

**Ebola Transmission Dynamics among Household Contacts in West Africa:  
a Public Health Response Evaluation in Western Area, Sierra Leone**

**Request for OMB Approval for an  
Emergency Information Collection Request**

**January, 2015**

**Supporting Statement A  
Justification**

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# **Ebola Transmission Dynamics among Household Contacts in West Africa: a Public Health Response Evaluation in Western Area, Sierra Leone Emergency Information Collection Request**

## **A. Justification**

### **1. Circumstances making the Collection of Information Necessary**

Beginning on March 10, 2014, West Africa experienced the largest known Ebola virus disease (EVD) epidemic with approximately 13,000 persons infected by the end of October (1,2). As of December, 2014, continued federal assistance in West Africa indicates that it is important to identify the factors that sustain ongoing transmission of disease among household members, as it is unknown how household transmission affects spread of EVD. Sierra Leone now has the greatest number of confirmed cases of any of the affected countries, and its Western Area has one of the highest incidence rates in Sierra Leone. The Sierra Leone Ministry of Health and Sanitation (MOH), with CDC assistance, proposes to investigate risk factors associated with household transmission which can be used to develop public health interventions to arrest ongoing spread of disease.

Transmission of Ebola in the rural areas of Sierra Leone typically occurs through attending funerals, participating in unsafe burial practices, and to a lesser extent, through household transmission. In a densely populated area, such as Western Area, Sierra Leone, it is unknown if household contact is a major route of transmission. CDC will be requesting a regular clearance to help understand the potential role of household contact associated with the current outbreak in Western Africa more generally, but to expedite the initiation of this work, the CDC is seeking an emergency 180-day OMB approval to conduct information collections related to EVD investigations among household cohorts and individual household contacts of case-patients in Western Area, Sierra Leone. In the short term, the information collected via this emergency clearance will enhance the MOH in Sierra Leone's ability to identify more targeted control measures, thus more rapidly control the spread of EVD within its country's affected households.

These information collections are authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Appendix A).

### **2. Purpose and Use of Information Collection**

The purpose of this public health response evaluation is to identify and control an emergency health problem. Because the global case fatality rate averages about 50% (3), the urgency to collect this needed information quickly is of the utmost importance to control EVD transmission in West Africa. Eventually, (through a regular ICR clearance mechanism), this project is expected to be implemented up to five times throughout the countries highly affected by EVD in West Africa. Future projects are expected to follow similar designs, though adjustments may be made to accommodate local context, new information, and/or the evolving situation in West Africa. Beyond this emergency request

for Western Area, Sierra Leone, OMB PRA approval will be sought prior to beginning these future information collections.

The data collected from this project will be used to characterize key epidemiological transmission features of Ebola virus among household contacts of individuals known to be infected. Because Ebola transmission frequently occurs through direct contact, knowledge of these transmission factors in households will help to determine whether future control measures can be implemented through effective resource allocations to potentially limit/stop Ebola transmission in affected communities. In addition, this project will provide insight on potential recommendations of preventive measures to interrupt household transmission. Evaluating the case definition for Ebola will help ensure that all persons with Ebola can be promptly detected and isolated, thus preventing further exposure and breaking the chain of transmission. For quickly spreading, high mortality outbreaks in resource-constrained environments, like the current Ebola epidemic in Sierra Leone, identifying the transmission factors is crucial to contain the outbreak and prevent further transmission.

Specific primary objectives are:

- Measure the secondary symptomatic attack rate of Ebola among household cohorts and individual household contacts of case-patients in Western Area Sierra Leone;
- Identify the household transmission risk factors driving the secondary attack rate;
- To measure the association between secondary transmission and types of contact (direct, indirect), interaction, and other risk or protective factors for household contacts of a person diagnosed with Ebola virus; and
- Identify the stage of illness at which cases are most infectious.

Information from this project will be used to describe the features of household transmission of Ebola virus. Knowing the age of highest risk of household transmission, risk factors among household contacts and exposures as well as the time period of greatest transmissibility will assist in creating and targeting public health interventions to decrease spread of the disease. These public health interventions can be applied to control the current outbreak and efficiently contain future outbreaks.

### **3. Use of Improved Information Technology and Burden Reduction**

A CDC data manager will oversee data management and data integration activities. Locally hired project assistants trained in conducting interviews and the ethical protection of human subjects will be the data collectors. They will be trained to conduct case, household, and contact interviews using tablet computers programmed with an Epi Info data entry platform (paper questionnaires will be used as backup).

Local data entry staff will be hired and trained as needed to enter questionnaire data. Contact tracing data will be entered into the Epi Info VHF Application following

standard procedures; in collaboration with the MOH, the project will provide supplemental support for hiring and training contact tracing data entry staff as needed.

Case information will be entered by project staff into the project database. The CDC data manager will integrate all data sources for analysis using SAS or SPSS. A de-identified data set will be shared with CDC staff in Sierra Leone and Atlanta for analysis. The MOH will maintain ownership over all data.

We estimate that 80% percent of estimated annualized burden hours that will be conducted using improved information technology such as Epi-Info.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

This is the first information collection related to risk factors for household transmission of EVD in this setting. There is no duplication or similar information.

#### **5. Impact on Small Businesses or Other Small Entities**

This is a household investigation. None of the respondents will be small businesses or other small entities.

#### **6. Consequences of Collecting the Information Less Frequently**

On an individual basis, it is anticipated that respondents will be requested to provide information one time per form administered. If data are not collected at the recommended frequency from the respondents, there is a risk of continued transmission of EVD both in West Africa and potentially into the US by travel related routes. There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation in 5 CFR 1320.5.

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

A. OMB has waived the requirement to publish a 60-day and a 30-day Federal Register Notice seeking public comment.

B. As part of the emergency request and understanding that the potential for household transmission of EVD is ongoing in Western Area, Sierra Leone, the request for public comment and external consultation has been waived by OMB. For this project, the Sierra Leone MOH is involved in the concept, design, planning, staff hiring, data collection, analysis, reporting, and data storage. The Sierra Leone MOH will ensure coordination of project activities with routine MOH response activities. Data from routine MOH response activities (case investigation and contact tracing) will be shared for project purposes. The Sierra Leone MOH

will advise in hiring local project assistants and data entry staff. Project assistants will interact with participants; project assistants and data entry staff will have access to individually identifiable data.

CDC will provide technical assistance in all project aspects and will supervise field staff and lead data analysis. As supervisory staff, CDC field staff will interact with participants and have access to individually identifiable data. The CDC Country Lead for the Ebola response will serve as the principal investigator.

## **9. Explanation of Any Payment or Gift to Respondents**

There is no payment or gift to respondents.

## **10. Assurance of Confidentiality Provided to Respondents**

This ICR has been reviewed by the OMB PRA Advisor for the CDC emergency response who determined that the Privacy Act does apply.

In addition, the Human Subjects Regulatory Advisor for the CDC emergency response has reviewed the proposed information collection, which is determined to be public health response and not research. CDC Institutional Review Board (IRB) review and approval is not required. The Sierra Leone MOH National Ebola Pillar has also determined this project to be non-research and is “thereby exempt from Sierra Leone Ethics and Scientific Review Committee clearance requirements.” This project is not intended to create generalizable knowledge outside of the scope of the current Ebola epidemic, and will impose minimal risk or hardship to the study population.

### **10.1. Privacy Impact Assessment**

#### *10.1.1. Overview of the data collection system*

**Appendix C** provides a schematic on the existing Ebola surveillance system and alert criteria. Once reported, suspect cases are visited by case investigators. If the individual meets the case definition for suspect case he/she is removed from the household and relocated to a holding facility to await laboratory confirmation of infection. As part of the initial evaluation, contacts of the suspect case-patient are identified and recorded. These contacts are then monitored pending laboratory confirmation of infection in the suspect case-patient, with daily visits from case monitoring staff from the MOH. In the event that infection is confirmed in the case-patient, daily monitoring of the contacts continues for 21 days after last contact with the case-patient. These routine MOH procedures will be conducted by MOH staff.

This project will supplement this existing surveillance system and will involve the monitoring of household contacts of a convenience sample of first cases of laboratory confirmed Ebola infection in a household. Case-patients will be identified prospectively through the existing alert system for Ebola suspect case notification managed by the Sierra Leone MOH. The laboratory confirmed case-

patients and their household contacts identified during this project will make up the project cohort. To accomplish primary objectives, once infection is confirmed in the case-patient, a questionnaire will be administered to: 1) the case-patient or caregiver (as proxy) to document clinical time course in household (**Attachment 1**); 2) heads of households to document household characteristics (**Attachment 2**); and 3) all household contacts to document the nature, duration, and intensity of interaction between the contact and the case-patient and the stage of illness of the case-patient at the time of isolation and last interaction with the contact (**Attachment 3**). To maximize information quality during interviews (**Attachment 1&3**), the proxy for the case-patient and household contacts may coincidentally use a visual storyboard to diagram and display the time course of case-patient symptoms and the contacts' exposures/protective behaviors while the case-patient was in the household (**Attachment 4**). The time burden for using the visual storyboard is included in the estimates for both **Attachment 1 and 3**. Monitoring will continue until 21 days after the last exposure of an enrolled contact to a confirmed case-patient in the household environment. A brief exit questionnaire (**Attachment 5**) will also be administered to household contacts at the end of the contact monitoring period to document any additional non-household exposures. Symptomatic contacts will be reported through the standard alert system and tested according to standard MOH practices. Project staff will record lab results to confirm Ebola transmission status using a patient laboratory record (**Attachment 6**). Each of these forms is listed in Table A.12.A.

The CDC role is described below:

- The CDC is not providing monetary resources for the collection of information.
- The CDC initiated the idea for the project. The information obtained will assist in creating and targeting public health interventions to decrease spread of the disease in Sierra Leone.
- The CDC designed and had significant input or control into the design of the data collection instruments.
- The CDC will provide technical assistance for analysis and reporting jointly with MOH staff.
- Locally hired staff trained in conducting interviews and the ethical protection of human subjects will collect the data.
- Joint data analysis will be collaboratively performed by the MOH and CDC staff.
- The CDC will be co-authors on manuscripts from this project.

#### *10.1.2. Items of information to be collected*

This data collection includes the following information in identifiable form:

Name

Age or Date of Birth

Household Address

Global Positioning System (GPS) Coordinates of Household

Medical Information and Notes

Medical Records Numbers  
Occupation or Employment Status  
Other – list of personal identities of contacts at time of onset of EVD case symptoms

*10.1.3. How information will be shared and for what purpose*

Data will belong to the MOH, and joint analysis will be collaboratively performed by the MOH and CDC staff. The data will be stored in a MOH-owned database. 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.

*10.1.4. Impact on the respondent's privacy*

Data are treated in a private manner, unless otherwise compelled by law. Highly sensitive information is being collected and would affect a respondent's privacy if there were a breach of confidentiality. 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 about the voluntary nature of their participation (**Attachments 1-3**).

*10.1.6. Opportunities to consent, if any, to sharing and submission of information*

Verbal consent scripts are included on the information collection forms (**Attachments 1-3**). Project assistants will obtain verbal consent from respondents prior to conducting all questionnaires. For children under the age of 18 years old, interviewers will obtain permission to participate from parents or guardians. Project assistants will be encouraged to use the consent script included in the questionnaires, but specific language may be added at the discretion of the Sierra Leone MOH.

*10.1.7. How the information will be secured*

Project assistants will be trained in ethics and the protection of respondent privacy and rights. All supplemental information collected during the project (information collected beyond routine case/contact management practices) will be kept private to the extent allowable by law. Completed information collection records will be secured by the data collectors at all times. Information recorded in the data management system will be password protected. Data shared with CDC for analysis will be de-identified (the following data items will be removed: household location, names of case-patients and household contacts, and dates of birth); only MOH will retain the master list linking participants to their unique identifiers. After analysis and reporting is completed, data from project assistants' computers will be deleted and stored only on the protected CDC LAN for approximately five years while report dissemination, publication, and subsequent



inquiries are completed. Ethical review and approval for the project will be sought from CDC and Sierra Leone MOH ethical review boards.

*10.1.8. Whether a system of records is being created under the Privacy Act.* Records are covered under CDC Privacy Act System Notice 09-20-0113, “Epidemic Investigation Case Records Systems Notice” (**Appendix B**). These data are being collected to fulfill regulatory requirements under the Public Health Service Act, Section 301, “Research and Investigations, (42 U.S.C. 241); Sections 304, 306, and 308(d), which discusses authority to maintain this data (**Appendix A**). The MOH will not deliver data to CDC except in de-identified or aggregate formats. The de-identified data at CDC will be deleted after five years.

**11. Justification for Sensitive Questions**

These forms collect three types of data (**Attachments 1-6**):

- 1) 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 to accurately determine a respondent’s public health risk for EVD;
- 2) Demographic data such as age, ethnicity, sex, and geographic location are routinely collected as part of standard public health surveillance; and
- 3) Identifying and contact information such as name, telephone number, address for follow-up or contact tracing.

All of these data elements are essential to efficiently detect a public health threat and rapidly implement appropriate public health control measures to prevent the introduction and spread of communicable disease.

**12. Estimates of Burden Hours and Costs**

Each row in Table A.12.A corresponds to **Attachments 1-3 and 5-6**, respectively. In order to obtain OMB approval for sufficient burden hours, the estimated number of respondents is maximized by assuming that sufficient resources can be leveraged to conduct the objectives described in Section A.2. The Visual Storyboard (**Attachment 4**) is an interview aid; burden corresponding to its use is included in **Attachments 1 and 3** burden estimates.

For the 180-day emergency approval, the total estimated time burden to Sierra Leone respondents is 791 hours at a total cost burden in respondent wages of \$530 in US dollars (USD).

**A. Estimated Burden Hours**

The estimated number of households needed to meet statistical objectives equals 119. Household size is assumed to be 10; therefore, there will be 1,190 household contacts. It is also assumed that 16 percent of the contacts will become cases (n=191) requiring abstraction of laboratory records.

Type of Respondent	Form	No. of	No. of	Average	Total
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	Name	Respondents	Responses per Respondent	Burden per Response (in hours)	Burden Hours
Case-patients or caregiver (as proxy)	Initial Questionnaire for Case-Patients	119	1	20/60	40
Heads of household	Questionnaire for Ebola-affected Households	119	1	20/60	40
Household contacts of case-patient	Questionnaire for Investigation of Household Contacts of Ebola-infected Case-patients	1,190	1	30/60	595
Household contacts of case-patient	Contact Exit Questionnaire	1,190	1	5/60	100
Laboratory and project staff	Patient Laboratory Record	191	1	5/60	16
Total					791

## B. Estimated Burden Costs

On June 23, 2013, the US Bureau of Labor Statistics discontinued its International Labor Comparisons Program (**Appendix D**). Therefore, we sought public information sources to estimate burden costs among respondents in Sierra Leone. The government of Sierra Leone has approved a monthly minimum wage of 500,000 Sierra Leone Leones (SLL), effective January 1, 2015 (**Appendix E**), which is equal to \$116.14 USD as of December 28, 2014 (**Appendix F**). Presuming there are 173.33 working hours per month (52 weeks per year divided by 12 months per year times 40 working hours per week), the minimum hourly wage in Sierra Leone is \$0.67 USD (\$116.14 per month divided by 173.33 working hours per month). We applied this minimum wage rate to all respondents.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Case-patients or caregiver (as proxy)	Initial Questionnaire for Case-Patients	40	\$0.67	\$26.80
Heads of household	Questionnaire for Ebola-affected Households	40	\$0.67	\$26.80
Household contacts of case-patient	Questionnaire for Investigation of Household Contacts of Ebola-infected Case-Patients	595	\$0.67	\$398.65
Household contacts of case-patient	Contact Exit Questionnaire	100	\$0.67	\$67.00
Laboratory and project staff	Patient Laboratory Record	16	\$0.67	\$10.72
Total				\$529.97

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

There are no capital and maintenance costs incurred by respondents.

#### 14. Cost to the Government

The cost to the federal government is estimated at \$32,212. This estimate represents the amount of time for the CDC staff to advise and to design the data collection methodology, to provide statistical support to the MOH, in addition to the time spent managing the response in the EOC. We presume that the CDC will support the MOH for the duration of the 791 burden hours of information collection over the 180-day emergency approval period in various capacities in the field and in the EOC.

##### Staff Time:

Atlanta-based Support Hourly Wage			
Design of methods	1 FTE 90 hours	GS14 \$55.41	\$4,986.90
	2 FTE 40 hours	GS14 \$55.41	\$4,432.80
Statistical support	2 FTE 50 hours	GS13 \$48.27	\$4,827.00
Field-based Support Hourly Wage			
Field operations support	3 FTE 50 hours	GS14 \$55.41	\$8,311.50
Data management	1 FTE 200 hours	GS13 \$48.27	\$9,654.00
Total salary costs			\$32,212.20
<a href="http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/ATL_h.pdf">http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/ATL_h.pdf</a>			

#### 15. Explanation for Program Changes or Adjustments

This is an emergency information collection request.

#### 16. Plans for Tabulation and Publication and Project Time Schedule

A copy of the project dataset will be provided to the MOH, who will maintain ownership of the data according to standard procedures. In collaboration with the MOH, CDC project staff will summarize project methods and results into a report to be disseminated by the MOH and shared with relevant partners. Results from detailed analyses will be drafted into one or more manuscripts for publication. Data collection is expected to be conducted between January and April 2015; data analysis is expected to be conducted between April and June 2015; reporting and publication is expected to be completed between July and September 2015.

#### 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

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6. Umoquit, M. J., Tso, P., Burchett, H. E., & Dobrow, M. J. (2011). A multidisciplinary systematic review of the use of diagrams as a means of collecting data from research subjects: application, benefits and recommendations. *BMC medical research methodology*, 11(1), 11.

**List of Appendices**

- Appendix A. Authorizing Legislation
- Appendix B. CDC Privacy Act System of Records Notice 09-20-0113
- Appendix C. Ebola Alert Criteria and Surveillance System Schematic
- Appendix D. US Bureau of Labor Statistics International Labor Comparison Program Discontinuation Notice
- Appendix E. Sierra Leone Monthly Minimum Wage Statute
- Appendix F. Sierra Leone Leone (SLL) Currency Conversion to US Dollars

**List of Attachments – Information Collection Forms**

- Attachment 1. Initial Questionnaire for Case-Patients
- Attachment 2. Questionnaire for Ebola-affected Households
- Attachment 3. Questionnaire for Investigation of Household Contacts of Ebola-infected Case-Patients
- Attachment 4. Visual Storyboard (interview aid – burden included in Attachments 1&3 estimates)
- Attachment 5. Contact Exit Questionnaire
- Attachment 6. Patient Laboratory Record