Information Collection Request for
"Monitoring and Coordinating Personal Protective Equipment (PPE) in Healthcare to Enhance Domestic Preparedness for Ebola Response"

Dr. Charles Oke
Senior Epidemiologist
Tel. 412.386.6848
Cao1@cdc.gov
FAX 412.386.6485

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Part A: Justification

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- Goal of the study is to garner a better understanding of the particular PPE needs of healthcare workers to ensure the health and safety of this workforce during emergencies, and to address an urgent need to monitor and assess PPE needs for the Ebola response.

- Intended use of the resulting data is to directly respond to the following research questions: (1) “What is the best way to optimize the PPE supply chain in real time?” and (2) “How can predictive modeling assist in resource allocation?” Also, the information to be collected will aid in improving the health and safety of healthcare workers by assessing PPE training and supply management.

- Methods to be used to collect PPE data will be from a web-based tool. Specific data related to the importance of PPE supply chain for influencing health/safety toward healthcare workers currently exists at the hospital level. The system will use a general interface engine designed to accept, validate, and process data from multiple, disparate sources.

- The subpopulation to be studied is healthcare workers who will be treating and caring for people infected with the Ebola virus.

- The data will be analyzed using descriptive analysis, predictive modeling analytics, linear and logistic regression etc.

The Centers for Disease Control and Prevention (CDC) requests OMB approval of a new research project for the National Institute for Occupational Safety and Health (NIOSH) Personal Protection Technology Program for a 3-year period.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection request (ICR) is a new request. This collection request describes data collection tasks under the project entitled "Monitoring and Coordinating Personal Protective Equipment (PPE) in Healthcare to Enhance Domestic Preparedness for Ebola Response." This surveillance project is being conducted by the National Institute for Occupational Safety and Health (NIOSH). NIOSH's authority under the Occupational Safety and Health Act [29 CFR § 671] **(Attachment A)** is to "develop recommendations for health and safety standards", to "develop information on safe levels of exposure to toxic materials and harmful physical agents and substances", and to "conduct research on new safety and health problems". The National Personal Protective Technology Laboratory (NPPTL) is a division of NIOSH within CDC that has, as its mission, the prevention of work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies (PPT).

There is growing national interest to monitor and assess PPE needs for the Ebola response. Infection control is a key strategy in stopping the spread of Ebola as well as identifying and managing patients with the Ebola virus, but does not expand to those working on other infectious diseases. It was determined during the pilot phase that there was a high level of hospital interest in the benchmarking value that such a system might provide. Partners began to identify key performance indicators that this data might provide them, such as average number of respirators used per isolation order in the hospital, and identification of stakeholders and protocols impacting effective respirator use. Recommendations were made for monitoring schedules and survey improvement. After this study has been completed, a similar study could be undertaken that will include a much wider audience with the results being more valuable to a wider population.

On October 20, 2014 CDC issued new guidance for PPE. While HHS has been working with distributors and manufacturers to understand various ways customers may be able to find PPE supplies needed for training, and for use during the evaluation and/or treatment of patients with suspected or confirmed cases of Ebola, a more systematic approach would benefit the nation. In collaboration with the CDC, hospitals may be recruited from each tier of the CDC's tiered approach for caring for patients with the Ebola Virus Disease: (1) frontline healthcare facilities, (2) Ebola assessment hospitals, and (3) Ebola treatment centers. The CDC guidance recognizes the vital role that many state health organizations perform in monitoring PPE usage rates throughout each tier and determining approaches to effectively distribute resources throughout the tiered components to sustain preparedness.

In November 2014, The Institute of Medicine (IOM) published a report, "Research Priorities to Inform Public Health and Medical Practice for Ebola Virus Disease—Workshop in Brief." The report identified research questions related to PPE and behaviors.

This effort is designed to directly respond to the following research questions identified in the report: (1) "What is the best way to optimize the PPE supply chain in real time?" and (2) "How can predictive modeling assist in resource allocation?"

2. Purpose and Use of Information Collection

There is growing national concern for better understanding of the particular personal protective equipment (PPE) needs of healthcare workers to ensure the health and safety of this workforce during times of pandemic disease or bioterrorist threat. The use and effectiveness of the proper PPE are paramount to the management and mitigation of the effects of a disaster. The development of an ongoing PPT sentinel surveillance system in the hospital setting will document data used to evaluate and monitor use and effectiveness for PPE usage in healthcare workers including Ebola protection.

Since healthcare workers are at the forefront of treating pandemic disease and bioterrorist threats, it is extremely important for NIOSH to collect this information. The data will be collected quarterly over a three year period by using a web-based data collection tool. The information will be used by NIOSH researchers to assess the impact of PPE usage throughout the hospital facilities in near real time. Results from this effort will guide further research in the development of best practices toward PPE training and supply management of a variety of health/safety issues. This project and data collection has already been fully funded by the NIOSH National Personal Protective Technology Laboratory.

As mentioned earlier, the information to be collected will aid in improving the health and safety of healthcare workers by assessing PPE training and supply management. This data is not available from any other sources. Previous pilot studies began with the identification of measures to monitor the use of N95 respirators and powered air purifying respirators (PAPRs) in the acute hospital setting. This showed that there was a high level of hospital interest in the benchmarking value that such a system might provide, such as average number of respirators used per isolation order in the hospital, and identification of stakeholders and protocols impacting effective respirator use. It is essential to assess the near real time collection of PPE usage to understand the optimal emphasis of PPE supply management in the healthcare organization in making recommendations for use of this information by healthcare safety and health practitioners, executives, and industry officials.

The Web-based data collection tool collects routine and non-routine hospital data related to PPE use and supply. The data collection will consist of four surveys. Two of the surveys are designed for routine data collection (Baseline/Annual and Quarterly). The Baseline and Annual surveys are the same, but are separated into two to make it easier to calculate burden hours (baseline form takes about 8 hours to fill out, annual form about 3 hours). Two are designed for non-routine data collection (Emergency and Crisis).

- **Baseline/Annual:** This survey is completed during training in the first year (Baseline), and during annual checkpoints in following years (Annual). Hospital responses in this survey will pre-fill the Quarterly Survey with organizational information, such as makes (brands), models, and sizes of PPE stocked.
- **Quarterly:** This survey is completed on a quarterly basis, and serves as a means for reporting quarterly statistics and updating any outdated information from the Annual Survey.
- **Emergency:** The Emergency Survey enables weekly data collection during an emergent scenario, like a pandemic event that will typically last multiple weeks. There are three questions on this survey, which will be administered via text message. During the project, hospitals will participate in a four-week training/testing period to prepare for Emergency data collection.
- **Crisis**: The Crisis Survey is designed for localized, rapid data collection, which will span a short duration to enable timely decision-making. The Crisis Survey will leverage a text message interface and will be 1-3 questions maximum. Note that the texting functionality

will be deployed in the August 2016 timeframe. Once deployed, hospitals will participate in a one-week training/testing period to prepare for Crisis data collection.

3. Use of Improved Information Technology and Burden Reduction

Approximately 95% of the information collected via data collection instruments will require respondents to use a web-based data collection tool **(Attachment E)** to comply with the Government Paperwork Elimination Act, Public Law 105-277, title XVII, which was signed into law on October 21, 1998.

4. Efforts to Identify Duplication and Use of Similar Information

Protecting healthcare workers was a concept that was brought up throughout a workshop, convened on November 3, 2014 by the IOM. Discussions began with perspectives from the Occupational Safety and Health Administration (OSHA) and the CDC's NIOSH, and continued with Emory University Hospital's paradigm shift from "patient-centered care" to "provider-centered care" to keep their entire team healthy and protect other patients and contacts. The report from this workshop identified the following research questions related to PPE and behaviors: (1) "What is the best way to optimize the PPE supply chain in real time?" and (2) "How can predictive modeling assist in resource allocation?" No similar data collection for PPE supply chain currently exists.

Specific data related to the importance of PPE supply chain for influencing health/safety toward healthcare workers currently exists at the hospital level. However, to optimize the PPE supply chain a national collection tool is required. In order to provide specific recommendations, during an Ebola outbreak, to the industry about PPE supply chain, this data collection tool is imperative. After this study has been completed, a similar study could be undertaken that will include a much wider audience with the results being more valuable to a wider population.

There is growing national interest to monitor and assess PPE needs for the Ebola response. Infection control is a key strategy in stopping the spread of Ebola as well as identifying and managing patients with the Ebola virus.

On October 20, 2014 CDC issued new guidance for PPE. While HHS has been working with distributors and manufacturers to understand various ways customers may be able to find PPE supplies needed for training and for use during the evaluation and/or treatment of patients with suspected or confirmed cases of Ebola, a more systematic approach would benefit the nation. The CDC guidance recognizes the vital role that many state health organizations perform in monitoring PPE burn rates throughout each tier and determining approaches to effectively distribute resources throughout the tiered components to sustain preparedness.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

Approximately 20 hospital facilities will be participating in the data surveillance collection– at least quarterly updates of PPE use over a three year period through a web-based data collection tool. It is expected that the data collection of the participating facilities shall reflect the tiered approach (as described in A.1) recommended by CDC involving Frontline Healthcare Facilities, Ebola Assessment Hospitals and Ebola Treatment Centers. The data collection tool will be held to the absolute minimum required for the intended use of the data. The data collection tool will take no more than 240 minutes to complete on a quarterly basis.

6. Consequences of Collecting the Information Less Frequently

NIOSH's researchers are the only individuals in the United States specifically dedicated to the development and testing of instruments that can be used to provide specific, tailored health and safety recommendations for the healthcare industry. If NIOSH does not conduct the subject research, it is doubtful the healthcare industry, academia or enforcement agencies will conduct such an extensive surveillance project to assess the values of monitoring PPE use through healthcare facilities that may deal with pandemics and bioterrorist threats. If this research is not conducted, assessments and subsequent recommendations about how to improve PPE supply usage during high demand situations would remain the same as it is now.

This request is for data collection over a three year period. To our knowledge there are no legal obstacles to the collection as planned.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the Federal Register on January 21, 2016 vol.81, No. 13 pp. 3421- 23**(Attachment B).** CDC did not receive any public comments.

B. There were no personal consults outside NIOSH.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any form of payment or gifts.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NIOSH's Information Systems Security Officer reviewed this submission and determined that Privacy Act does not apply. Respondents will not provide any form of identifying information (e.g., name or SSN); therefore no IIF will be included in the data records. No IIF will be collected as part of the data

collection processes. Information will be collected electronically. Computer instruments will be used to collect information from facilities about their PPE usage.

All information provided by respondents will be maintained by CDC/NIOSH researchers in a secure manner unless compelled otherwise by law. The data files will be analyzed in the aggregate and no individual respondents will be identified.

Activities do not involve the collection of Individually Identifiable Information.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This data collection has been submitted for approval to the NIOSH Human Subjects Review Board (HSRB) **(Attachment D).**

Respondents will not be asked any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

A. The respondents targeted for this study are the CDC identified Ebola treatment facilities. A sample of up to 20 facilities will be collected from various Ebola designated facilities which have agreed to participate. The amount of time to complete a data collection instruments will be about 230 hours. Data collection will be done with various data collection instruments. The baseline form is completed once by each hospital as they begin participating (20/3 = 7 rounded up). It is the same as the annual survey but will take longer to complete (about 8 hours), because all fields in the collection tool will need to be entered. The annual form is completed by the hospitals in each year following their start and will take about 3 hours to complete. Example: year one, 5 hospitals start (baseline); year two 6 new (baseline) + 5 from previous year (annual); year three 9 new (baseline) + 11 from previous years (annual). Thus, taking the sum of the previous year hospitals (annual) leads to 16 total (5 + 11 =16, 16/3 = 5 rounded down). The quarterly form is completed by all participating hospitals four times a year. Using the example above we get (5+11+20=36, 36/3= 12). The emergency and crisis forms are completed on all participating hospitals as needed but at least once for training and use the annualized number in the baseline form.

The following table provides an estimate of the annualized burden hours. The estimates are based on the past contracts conducting similar methods of data collection.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Hospital	Baseline	7	1	8	56
Hospital	Annual	5	1	3	15
Hospital	Quarterly	12	4	3	144
Hospital	Emergency	7	4	15/60	7
Hospital	Crisis	7	7	10/60	8
Total					230

B. The estimated total cost for this information collection is $33,465.00

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hospital Manager	230	$48.50	$11,155
			$11,155

The value assigned for the hourly wage rate is based on the average U.S. hourly wage rate for hospitals available in the following information: Bureau of Labor Statistics, U.S. Department of Labor, *May 2014 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622100 - General Medical and Surgical Hospitals (including private, state, and local government hospitals)*, on the Internet at **http://www.bls.gov/oes/current/naics4_622100.htm** (visited *November 30, 2015*).

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

None.

14. Annualized Cost to the Government

Data will be collected for three years. The estimated annual cost to the Federal Government is $75,351.40. This includes data collection by CDC/NIOSH employees and data analysis. The hours designated for government staff were calculated as shown in the table below. The total annual cost average for the three year approval period is $75,351.40.

	Hours	Hourly Rate	Cost at Hourly Rate	Other Costs (data collection, etc.)	Total
Federal Government Employee	1020	$64.07	$65,351.40	$10,000	$75,351.40

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Attachment F shows the analysis plan tool shells. Data analyses will be conducted over the life of the project. An important component of the PRO PPE Sentinel Surveillance system is reporting of key PPE preparedness, responsiveness, and outcomes measures. The measures generally address supply and effective use of PPE. In the MVP version to be deployed in August 2016, the measures reflect descriptive, trend, and comparative analyses. The descriptive analysis provides hospitals with a good understanding of current situations and activities. This analysis helps hospitals assess readiness and response. The trending

analysis provides hospitals with an understanding of existing seasonality and developing trends. These trends can be used to predict future activity. The comparative analysis allows hospitals to compare their measures with those of other hospitals. These comparisons prompt important exploration into why there are differences. Data export is available so that CDC and participants can perform robust predictive analytics as well as scenario modeling. The project schedule below provides an estimate of data collection activities, analysis.

Project Time Schedule

Activity	Time Schedule
Data Collection Hospitals 1 - 5	1-3 months after OMB approval
Analysis	11 months after OMB approval
Data Collection Hospitals 6 - 14	12 months after OMB approval
Analysis	23months after OMB approval
Data Collection Hospitals 15 - 20	24 months after OMB approval
Analysis	35 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

“The display of the OMB expiration date is not inappropriate.”

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.