. Baize S, Pannetier D, Oestereich L, et al. Emergence of Zaire Ebola virus disease in Guinea. *N Engl J Med* 2014;371:1418–25.
2. CDC. Ebola (Ebola virus disease). Ebola outbreak in West Africa 2014. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at <http://www.cdc.gov/vhf/Ebola/outbreaks/2014-west-africa/index.html>.
3. Chervalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States —Dallas County, Texas, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63. Available December 3, 2014 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6346a11.htm>.
4. McCarty CL, Basler C, Karwowski M. Response to importation of a case of Ebola virus disease – Ohio, October 2014. *MMWR Morb Mortal Wkly Rep* 2014. [In press]. November 14, 2014 / 63(Early Release);1-3. Available December 3, 2014 at <http://www.cdc.gov/mmwr/pdf/wk/mm63e1114a6.pdf>
5. CDC. Factsheet – Legal Authorities on Isolation and Quarantine, October, 2014. Available December 2, 2014 at <http://www.cdc.gov/quarantine/pdf/legal-authorities-isolation-quarantine.pdf>.
6. Cole JP. Federal and State Quarantine and Isolation. October 9, 2014. Congressional Research Service. Available December 3, 2014 at <http://cdn5.freedomoutpost.com/wp-content/uploads/2014/10/RL33201.pdf>.
7. CDC. Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure, November 28, 2014. Available December 2, 2014 at <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>.
8. World Health Organization (WHO). Ebola virus disease. Fact sheet N°103, September 2014. Available December 2, 2014 at <http://www.who.int/mediacentre/factsheets/fs103/en/>.

## **List of Appendices**

Appendix 1. Authorizing Legislation

Appendix 2. Consultations

2a. Council of State and Territorial Epidemiologists (CSTE)

2b. Association of State and Territorial Health Officials (ASTHO)

2c. National Association of County and City Health Officials (NACCHO)

Appendix 3. CDC Privacy Act System of Records Notice 09-20-0113

## **List of Attachments for CDC Domestic Ebola Virus Disease Toolkit**

*Forms for Cases and Persons Under Investigation*

Attachment 1. Ebola Virus Disease Case Investigation Form – United States

Attachment 1b. Ebola Virus Disease Person Under Investigation (PUI) Form

*Forms for Contacts*

Attachment 2. Ebola Virus Disease (Ebola) Contact Tracing Form – United States

*Guidance for Health Departments*

Attachment 3a. Guidance for Health Departments for Travelers (Not Health Care Workers\*) Arriving in the U.S. from Countries with Widespread Ebola Transmission

Attachment 3b. Guidance for the Evaluation and Triage of Contacts of Confirmed Ebola Virus Disease (Ebola) Cases for Routine or Urgent Medical Concerns, including Symptoms Compatible with Ebola

Attachment 3c. Guidance for Health Departments for Identifying and Monitoring Community Contacts of Persons Under Investigation (PUI) for Ebola Virus Disease (Ebola) or Ebola Cases

*Guidance for Individuals*

Attachment 4a. Guidance for Contacts of Ebola Virus Disease (Ebola) Patients, United States

Attachment 4b. Information for Healthcare Workers Returning from Countries with Widespread Ebola Transmission or Treating Patients with Ebola in the United States

*Templates to facilitate data collection during prospective monitoring of health care personnel caring for Ebola patients*

Attachment 5a. EVD Tracking Form for Healthcare Workers with Direct Patient Contact (e.g. nurses, physicians, respiratory therapists, others)

Attachment 5b. Ebola Tracking Form for Laboratory Personnel

Attachment 5c. Ebola Tracking Form for Environmental Services Personnel

*Template to facilitate twice daily 21-day follow-up*

Attachment 6. Symptom Monitoring Form

*Generic end-of-monitoring letter*

Attachment 7. Generic End-of-Monitoring Letter

*Data requests by federal government*

Attachment 8: White House Evening Report