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

**Request for OMB Approval for a**

**New Information Collection Request**

**January, 2015**

**Supporting Statement B**

**Collections of Information Employing Statistical Methods**

Contact:

Alex Kallen, MD, MPH

Clinical Team Medical Officer

Medical Care Task Force

2014 Ebola Virus Response

Centers for Disease Control and Prevention

Office: (404) 639-4275, Mobile: (404) 729-2628

Email: [ffp0@cdc.gov](mailto:ffp0@cdc.gov)

**Table of Contents**

|  |  |
| --- | --- |
| B.Collections of Information Employing Statistical Methods |  |
| 1. Respondent Universe and Sampling Method |  |
| 2. Procedures for the Collection of Information |  |
| 3. Methods to Maximize Response Rates and Deal with Nonresponse |  |
| 4. Tests of Procedures or Methods to be Undertaken |  |
| 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data |  |
|  |  |
| References |  |
|  |  |
| List of Appendices |  |

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

**Emergency Information Collection Request**

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

**1. Respondent Universe and Sampling Methods**

1.1 Respondent Universe

The respondents will be the Centers that have provided care for at least one Ebola 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] during the time period August 1, 2014 –January 7, 2015. The senior clinicians on the treatment teams will complete the forms for the Centers.

1.2 Sampling Methods

The Clinical Team on the Medical Care Task Force in the Center for Disease Control and Prevention (CDC) 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. All Centers from this Clinical Network that have managed a patient with EVD will be invited to participate in the information collection. No statistical sampling methods will be employed. As of January 7, 2015, this data collection will involve fifteen Centers that have treated twenty-four patients. CDC’s goal is to obtain clinical information on 100 percent of the patients.

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

Before the Clinical Network calls, the CDC will announce that this information collection is to begin. All eligible Centers will be encouraged to participate.

A reminder email inviting participation will be sent out (**Appendix B**). The email will include the data collection form (**Appendix C**), which is an Excel spreadsheet with tabs for twelve domains. Instructions will be provided on how to securely deliver the completed forms via secure encrypted file transfer protocol (SFTP) provided by the CDC.

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.

A CDC data manager will oversee data management and data integration activities. The CDC data manager will integrate all data sources for analysis using SAS or SPSS.

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

Respondents may refuse to participate. However, the purpose of the project and the importance of their participation in exploring and sharing clinical insights based on the experiences of these fifteen Centers caring for EVD patients will be emphasized to all respondents. Their participation in the regular Clinical Network calls indicates that response rates will be high.

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

This data collection represents a small survey of a limited number of providers, data elements on the survey have been discussed on ongoing clinical calls, respondents have had a chance to review the forms and provide comments, and data elements represent standard medical information that is collected in routine care. The survey has been reviewed by a clinical consultant to this project (Julie Gutman below). In light of this and the urgent need for this information piloting of the survey was not undertaken.

All data analysis will be descriptive (e.g., proportion of respondents with an event, median or mean for continuous variables). Comparisons requiring tests of association will not be undertaken. Data will only be presented in aggregate; individual patient information or stratifications that might identify individual patients or Centers will not be undertaken.

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

The following CDC staff will manage the data collection and data analysis. Statistical consultation is not needed because all analysis will be descriptive only.

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Telephone Number** | **Email** |
| Data collection and analysis | Julie Gutman, MD | 404-718-4730 | Fff2@cdc.gov |

**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>.

|  |
| --- |
| **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 |
|  |