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

Request for OMB Approval for a
New Information Collection Request

June 4, 2015

Supporting Statement B
Collections of Information Employing Statistical Methods

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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 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.

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 June 6, 2015, this data collection will involve fifteen Centers. This emergency request will allow additions of up to six Centers to the Clinical Network as the need arises. CDC's goal is to obtain clinical information on 100 percent of the patients.

2. Procedures for the Collection of Information

The CDC will contact and encourage eligible Centers 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 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. World Health Organization. Ebola Situation Report. 27 May 2015. Accessed June 2, 2015 at: http://apps.who.int/iris/bitstream/10665/174011/1/roadmapsitrep_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