I-Catalyst Program - Project 2: Respiratory Protective Device (RPD) Stockpiles

GenIC Submission under OMB #0920-1158

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GenIC Package & Attachments

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2. Supporting Statement A
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- Respiratory Protective Devices (RPDs) Stockpiles for use by healthcare workers (HCWs) are projected to be in significant short supply during the next pandemic influenza event. Lack of RPDs may expose healthcare workers to infection and decrease their willingness to come to work during a pandemic. In order to address this issue and increase preparedness, CDC is exploring strategies to increase supply and decrease demand of these critical countermeasures needed to protect health care workers. The purpose of this ICR is to determine if decentralized RPD stockpiles are feasible and acceptable option for stakeholders (stakeholder focus is on emergency planners within hospitals with more than 500 beds).

- Teams will use convenience sampling methods to select subjects who are readily available and within close proximity.

- Populations and customers to be interviewed will be emergency planners from hospitals, hospital

Diseases Control and Prevention, encourages, fosters, and develops innovative science, technologies, processes and policies that support the CDC/ATSDR. Federal scientific agencies, like the CDC, rely on research and scientific findings to help them develop solutions to public health problems which ultimately are disseminated to customers and stakeholders for adoption and use. However, anecdotal and empirical data show that many well-meaning, robust solutions are never used or adopted by the intended customer. This has resulted in a path littered with failed and unused government sponsored outputs. The CDC I-Catalyst program guides participants through a "customer discovery" process aimed at helping teams with a new solution to identify their customers. This is done by taking a team's main assumptions about who their customer is, the exact problem they are solving for the customer, and how the customer wants to receive or use the solution from the team—and turning those assumptions into hypotheses which the teams will then test (mainly through interviews with potential customers). Only conversations with potential customers (stakeholders) can provide the facts from which hypotheses are proven or disproven about whether a solution (product, process, etc.) creates value for the intended beneficiaries. It is expected that participants will leave the program with the ability to evaluate and translate their insights into solutions that have high levels of efficacy and user acceptability. The information collection is necessary to guide CDC project teams to create usable solutions that are customer centric and meaningful to users, whether it's adhering to recommendations, policies, protocol or interventions.

This request seeks approval for a GenIC approval for subproject I-Catalyst – Respiratory Protective Devices (RPD) Stockpiles. The ultimate goal of the I-Catalyst Project RPD Stockpile is to determine whether decentralization of respiratory protective devices for use by healthcare workers will be a useful solution to prevent shortage during influenza pandemics. The results of the project will help CDC teams make the case for support to advance important improvements and solutions of RPDs that customer's value, which is critical for ensuring that the CDC continues to deliver on its public health mission. The efforts of CDC activities is authorized under Section 301 of the Public Health Service Act 42 U.S.C.241.

2. Purpose and Use of Information Collection

Respiratory protective devices (RPDs) for use by healthcare workers are projected to be in significant short supply during the next pandemic influenza event. Lack of RPDs may expose healthcare workers to infection and decrease their willingness to come to work during a pandemic. In order to address this issue and increase preparedness, CDC, is exploring strategies to increase supply and decrease demand of these critical countermeasures needed to protect health care workers. Unlike other medical countermeasures, it is not feasible to address this gap through a centralized federal stockpiles due to costs, logistics, and operational considerations (e.g. having the right make and model used by facilities). Creation of decentralized stockpiles (stockpiles of RPDs held in or nearby healthcare facilities) are part the overall strategy to ensure that RPD

supplies are available when needed. However, it is unclear at this time if decentralized RPD stockpiles are feasible or acceptable for healthcare facilities. Therefore the project hopes to test this innovation effort through I-Catalyst and determine whether decentralized RPD stockpiles are feasible and acceptable option for stakeholders (hospitals and healthcare facilities with 500 or more beds), to improve access to these products during a pandemic. The information collected will be used for internal CDC decision making purposes and to provide suggestions for improving development of public health solutions. Information gathered will be used by teams to make more informed decisions about solutions to address and prevent national respiratory pandemics like H1N2 or Ebola. The customer interviews will help the project team determine if the proposed solution of decentralized stockpiles will be beneficial to hospitals/healthcare facilities or not. If the information collected indicates that the customer's problem surrounding supply and worker shortages during pandemics, would be relieved by the decentralized stockpiles, then the CDC teams would have some evidence with which to pursue leadership support and resources for further development. If the results of the information collection do not support the need for the proposed solution, then internal discussions and decisions will need to be made to either change directions or stop activity altogether. The information collected is not designed to drive important budgetary and/or public policy decisions.

3. Use of Improved Information Technology and Burden Reduction

The interviews will be conducted in person, on-site or by virtual video conference (Att. 1 – Interview guide). Using formative interview protocols allows the interviewer to follow the respondent's lead during in-person conversations. This wouldn't be possible if a list of fixed questions were used. This also is not possible if automated, technological-based collection techniques, such as a web-based survey, are used. On-site, in-person interviews allow interviewers to establish rapport with respondents and produce visual cues for interpreting responses that may require further probing or clarification. However, there are instances where teams can use improved information technology such as Skype or video conferencing for interviews to reduce the burden and provide flexibility in responder's schedule.

4. Efforts to Identify Duplication and Use of Similar Information

This is a unique I-Catalyst project and a new proposed solution. Other than proprietary business databases, there is no existing database that can provide the level of detail about the customer experiences, wants, and needs necessary to support innovations on Respiratory Protective devices.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this project.

6. Consequences of Collecting the Information Less Frequently

Data is collected once at this stage in the discovery process, respondents will participate in an interview once lasting no more than 30 minutes.

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

This request fully complies with the regulation 5 CFR 1320.5. There are no special circumstances.

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

Not Applicable

9. Explanation of Any Payment or Gift to Respondents

There is no exchange of payment or gifts to respondents for the voluntary interviews.

10. Assurance of Confidentiality Provided to Respondents

Activities for this request do not involve the collection of Individually Identifiable Information.

11. Justification for Sensitive Questions

There are no sensitive data items to be asked of individual respondents. CDC Human Research Protection Office determined that data /IC is not research involving human subjects and IRB is not required - OADS Project Determination approval.

12. Estimates of Annualized Burden Hours and Costs

Project RPD Stockpiles project team will interview 50 respondents for this ICR. The project will interview hospital emergency planners an average of 30 minutes and maximum of 1 responses per respondent. Each project team will interview approximately 50 respondents. Annualized burden will be 25 hours and an estimated annualized burden cost of $847.25.

Estimated Annualized Burden Hours

Table A: Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Hospital/Healthcare Facilities Emergency Planners	Interview Guide	50	1	30/60	25
Total					25

Table B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)	Hourly Wage Rate*	Total Respondent Costs
Hospital/Healthcare Facilities Emergency Planners	Interview Guide	50	1	30/60	25	$33.89	$ 847.25
							$ 847.25

*Average of hourly wage of (Healthcare emergency management staff) from http://www.bls.gov/home.htm

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

There are no projected cost burdens for reporting.

14. Annualized Cost to the Government

a. The project cost is associated with the CDC project team members responsible for conducting the interviews. These figures were estimated as the sum of the anticipated direct labor; fringe and burden on direct labor.

Project Staff Oversight	Annual Cost
CDC Cost: Deputy Director (2% of time)	$ 3,000.00
CDC Cost: Health Scientist (3% of Time)	$3,480.00
CDC Cost: Executive Assistant (5% of Time)	$3,600.00
Total	**$10,080.00**

15. Explanation for Program Changes or Adjustments

This information collection request is a new submission.

16. Plans for Tabulation and Publication and Project Time Schedule

The proposed interviews will be conducted within 2-3 months after approval of GenIC. There is no planned publication from this information collection. Interim reports will be developed, which will incorporate data collected from these sources in 2017 and 2018.

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 statement.