

**Data Supplement for Ebola Virus Disease Patients Treated Outside of West Africa**

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

**June 4, 2015**

**Supporting Statement A  
Justification**

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## **Data Collection for Ebola Virus Disease Patients Treated Outside of West Africa Emergency Information Collection Request**

### **A. Justification**

This is an emergency request for 6-month Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) approval to allow the Centers for Disease Control and Prevention (CDC) to collect clinical data on the presentation, course, and management of patients with Ebola virus disease (EVD) cared for in higher-resource settings outside of West Africa [including in Western Europe and the United States (US), as well as in countries in other regions]. This information collection is necessary to inform the public health response to the ongoing Ebola virus disease outbreak. Due to the urgent need for this information for dissemination to global audiences in a timely manner, the CDC is requesting that OMB approval is granted by June 6, 2015.

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

According to the World Health Organization (WHO) update on May 27, 2015 (1), over 27,000 Ebola virus disease cases with more than 11,000 deaths have been reported in Guinea, Liberia, and Sierra Leone. Although EVD cases have declined, and Liberia has been declared “Ebola-free,” new EVD cases continue to occur in Guinea and Sierra Leone. As of June 2, 2015, twenty-seven patients with Ebola virus disease (EVD) have received care outside of West Africa. This has included patients medically evacuated from the affected countries, patients who developed symptoms after leaving West Africa (imported patients), and patients who had transmission of Ebola virus outside of Africa. These EVD patients have been cared for in medical facilities in Western Europe and in the US where the level of clinical care and monitoring available has been greater than that generally available in Africa. Subsequently, a large amount of information on the clinical course and management of these patients is available; this information has the potential to inform the ongoing prevention efforts, the planning for the public health response, and the management of EVD patients in both higher-resource settings and in West Africa. Previously, clinical data were collected for 23 of 24 EVD patients in the US and Europe as of the end of January 2015 through a prior emergency request (OMB Control No. 0920-1040, expiration date 02/28/2015). This request is to allow further collection of clinical data on these 23 patients and to collect clinical data on additional EVD patients treated outside of West Africa; including four EVD patients previously treated and any additional patients treated in the next six months. This information collection is 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 project will be to collect clinical data on the presentation, course, and management of patients with EVD cared for in higher-resource settings to inform the public health response to the Ebola virus disease outbreak. These data are novel and have the potential to allow for a clearer understanding of the treatment issues associated with the management of an EVD patient and can inform the level and types of care that might be needed in these situations. This can assist providers by clarifying the complications that need to be carefully watched for

and can assist local and national planners by clarifying the types of resources that must be available. These data will not be granular enough and are not intended to provide specific treatment recommendations (i.e., which drugs should be given when) rather, they are intended to provide a description of what might be expected to occur during the course of an EVD patient's illness.

The respondents will be the Centers that have provided care for at least one Ebola virus disease patient in Europe (Madrid, Frankfurt, Leipzig, Hamburg, Paris, Oslo, Geneva, Rome, Utrecht, London) and the US [Emory, National Institutes for Health (NIH), Nebraska, Dallas, Bellevue-NYC] to date and any other new Centers during the remainder of the emergency approval period granted by OMB. The senior clinicians on the treatment teams will complete the forms for the Centers. The Clinical Team on the Medical Care Task Force/Domestic Task Force in the CDC's Emergency Operations Center (EOC) and the clinicians caring for these patients take part in a CDC/WHO International Clinical Network on Clinical Management of Ebola Virus Disease Patients (hereafter, the Clinical Network) that regularly (weekly) convenes by phone to discuss the real-time management of these patients.

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

These clinicians who provided medical care for EVD patients in higher-resource settings will be contacted by email to complete a retrospective data collection for each patient that the Center cared for (**Appendix B**). They will be asked to complete an Excel spreadsheet for each patient (**Appendix C**), and to deliver it using a secure encrypted file transfer protocol (SFTP) site provided by the CDC.

A CDC data manager will oversee data management and data integration activities. The patients' clinical information in electronic format will be imported into the project database. The CDC data manager will integrate all data sources for analysis using SAS or SPSS.

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

Previous Ebola virus disease outbreaks were smaller in scale and patient care was limited to Africa. This will be a continuation of the first information collection of clinical data (OMB Control No. 0920-1040, expiration date 02/28/2015) on the presentation, course, and management of patients with EVD cared for in higher-resource settings in Western Europe and the US. There is no duplication or similar information.

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

The respondents will be Network Centers which are small businesses or small entities. As of June 4, 2015, this data collection will involve fifteen Centers that have treated twenty-seven EVD patients; therefore, the impact on small businesses will be limited.

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

Because there are limited numbers of centers in Western Europe and the US caring for EVD

patients, each respondent will be requested to complete the form for each new patient admitted and treated, or approximately two times. If information is not collected at the recommended frequency from the respondents, the ability to reduce health risks and to improve medical management practices for future EVD patients in higher-resource settings in Western Europe and the US and in lower-resource settings in West Africa will be diminished. There are no legal obstacles to reduce 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. Under the procedures for emergency processing, OMB has waived the requirement to publish a 60-day and a 30-day Federal Register Notice seeking public comment.

B. The clinicians and the CDC participate in the Clinical Network on a regular basis.

## **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. Personally identifiable patient information will be collected. Respondent identities will be known, but these clinicians will respond as representatives of their Centers in their business roles. To protect patients and respondents, data will only be presented in aggregate in reports, and datasets with individual records will not be shared outside of CDC, to the extent allowable by law.

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.

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

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

Senior clinicians whose teams provided medical care for EVD patients in higher-resource settings will be contacted to complete a retrospective data collection form for each patient cared for at the Center. Clinicians will be asked to complete an Excel spreadsheet (**Appendix C**). The data collection methods are the same as the initial emergency request (OMB Control No. 0920-1040, expiration date 02/28/2015).

The data collection form continues to collect data from 12 different domains including:

- Demographics and Background
- First Signs and Symptoms
- Signs and symptoms at first admission (generally in Africa)
- Signs and symptoms at second admission (generally following medical evacuation)
- Clinical findings during hospitalization
- Interventions employed during hospitalization
- Treatments employed
- Investigational Therapeutics given
- Admission laboratory values (from final admission)
- Laboratory testing during hospitalization
- Virology and Immunology laboratory results
- Outcomes

Additional data domains and critical information gaps, not previously collected include:

- Signs and symptoms present on the day that the illness started
- Volume of intravenous fluids administered
- Electrolyte replacement
- Treatment for prothrombotic state
- Markers of inflammation (CRP, ESR) at hospital admission
- Ebola virus testing results (RT-PCR, immunologic, and virology tests) from any sampled body tissue

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 more clearly describe the detailed clinical course of EVD patients managed in higher-resource settings allowing for a better understanding of the complications that might arise and the resources needed to manage them.
- The CDC designed and had significant input or control into the design of the data collection instrument.
- Data analysis will be performed by CDC staff.
- The CDC will co-author reports and manuscripts from this project.

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

As part of the Clinical Network, the clinicians who will respond for their Centers will be known to the CDC. They will be recruited by their business email address.

The following personally identifiable patient information will be collected.

- Geographic locations of EVD diagnosis and clinical treatment
- Dates directly related to the patient (including admission date, date of diagnosis)
- Medical Information and Notes
- Employment Status such as Occupation in an Ebola Treatment Unit (ETU)

Data will be aggregated to summarize the clinical information for patients, to understand resource needs to assist in the public health response. No information will be presented on individual patients. All data will be presented in aggregate and will not be stratified

into subcategories that might allow for identification of individual patients.

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

Statistical analysis will be performed by CDC staff. The data will be stored in a CDC database.

The data will be shared in aggregate format with Clinical Network respondents and with the WHO. Because the number of patients is small, a breach in privacy is a concern, CDC will not include information in these aggregate datasets that may identify the patient, including geographic locations of EVD diagnosis and clinical treatment, and dates directly related to the patient such as admission dates and dates of diagnosis. Suppression of data where small numbers occur is another technique to protect privacy. Variables constructed from potentially identifiable elements such as Center or a patient's country of origin will be anonymized prior to data sharing.

*10.1.4. Impact on the respondent's privacy*

The respondents' identities will be known to the CDC; however, they will be responding as representatives of their Centers in their official clinical role and not as private citizens.

Patient data are treated in a private manner, unless otherwise compelled by law. Highly sensitive information is being collected and would affect a patient'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 (**Appendix B**).

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

In addition to the email invitation, consent information will be provided in **Appendix B**. CDC will not collect written documentation of consent. Potential respondents will be advised that their participation is voluntary and with whom the data will be shared (**Appendix B**).

*10.1.7. How the information will be secured*

The Excel spreadsheet (**Appendix C**) will be completed by the respondent for each patient cared for at the Center. In order to protect the patient's privacy, the completed spreadsheet will be delivered via a SFTP site provided by the CDC. Each Center will have its own SFTP site and password.

The Information Systems Security Officer (ISSO) from the CDC National Center for Zoonotic and Emerging Infectious Diseases (NCEZID) will provide separate SFTP sites for each respondent. Each Center will be able to view its own data and no others'. The ISSO will be the only person who can download the data, and the Clinical Team will retrieve the data in a secure manner from the ISSO.

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 and CDC Quarantine Stations.

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.*

Records are covered under CDC Privacy Act System Notice 09-20-0113, "Epidemic Investigation Case Records Systems Notice" (**Appendix D**). 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**).

## **11. Justification for Sensitive Questions**

The form collects medical and laboratory data which is highly sensitive (**Appendix C**):

- 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 and sex.

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

## 12. Estimates of Burden Hours and Costs

The course of the Ebola virus disease outbreak is unpredictable; therefore, we are allowing for up to six additional Centers to be added to the Clinical Network. The estimated number of responses (number of patients admitted) per respondent is 2. For the 6-month emergency approval, the total estimated time burden to respondents is 32 hours at a total cost burden in respondent wages of \$2,952.

### A. Estimated Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Centers treating Ebola patients	US/WHO International Clinical Network Ebola Virus Disease Clinical Data Collection Tool	21	2	45/60	32
Total					32

### B. Estimated Burden Costs

The US Bureau of Labor Statistics hourly wage estimate for physicians and surgeons in the US is \$92.25. We applied this wage rate to all respondents, both international and US.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Centers treating Ebola patients	US/WHO International Clinical Network Ebola Virus Disease Clinical Data Collection Tool	32	\$92.25	\$2,952
Total				\$2,952

May 2013 National Occupational Employment and Wage Estimates, United States  
 Occupation Code 29-1060 (Physicians and Surgeons). Accessed January 7, 2015 at [http://www.bls.gov/oes/current/oes\\_nat.htm#29-0000](http://www.bls.gov/oes/current/oes_nat.htm#29-0000)

## 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 \$1,662.30. This estimate represents the amount of time for the CDC staff to design the data collection methodology, conduct the statistical analysis, in addition to the time spent managing the response in the EOC.

Staff Time:

Atlanta-based Support Hourly Wage			
Design of methods	1 FTE 10 hours	GS14 \$55.41	\$554.10
	1 FTE 10 hours	GS14 \$55.41	\$554.10
Statistical support	1 FTE 10 hours	GS14 \$55.41	\$554.10
Total salary costs			\$1,662.30
<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**

The project dataset containing individual records will be kept at CDC and will not be shared. Facilities can have access to the data they provide from their Center if requested. Data summaries (aggregate data only) will be available to the participating Centers and to WHO collaborators.

To protect patients and respondents, individual patient level data will not be shared or presented. Data will only be presented in aggregate in reports. Care will be taken to suppress reports where small numbers, including those resulting from cross-tabulation, may allow accidental or intentional re-identification of patients.

Results from detailed analyses might be drafted into one or more manuscripts for publication. Data collection is expected to be conducted during June to December 2015; data analysis is expected to be conducted between June to December 2015; reporting and publication is expected to be completed between July 2015 and June 2016.

**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. World Health Organization. Ebola Situation Report. 3 June 2015. Accessed June 4, 2015 at: [http://apps.who.int/iris/bitstream/10665/174011/1/roadmapsitre\\_3June15\\_eng.pdf?ua=1&ua=1](http://apps.who.int/iris/bitstream/10665/174011/1/roadmapsitre_3June15_eng.pdf?ua=1&ua=1)

## List of Appendices

- Appendix A. Authorizing Legislation
- Appendix B. Email Invitation
- Appendix C. US/WHO International Clinical Network Ebola Virus Disease Clinical Data Collection Tool
- Appendix D. CDC Privacy Act System of Records Notice 09-20-0113