

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

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Part B: Collection of Information Employing Statistical Methods

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1. Respondent Universe and Sampling Methods

Over 18 million people are employed within the Healthcare and Social Assistance (HCSA) sector. Workers are at risk for illness and injuries because of long hours, changing shifts, lifting and repetitive tasks, violence, stress, and exposures to infectious diseases and hazardous chemicals. There is growing national concern for better understanding the particular personal protective equipment (PPE) needs of healthcare workers to ensure the health and safety of this workforce during times of emergency, and an urgent need to monitor and assess PPE needs for the Ebola response, 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.

This project will leverage the pilot solution developed in previous projects to serve as a temporary data collection tool in the event of an emergent infection outbreak, during an estimated nine-month timeframe until the Minimum Viable Product (MVP) has been successfully deployed, at which point the hospitals will transition to the MVP solution. Participation will be requested from the hospitals already trained in the pilot. Additional hospitals will be asked to participate, in collaboration with 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 project team will begin collecting baseline and quarterly data from hospitals as they start on a rolling basis, so total data collection periods may vary by hospital over the length of the project.

All U.S. acute healthcare facilities have an important role in preparing to identify, isolate, and evaluate patients under investigation (PUI) for Ebola virus disease (EVD) and promptly informing public health authorities. However, the roles and the preparations required to perform these tasks will differ by facility. Acute healthcare facilities can serve one of three roles: as a frontline healthcare facility, Ebola assessment hospital, or Ebola treatment center. The system will use a general interface engine designed to accept, validate, and process data from multiple, disparate sources. The facilities for this surveillance project will come from acute healthcare organizations identified by the CDC. All facilities will be given the option of declining participation in the study.

From the CDC identified acute healthcare facilities a total of 15-20 will be selected for the Monitoring and Coordinating of PPE in real time. The selected acute healthcare facilities will be recruited based on the continuum of size, region and willingness to participate. Our outreach to targeted hospitals consists of an email with an Executive Summary of the Minimum Viable Product Preparedness, Responsiveness, & Outcomes (MVP PRO) System included. After gauging a hospital's initial interest level, the Principal

Investigator conducts follow-up to answer any questions and schedule an Introductory Presentation that occurs via a web teleconference. If the hospital decides to participate, the first Annual Interview is scheduled, either onsite or via web teleconference. A pre-Baseline packet is sent to prepare the hospital for the interview process. Following the Baseline Interview, the project team will administer quarterly surveys and schedule regular checkpoints with each hospital to provide ongoing support and solicit feedback. Because of the nature, scope, and complexity of the surveillance project, data collection is expected to last 36 months.

2. Procedures for the Collection of Information

The MVP PRO recruitment efforts in year 1 have focused primarily on connecting with the hospitals that previously participated in the pilot phases.

The pilot programs were limited in scope to one hazard (airborne pathogens), two PPE (N95 and Powered Air Purifying Respirators), and one workplace type (acute-care hospitals). The scope of the MVP PRO is expanded to include one additional hazard (Ebola) and additional types of PPE (gloves, gowns, boot covers, face shields, etc.), such as that used to protect against the spread of EVD.

The next strategy employed, was to research hospitals with Ebola treatment programs. This led us to examine ASPR grant recipients that are Regional Ebola and Other Special Pathogen treatment centers and National Ebola Training and Education Centers (NETECs). The reporting measures of these grants provided an opportunity to synergize measures surrounding the supply and effective use around Personal Protective Equipment (PPE).

Data will be collected through a graphical user interface with each participating facility; this is not a longitudinal study.

The data collected for this study will be quantitative in nature. Upon collection of the data, it will be used in the establishment of a national system to monitor usage and training for PPE used to protect against the Ebola virus based on current CDC recommendations.

A tool shall be developed and deployed to include a contingent of the domestic acute healthcare facilities in a three tier approach. The system content shall include status information for all PPE categories identified for protection against the hazards of Ebola exposure. The system shall use a general interface engine designed to accept, validate, and process data from multiple, disparate sources.

The system shall be developed to identify PPE replenishment needs to facilitate local, state, and eventually regional resource sharing and local purchasing as needed, and compatible with PPE previously used at these facilities to allow seamless continuity of patient care and worker protection. This capacity shall offer a much-improved process for monitoring and maintaining appropriate PPE supplies for the Ebola virus through the constant, real-time monitoring of user demand, thus avoiding the misdirection of

tens of millions of dollars' worth of respirators and other PPE to facilities that may not use distributed supplies due to a mismatch between products typically used and the supplies provided.

3. Methods to Maximize Response Rates and Deal with Nonresponse

This project will recruit up to 20 hospitals over three years to provide periodic data related to the PPE used in the care of infectious patients. The intended outcomes are better protected healthcare workers, benchmarking and collaboration, PRO (Preparedness, Responsiveness, and Outcomes) metrics, and more informed decision making. It is estimated that a sample of up to 20 hospitals will agree to participate among a variety of Ebola treatment facilities across the United States that currently totals over 55 facilities. Since the facilities are agreeing to participate in the study and will be trained in the data collection process, the response rate is maximized, because of the benefits to the hospitals and the non-response rate should be nearly zero. Participating hospitals will gain a cross-functional understanding of their internal PPE infrastructure. They will also have the opportunity to benchmark with other participating hospitals to evaluate their hospital programs as well as measures of supply and effective use of PPE. In an emergency, hospitals will be able to communicate their PPE needs to a national level via the PRO platform. If a facility would decide to opt out after they begin the study, it would not be detrimental to the project. Depending on the time frame remaining in the project, another facility would be recruited from the list.

4. Tests of Procedures or Methods to be Undertaken

The data collected in the pilot projects provided experience and knowledge of respirator selection, availability, fit testing, usage patterns, outcomes, and confounders of respirator use and effectiveness at the four participating hospitals. The four hospitals identified key performance indicators that the collected data might provide them, such as: (1) average number of respirators used per isolation order in the hospital, (2) number of staff requiring fit testing, (3) stakeholders (i.e. hospital departments responsible for PPE purchase, use, and training) involved in each step of the process, and (4) protocols impacting effective respirator use purchase decisions. NIOSH now seeks to execute an expedited approach for a MVP multi-hospital (15-20), real-time monitoring phase. The 15-20 facilities shall reflect the tiered approach recommended by CDC involving Frontline Healthcare Facilities, Ebola Assessment Hospitals and Ebola Treatment Centers. The effort shall be built upon the experience and knowledge obtained from the pilot projects, and shall be structured as the next step in the establishment of a national system to monitor usage and training for PPE used to protect against the Ebola virus based on current CDC recommendations.

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

The persons who will collect and/or analyze the data are listed below. Should the project require further guidance on scientific issues regarding data, other internal resources are available through teams within the project staff's branch.

1Project Staff:

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These are the primary individuals who are leading study design, data collection, and analysis efforts.