Surveillance Data Collections for Ebola Virus Disease in West Africa

NEW

Request for OMB Approval

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Supporting Statement A Justification

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Surveillance Data Collections for Ebola Virus Disease in West Africa

The goal of this information collection request is to seek Paperwork Reduction Act (PRA) clearance to continue Ebola-related information collections beyond their current emergency expiration dates and to prepare for information collections within Ebola-affected countries in the future.

The information collections are designed to continue CDC assistance in establishing and supporting active surveillance systems for Ebola virus disease (EVD) for West African Ministries of Health (MoH).

The intended use of these information collections is to continue existing ways or to find new ways to monitor and reduce Ebola transmission throughout West Africa and to extend the use of emergency approved case and contact investigation forms. New forms have also been developed for adult sexual transmission case investigations.

The respondents are the general public in the affected countries including Ebola virus disease (EVD) cases/patients, their contacts, and their households. Also included are workers providing healthcare, laboratory, and environmental services.

The collection methods include recruitment of respondents through an EVD case series design.

The information collection will support non-research surveillance activities, and the data will be analyzed using descriptive statistics.

A. Justification

1. Circumstances making the Collection of Information Necessary

Since the Centers for Disease Control and Prevention (CDC) activated its Emergency Operations Center (EOC) for the 2014 Ebola Virus Response on July 9, 2014, the agency used expedited and emergency Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) clearance procedures to initiate multiple urgently needed information collections in West Africa, at US ports of entry, and within US state, territorial, and local (STL) jurisdictions. These procedures allowed the agency to accomplish its primary mission on many fronts to quickly prevent public harm, illness, and death from the uncontrolled spread of the Ebola virus disease (EVD).

According to the World Health Organization (WHO) and Ministries of Health (MoHs) update, by April 17, 2015 (1), over 25,855 Ebola cases were reported in three countries in West Africa (Guinea, Liberia, and Sierra Leone). Ebola transmission is widespread and the outbreak, still ongoing; therefore, the CDC must seek PRA clearance to continue this existing information collection and to prepare for future outbreaks within Ebola-affected countries in West Africa. This information collection request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Appendix A**). The 60-day Federal Register Notice was published on March 27, 2015, and is discussed further in Section A.8 (**Appendix B**).

2. Purpose and Use of Information Collection

It is impossible to know when and where an EVD outbreak may occur. CDC is requesting a three-year approval because EVD still remains a public health emergency in West Africa and may re-emerge in the future. The current outbreak has affected countries in West Africa (Guinea, Liberia, Mali, Nigeria, Senegal, and Sierra Leone) among others (**Appendix C**). In the past, Ebola has emerged multiple times and in multiple countries, including West and Central Africa since 1976 (**Appendix C**).

CDC wishes to extend the use of existing international EVD case and contact investigation forms. This will be the first information collection request (ICR) to be submitted for PRA clearance for ongoing case and contact investigations conducted by CDC beyond the agency's most recent emergency approval ["2014 Emergency Response to Ebola in West Africa" (OMB Control No. 0920-1033, expiration date 4/30/2015)]. As new knowledge about potential routes of Ebola transmission was encountered, new forms for sexual transmission were developed. These are also included in the current ICR.

Maintaining a three-year approval for future outbreaks will eliminate the need for the multiple steps in emergency approvals experienced in the first year of the 2014 Ebola Virus Response. This ICR is generalized to cover any West African country in any future response. To define the covered countries and their associated time and cost burden estimates per ICR, we used the United States Agency for International Development (USAID) list of 21 countries in the West Africa region² (**Appendix D**). Obtaining pre-approval for any West African country will allow the CDC to move quickly to establish Ebola case and contact surveillance without delay.

3. Use of Improved Information Technology and Burden Reduction

For proper control of Ebola outbreaks, efficient identification of cases and contact tracing needs to occur. In the field, the data needed to accomplish this may be collected by CDC staff on behalf of local MoH authorities. Data collected from hardcopy forms will be entered into Epi-Info, or a database designed by the MoH. When information technology is not available, hard copy forms will be completed and transmitted through fax, email, or other means. We estimate that the percentage of estimated annualized burden hours that will be incurred by respondents using improved information technology such as CDC's Epi-Info is approximately 20 percent.

4. Efforts to Identify Duplication and Use of Similar Information

Active surveillance requires the continuous collection of information so that EVD transmission can be monitored and systematic and complete case identification is achieved throughout an outbreak. All collections of information from cases and contacts are unique and specific to the 2014 Ebola public health emergency in any given country. The information is needed to dynamically track each country's success in eliminating Ebola transmission district-by-district, and to identify where infection control resources should be directed.

- French Benin, Burkina Faso, Cameroon, Côte D'Ivoire, Equatorial Africa, Gabon, Guinea, Mali, Niger, Senegal, and Togo.
- English The Gambia, Ghana, Liberia, Nigeria, and Sierra Leone.
- Portuguese Cape Verde, Guinea-Bissau, Sao Tome and Principe.
- Arabic Chad and Mauritania.

¹ Previously, West Africa EVD surveillance data collection forms were approved for 90 days as a series of generic information collections (GenICs) under the "*Generic Emergency Epidemic Investigation Data Collections*" (OMB Control No. 0920-1011). The last GenIC had an expiration date of 12/31/2014. These forms were migrated into and their approvals were extended to 04/30/2015 under the emergency request (OMB Control No. 0920-1033).

² By official language, the 21 countries in West Africa are:

5. Impact on Small Businesses or Other Small Entities

There is no anticipated impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

CDC activities regarding the international Ebola response would be significantly hindered if it were not able to collect the information at the frequency necessary to prohibit the spread of this disease. Standard treatment for Ebola is still limited to treating the symptoms as they appear and to using supportive care. A strong, coordinated response is essential to interrupt the outbreak.

- Individuals designated for active Ebola monitoring are asked to undergo two health checks every day for 21 days. This includes: (1) temperature checks; (2) health symptom checks; and (3) writing these results in a log. Reporting frequency is specified for each ICR.
- A country's Ebola outbreak is considered to be over when 42 days has passed (double the 21-day incubation period of Ebola virus) after the last patient in isolation tests negative for the virus in blood.

There are no known legal obstacles to reduce the burden. Collecting information less frequently than the CDC recommendations will interfere with the public health actions required to contain EVD transmission and to do everything possible to limit, if not stop, deaths due to this disease.

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. The broad 60-day Federal Register Notice was published on Friday, March 27, 2015 (*Federal Register*, Vol. 80, No. 59, pp. 16405-16408 (**Appendix B**). No public comments were received.

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. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality has been obtained. The Privacy Act is not applicable. See Section A.10.1.8 for further explanation.

Information in identifiable form (IIF) will be collected from the cases or persons under investigation (PUIs), and from others such as MoH staff and healthcare providers and facility staff. IIF will be stored on MoH servers. As respondents, international public health authorities and healthcare providers will respond as representatives of their agencies or facilities in their business roles. To protect case and PUI identities, these entities will be reminded that release of identifiable personal information must be in accordance with the privacy requirements of their own jurisdictions.

The Human Subjects Regulations Advisor for the CDC emergency response has reviewed the proposed ICR, which is determined to be public health response and not research. CDC Institutional Review Board (IRB) review and approval is not required.

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

10.1. Privacy Impact Assessment

10.1.1. Overview of the data collection system

The investigations will follow a case series study design. Forms are collected through interviews of patients or family members if patients have died, are too ill to respond, or are infants. Relevant clinical data, including the patient's date of onset, date of death, hospitalization and funeral information, and contacts that the patient had after developing illness are collected in an effort to determine the risk factors that led to the patient's infection. Forms are translated into the following official languages in West Africa to allow this ICR to cover any future Ebola outbreak: English, French, Portuguese, and Arabic (**Appendix D**).

Type of Respondent	Attachment No.	Form Name	Description
General Public	1-4	Viral Hemorrhagic Fever Case Investigation Short Form	The Viral Hemorrhagic Fever Case Investigation
General Public	5-8	Viral Hemorrhagic Fever Case Investigation Form	 Forms and the Viral Hemorrhagic Fever Contact Listing Forms will be collected for every patient meeting the suspect case definition criteria and their
General Public	9-12	Viral Hemorrhagic Fever Contact Listing Form	contacts.
General Public	13-16	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form	If diagnostic testing confirms that a patient has EVD, a separate contact tracing form is completed to collect information of people who had contact with the patient while they were ill and prior to treatment in a facility with barrier nursing. These contacts are then followed daily for onset of fever and other EVD symptoms, and will be investigated as cases and treated under barrier nursing precautions if they develop illness.
General Public	17-20	Ebola Virus Disease Case Contact Questionnaire	The Ebola Virus Disease Case Contact Questionnaire will be used to assess the risk of exposure in identified contacts provided by patients to further inform the need for monitoring and movement restrictions, if necessary, in identified contacts.
General Public	21.24	Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form	This form is intended to be used to collect information to investigate and document possible sexual transmission from survivors of Ebola virus disease to their sex partners. The information collected on the forms will enable the public health authorities in affected countries to rapidly implement appropriate control measures to prevent the introduction and spread of EVD into and within their borders. Data collected on these forms will be

Healthcare Workers or Proxy	25-28	Healthcare Worker Ebola Virus Disease Exposure Report - West Africa (CDC- WHO)	used by public health authorities in these countries to make decisions about risks for illness among people with potential exposure to the Ebola virus as well as its communicability. The purpose of these forms is to investigate cases of Ebola virus disease in health care workers to determine what facility-based risk factors may have led to their infection, to allow for corrective changes
Healthcare Workers or Proxy	29	Healthcare Worker Ebola Virus Investigation Questionnaire (Liberia)	in health care facility infection prevention practices and to contribute to epidemiologic understanding of the Ebola epidemic in order to combat it more
Healthcare Workers or Proxy	30	Healthcare Worker Ebola Virus Disease Exposure Report (Sierra Leone)	effectively. These forms were developed through a consultative process between the national Ministry of Health and implementing partners, based on experience piloting earlier versions. CDC was involved as a consultant in its development. The request for multiple forms with small differences for each country in which they will be deployed reflects the reality on the ground.
Healthcare Workers or Proxy	31-34	Health Facility Assessment and Case Finding Survey (English and French)	The Health Facility Assessment and Case Finding Survey will be used to assess the cases found through use of the tracing form and Contact Questionnaire and the capacity of health facilities to triage such cases safely and properly. The information will be collected via direct oral interviews or by written surveys by public health personnel and healthcare providers.

10.1.2. Items of information to be collected The following IIF will be collected:

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

10.1.3. How information will be shared and for what purpose Identifiable data will belong to the MoH. This data will be stored in a MoH-owned database. Information owned by the MoH may be shared with CDC for assistance with data analysis and

publications as agreed, and joint analysis will be collaboratively performed by the MoH and CDC staff. While in the field, CDC will have access to identifiable information. Data delivered to the CDC for statistical analysis will be de-identified. The data will not be shared except in de-identified or aggregate formats. Datasets with individual records will not be shared beyond the various partnerships, to the extent allowed by law.

10.1.4. Impact on the respondent's privacy

In the field, the respondents' identities may be known to CDC. Case, patient, PUI, 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 privacy. CDC will make every effort to secure the information as described in Section A.10.1.7.

10.1.5. Whether individuals are informed that providing the information is voluntary or mandatory Respondents are informed that response is not mandatory; it is collected on a voluntary basis. If applicable, respondents are informed that biologic specimens are collected to provide information for the purpose of prevention and control of the Ebola virus outbreak, and no information will be used for the primary purpose of conducting research to contribute to generalizable knowledge.

10.1.6. Opportunities to consent, if any, to sharing and submission of information Respondents do not have to participate; participation is voluntary.

10.1.7. How the information will be secured

Data security in international fields will vary dependent on country and MoH procedures. Data collected and managed by CDC staff in the field will be strictly under CDC safeguards: restriction of access to authorized users, physical safeguards, and procedural safeguards.

<u>Authorized users:</u> 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.

<u>Physical safeguards:</u> 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.

10.1.8. Whether a system of records is being created under the Privacy Act. No system of records is being created because the Privacy Act does not apply.

- A system of records consists of any item, collection, or grouping of information about an
 individual, where those records can be retrieved by the name of the individual or by some other
 type of identifier unique to the individual.
- To qualify as a Privacy Act record, the information must identify an individual.
 - O The Privacy Act covers only records in the possession and control of federal agencies.
 - O The MoHs are the owners of the data and will not deliver data for storage on CDC servers except in coded or aggregate formats. These records will not be retrievable by any identifiers from CDC servers.
 - O The Privacy Act applies to records maintained on a living individual who is "a citizen of the United States or an alien lawfully admitted for permanent residence." All participants will be from West African countries; therefore, their records are not afforded privacy protections under the Act.

Regardless of the Privacy Act not applying to this information collection, CDC will take all efforts to the extent possible to protect the privacy of respondents' records in collaboration with the MoHs.

11. 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; circumstances about exposure to ill or dead people or their bodily fluids; history of illness, pregnancy, and sexual practices to accurately determine a respondent's public health risk for EVD;
- 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

See **Appendix D** for details and references for our international estimation assumptions. Time burden was weighted to account for country population estimates and four official languages (English, French, Portuguese, and Arabic).

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (English)	15,476	1	10/60	2,579
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (French)	10,122	1	10/60	1,687

General Public	Viral Hemorrhagic Fever Case Investigation Short Form (Portuguese)	176	1	10/60	29
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (Arabic)	1,226	1	10/60	204
General Public	Viral Hemorrhagic Fever Case Investigation Form (English)	1,720	1	20/60	573
General Public	Viral Hemorrhagic Fever Case Investigation Form (French)	1,125	1	20/60	375
General Public	Viral Hemorrhagic Fever Case Investigation Form (Portuguese)	19	1	20/60	6
General Public	Viral Hemorrhagic Fever Case Investigation Form (Arabic)	136	1	20/60	45
General Public	Viral Hemorrhagic Fever Contact Listing Form (English)	171,960	1	15/60	42,990
General Public	Viral Hemorrhagic Fever Contact Listing Form (French)	112,470	1	15/60	28,118
General Public	Viral Hemorrhagic Fever Contact Listing Form (Portuguese)	1,950	1	15/60	488
General Public	Viral Hemorrhagic Fever Contact Listing Form (Arabic)	13,620	1	15/60	3,405
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (English)	171,960	1	63/60	180,558
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (French)	112,470	1	63/60	118,094
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (Portuguese)	1,950	1	63/60	2,048
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (Arabic)	13,620	1	63/60	14,301
General Public	Ebola Virus Disease Case Contact Questionnaire (English)	171,960	1	5/60	14,330
General Public	Ebola Virus Disease Case Contact Questionnaire (French)	112,470	1	5/60	9,373
General Public	Ebola Virus Disease Case Contact Questionnaire (Portuguese)	1,950	1	5/60	163
General Public	Ebola Virus Disease Case	13,620	1	5/60	1,135

	Contact Questionnaire					
	(Arabic)					
	Ebola Outbreak Response					
	Sexual Transmission Adult	2.420		00//0		
General Public	Case Investigation Form	3,439	1	30/60	1,720	
	(English)					
	Ebola Outbreak Response					
General Public	Sexual Transmission Adult	2,249	1	30/60	1,125	
General Fublic	Case Investigation Form	2,247	1	30/00	1,123	
	(French)					
	Ebola Outbreak Response					
General Public	Sexual Transmission Adult	39	1	30/60	20	
General Tublic	Case Investigation Form	07	_	30,00	20	
	(Portuguese)					
	Ebola Outbreak Response					
General Public	Sexual Transmission Adult	273	1	30/60	137	
General Tublic	Case Investigation Form	2,0	_	00,00	107	
	(Arabic)					
Healthcare	Healthcare Worker Ebola					
Workers or	Virus Disease Exposure	2,455	1	30/60	1,228	
Proxy	Report - West Africa (CDC-	•			,	
,	WHO) (English)					
Healthcare	Healthcare Worker Ebola					
Workers or	Virus Disease Exposure	1,687	1	30/60	844	
Proxy	Report - West Africa (CDC-					
	WHO) (French) Healthcare Worker Ebola					
Healthcare	Virus Disease Exposure					
Workers or	Report - West Africa (CDC-	29	1	30/60	15	
Proxy	WHO) (Portuguese)					
	Healthcare Worker Ebola					
Healthcare	Virus Disease Exposure					
Workers or	Report - West Africa (CDC-	204	1	30/60	102	
Proxy	WHO) (Arabic)					
Healthcare	Healthcare Worker Ebola					
Workers or	Virus Investigation	52	1	30/60	26	
Proxy	Questionnaire (Liberia)			·		
Healthcare	Healthcare Worker Ebola					
Workers or	Virus Disease Exposure	73	1	30/60	37	
Proxy	Report (Sierra Leone)					
Healthcare	Health Facility Assessment					
Workers or	and Case Finding Survey	3,439	1	30/60	1,720	
Proxy	(English)					
Healthcare	Health Facility Assessment					
Workers or	and Case Finding Survey	2,249	1	30/60	1,125	
Proxy	(French)					
Healthcare	Health Facility Assessment					
Workers or	and Case Finding Survey	39	1	30/60	20	
Proxy	(Portuguese)					
Healthcare	Health Facility Assessment		_			
Workers or	and Case Finding Survey	273	1	30/60	137	
Proxy	(Arabic)					

Total		428,757
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B. Estimated Annualized Burden Costs

See **Appendix D** for details and references for our international estimation assumptions. Cost burden was weighted to account for country population estimates and four official languages (English, French, Portuguese, and Arabic).

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (English)	2,579	\$0.55	\$1,418.45
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (French)	1,687	\$0.43	\$725.41
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (Portuguese)	29	\$0.34	\$9.86
General Public	Viral Hemorrhagic Fever Case Investigation Short Form (Arabic)	204	\$0.30	\$61.20
General Public	Viral Hemorrhagic Fever Case Investigation Form (English)	573	\$0.55	\$315.15
General Public	Viral Hemorrhagic Fever Case Investigation Form (French)	375	\$0.43	\$161.25
General Public	Viral Hemorrhagic Fever Case Investigation Form (Portuguese)	6	\$0.34	\$2.04
General Public	Viral Hemorrhagic Fever Case Investigation Form (Arabic)	45	\$0.30	\$13.50
General Public	Viral Hemorrhagic Fever Contact Listing Form (English)	42,990	\$0.55	\$23,644.50
General Public	Viral Hemorrhagic Fever Contact Listing Form (French)	28,118	\$0.43	\$12,090.74
General Public	Viral Hemorrhagic Fever Contact Listing Form (Portuguese)	488	\$0.34	\$165.92
General Public	Viral Hemorrhagic Fever Contact Listing Form (Arabic)	3,405	\$0.30	\$1,021.50
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (English)	180,558	\$0.55	\$99,306.90
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (French)	118,094	\$0.43	\$50,780.42

	1			
General Public	Viral Hemorrhagic Fever Contact Tracing Follow-Up	2,048	\$0.34	\$696.32
	Form (Portuguese) Viral Hemorrhagic Fever			
General Public	Contact Tracing Follow-Up Form (Arabic)	14,301	\$0.30	\$4,290.30
General Public	Ebola Virus Disease Case Contact Questionnaire (English)	14,330	\$0.55	\$7,881.50
General Public	Ebola Virus Disease Case Contact Questionnaire (French)	9,373	\$0.43	\$4,030.39
General Public	Ebola Virus Disease Case Contact Questionnaire (Portuguese)	163	\$0.34	\$55.42
General Public	Ebola Virus Disease Case Contact Questionnaire (Arabic)	1,135	\$0.30	\$340.50
General Public	Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (English)	1,720	\$0.55	\$946.00
General Public	Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (French)	1,125	\$0.43	\$483.75
General Public	Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (Portuguese)	20	\$0.34	\$6.80
General Public	Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (Arabic)	137	\$0.30	\$41.10
Healthcare Workers or Proxy	Healthcare Worker Ebola Virus Disease Exposure Report - West Africa (CDC- WHO) (English)	1,228	\$5.23	\$6,422.44
Healthcare Workers or Proxy	Healthcare Worker Ebola Virus Disease Exposure Report - West Africa (CDC- WHO) (French)	844	\$4.29	\$3,620.76
Healthcare Workers or Proxy	Healthcare Worker Ebola Virus Disease Exposure Report - West Africa (CDC- WHO) (Portuguese)	15	\$3.38	\$50.70
Healthcare Workers or Proxy	Healthcare Worker Ebola Virus Disease Exposure Report - West Africa (CDC- WHO) (Arabic)	102	\$3.02	\$308.04
Healthcare Workers or	Healthcare Worker Ebola Virus Investigation	26	\$7.50	\$195.00

Proxy	Questionnaire (Liberia)			
Healthcare	Healthcare Worker Ebola			
Workers or	Virus Disease Exposure	37	\$7.00	\$259.00
Proxy	Report (Sierra Leone)			
Healthcare	Health Facility Assessment			
Workers or	and Case Finding Survey	1,720	\$5.51	\$9,477.20
Proxy	(English)			
Healthcare	Health Facility Assessment			
Workers or	and Case Finding Survey	1,125	\$4.29	\$4,826.25
Proxy	(French)			
Healthcare	Health Facility Assessment			
Workers or	and Case Finding Survey	20	\$3.38	\$67.60
Proxy	(Portuguese)			
Healthcare	Health Facility Assessment			
Workers or	and Case Finding Survey	137	\$3.02	\$413.74
Proxy	(Arabic)			
Total				\$10,043.20

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 estimated annual cost to the federal government is based on the federal general schedule (GS) pay scale for the federal employees involved in the development, oversight and analysis of the data collections is \$3,707,498. We assume that the CDC will support the MoHs for the duration of the annual burden hours of information collection for the various respondent types and affected countries. This is a maximized estimated cost based on the CDC experience in the 2014 Ebola Virus Response.

For any given outbreak, we assume at most that one-half of the West African countries (n=8) may require CDC personnel to support the response from headquarters. CDC personnel may also deploy and position themselves in an affected country, or pre-position themselves in the likelihood of an Ebola outbreak in an unaffected bordering country (**Appendix D**). In some of these unaffected countries, the Ebola outbreak may not materialize; however, as a preventive measure, the CDC must be in the field should disease transmission cross country borders. The estimated cost to the federal government is maximized to include these scenarios.

Less CDC staff time is needed in countries where existing EVD surveillance systems are established (e.g., Sierra Leone, Guinea, and Liberia); however, we include potential costs for the establishment of such systems in other countries where none previously exist. As country surveillance systems are established, the cost of US government-provided support may decrease in Years 2 and 3 of OMB approval.

Annualized Atlanta-based Support Hourly Wage†					
Design of methods	Design of methods 8 FTE 40 hours GS14 \$55.97 \$17,910.40				
Statistical support	8 FTE 1,040 hours	GS13 \$47.36	\$394,035.20		
Field-based Support Hourly Wage‡					
Field operations support	24 FTE 2,080 hours	GS14 \$55.97	\$2,364,211.20		
Data management 8 FTE 2,080 hours GS13 \$47.36 \$931,340.80					

Total salary costs \$3,707,497.60

http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/ATL h.pdf

- † Because methods are already established, assume 1 FTE at headquarters provides 1 40-hour work week (40 hours) for design of methods and 1 FTE at headquarters provides statistical support for 26 40-hour work weeks (1,040 hours) per country.
- ‡ Assume 3 FTEs as field operations support and 1 FTE as data manager per country; each working 52 40-hour work weeks (2,080 hours).

15. Explanation for Program Changes or Adjustments

Attachments 21-24 (Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form) are new forms. This is a case investigation form for gathering information about an Ebola case where it is suspected that the exposure was from sexual contact with a person who has recovered (e.g., a survivor). This form would be used in combination with the Viral Hemorrhagic Fever case investigation short or long form in use to investigate Ebola cases (**Attachments 1-8**).

For the current outbreak, forms were approved in English and French for a selection of forms required for the current outbreak in Guinea, Liberia, and Sierra Leone. The potential need for additional language translations was recently identified as a cluster of EVD cases in French-speaking Guinean counties bordering Portuguese-speaking Guinea-Bissau emerged. To address this identified preparedness need, this ICR provides translations for all forms in four official languages in West African countries (English, French, Portuguese, and Arabic).

16. Plans for Tabulation and Publication and Project Time Schedule

Containment measures and core public health intervention are still active in Guinea, Liberia, and Sierra Leone. This ICR is also developed to allow the CDC to assist any West African MoH for future Ebola outbreaks; therefore, a detailed timeline is not available.

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.

References

- 1. Centers for Disease Control and Prevention (CDC). 2014 Ebola Outbreak in West Africa Case Counts, January 4, 2015 (updated January 6, 2015). Accessed January 6, 2015 at http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html.
- 2. Karwowski M, Meites E, Fullerton K, Stroher U, Lowe L, Rayfield M, Blau D, Knust B, Gindler J, Van Beneden C, Bialek S, Mead P, Oster A. Clinical inquiries regarding ebola virus disease received by CDC United States, July 9–November 15, 2014. *MMWR*. 2014; 63(49):1175-1179. Accessed February 18, 2015 at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a8.htm?scid=mm6349a8 w.

List of Appendices and Attachments

- Appendix A. Authorizing Legislation
- Appendix B. 60-day Federal Register Notice
- Appendix C. Ebola Virus Disease Distribution and Chronology
- Appendix D. West Africa Definitions and Burden and Wage Estimates

Forms

- Attachment 1. Viral Hemorrhagic Fever Case Investigation Short Form (English)
- Attachment 2. Viral Hemorrhagic Fever Case Investigation Short Form (French)
- Attachment 3. Viral Hemorrhagic Fever Case Investigation Short Form (Portuguese)
- Attachment 4. Viral Hemorrhagic Fever Case Investigation Short Form (Arabic)
- Attachment 5. Viral Hemorrhagic Fever Case Investigation Form (English)
- Attachment 6. Viral Hemorrhagic Fever Case Investigation Form (French)
- Attachment 7. Viral Hemorrhagic Fever Case Investigation Form (Portuguese)
- Attachment 8. Viral Hemorrhagic Fever Case Investigation Form (Arabic)
- Attachment 9. Viral Hemorrhagic Fever Contact Listing Form (English)
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- Attachment 12. Viral Hemorrhagic Fever Contact Listing Form (Arabic)
- Attachment 13. Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (English)
- Attachment 14. Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (French)
- Attachment 15. Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (Portuguese)
- Attachment 16. Viral Hemorrhagic Fever Contact Tracing Follow-Up Form (Arabic)
- Attachment 17. Ebola Virus Disease Case Contact Questionnaire (English)
- Attachment 18. Ebola Virus Disease Case Contact Questionnaire (French)
- Attachment 19. Ebola Virus Disease Case Contact Questionnaire (Portuguese)
- Attachment 20. Ebola Virus Disease Case Contact Questionnaire (Arabic)
- Attachment 21. Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (English)
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- Attachment 23. Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (Portuguese)
- Attachment 24. Ebola Outbreak Response Sexual Transmission Adult Case Investigation Form (Arabic)
- Attachment 25. Healthcare Worker Ebola Virus Disease Exposure Report West Africa (CDC-WHO) (English)
- Attachment 26. Healthcare Worker Ebola Virus Disease Exposure Report West Africa (CDC-WHO) (French)
- Attachment 27. Healthcare Worker Ebola Virus Disease Exposure Report West Africa (CDC-WHO) (Portuguese)
- Attachment 28. Healthcare Worker Ebola Virus Disease Exposure Report West Africa (CDC-WHO) (Arabic)
- Attachment 29. Healthcare Worker Ebola Virus Investigation Questionnaire (Liberia)
- Attachment 30. Healthcare Worker Ebola Virus Disease Exposure Report (Sierra Leone)
- Attachment 31. Health Facility Assessment and Case Finding Survey (English)
- Attachment 32. Health Facility Assessment and Case Finding Survey (French)
- Attachment 33. Health Facility Assessment and Case Finding Survey (Portuguese)
- Attachment 34. Health Facility Assessment and Case Finding Survey (Arabic)