**Generic Clearance for CDC/ATSDR**

**Formative Research and Tool Development –**

**GenIC - Successes of and Barriers to Distribution of Personal Protective Equipment (PPE) During the 2024 Dairy Cattle H5N1 Outbreak**

**0920-1154**

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* The goal of this information collection is to perform a mixed-method evaluation of the distribution of PPE among dairy farm workers following CDC’s May 6, 2024, request to health departments (HDs) to work with state agriculture colleagues to make personal protective equipment (PPE) available to dairy farm, poultry farm, and slaughterhouse workers to protect workers and prevent the spread of the Avian Influenza A(H5N1
* Results of this project may help shape future asks of HDs and will help CDC’s NIOSH to understand the specific types of requested PPE. This could ultimately help inform messaging of the importance of specific PPE and future requests.
* The methods used to collect the information will include key informant interviews that will inform an online survey questionnaire.
* Subpopulation to be represented in this data collection are directors of public health preparedness, with inputs from state public health veterinarians and state animal health officials, and any other involved staff.
* Qualitative and quantitative data will be collected. Data will be stored in MS Excel. A descriptive analysis will be conducted on quantitative data using MS Excel. Qualitative data will be coded by hand and analyzed for themes.

**A. JUSTIFICATION**

**1. Circumstances Making the Collection of Information Necessary**

The CDC requests approval for a new GenIC titled: Successes of and Barriers to Distribution of PPE During the 2024 Dairy Cattle H5N1 Outbreak under OMB Control No. 0920-1154, expiration date 03/31/2026.

In March 2024, avian influenza A(H5N1) was confirmed in dairy cattle on a Texas dairy farm. On April 5, 2024, CDC issued a Health Alert Network notice indicating the spread of avian influenza A(H5N1) to a human dairy worker, likely linked to exposure to an infected cow. Since then, numerous herds of dairy cattle and multiple human cases linked to dairy farms have been detected across the U.S. On May 6, 2024, CDC requested that health departments (HDs) work with state agriculture colleagues to make personal protective equipment (PPE) available to dairy farm, poultry farm, and slaughterhouse workers. CDC requested a prioritized distribution of PPE, first to farms with known positive or presumptive positive herds with avian influenza A(H5N1), then to states that have submitted samples for pre-movement PCR testing, and then to farms with no evidence of positive herds or any tests awaiting results.

CDC proposes a mixed-method evaluation of the distribution of PPE among dairy farm workers following CDC’s May 6, 2024, request. The results of this project may help shape future asks of HDs and will help CDC’s NIOSH to understand the specific types of requested PPE. This could ultimately help inform messaging of the importance of specific PPE and future requests.

Data collection for this project is authorized under 42 U.S.C. 241, Chapter 6a - Public Health Service; Subchapter Ii - General Powers and Duties Part A - Research and Investigations.

**2. Purpose and Use of Information Collection**

Key informant interviews (KII) (**Attachment 1)** will be performed initially (as described below) which will inform any modifications to the draft online survey (Attachment 5) administered to state health department representatives, including State Public Health Emergency Preparedness (PHEP) Directors, State Animal Health Officials (SAHO), State Public Health Veterinarians (SPHV). CDC staff personnel will conduct one-on-one phone/online (with option to use video) discussions with 10–15 State Public Health Emergency Preparedness (PHEP) Directors, State Animal Health Officials (SAHO), and/or State Public Health Veterinarians (SPHV), that may last 30–45 minutes.

Online survey (**Attachment 2**) of state health departments including State Public Health Emergency Preparedness (PHEP) Directors, State Animal Health Officials (SAHO), State Public Health Veterinarians (SPHV), and any other involved staff will include a request for basic information such as jurisdiction, job category, and involvement in avian influenza A(H5N1) response. It will include multiple choice as well as a few open-ended questions regarding PPE distribution methods; use of trusted messengers; type of PPE requested, available, and distributed; and perceived reasons for any lack of requests for PPE. The survey will be completed on behalf of the state (rather than on the individual level of the person(s) completing the survey) and is anticipated to take no longer than 2 hours to complete, per jurisdiction. The findings may be used to inform CDC’s future PPE ask of HDs, help inform CDC’s NIOSH of the most requested PPE items by employers, and guide future response messaging.

The goal of this information collection is to evaluate the impact of CDC’s request that state and other jurisdictional health departments make personal protective equipment (PPE) available to dairy farm, poultry farm, and slaughterhouse workers via a one-time distribution of PPE from existing stockpiles. Aspects to be evaluated include jurisdictions’ activities and messaging related to distribution and/or availability of PPE and requests from workplaces or agricultural businesses.

**3. Use of Improved Information Technology and Burden Reduction**

KII data collection: CDC personnel will conduct one-on-one, phone/online (with option to use video) discussions with 10–15 State Public Health Emergency Preparedness (PHEP) Directors, State Animal Health Officials (SAHO), and/or State Public Health Veterinarians (SPHV), that may last 30–45 minutes. Data management and analysis: CDC staff will take notes and record discussions (if granted permission) to help modify the draft online survey and provide qualitative data that will be hand coded and analyzed for themes.

**4. Efforts to Identify Duplication and Use of Similar Information**

This is a unique information collection regarding CDC’s May 6, 2024, request to health departments (HDs) to work with state agriculture colleagues to make personal protective equipment (PPE) available to dairy farm, poultry farm, and slaughterhouse workers to protect workers and prevent the spread of the Avian Influenza A(H5N1) outbreak. CDC is working to ensure that there is no duplication in information collection efforts for this project.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in the data collection activities.

**6. Consequences of Collecting the Information Less Frequently**

This is a one-time data collection. Collecting this information less frequently will not allow CDC to obtain useful feedback on their response activities and would potentially reduce the impact of future messaging activities.

**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 Agencies**

The Federal Register notice was published for this collection on July 22, 2022, Vol. 87, No.140 , pp. 43860. No public comments were received.

**9. Explanation of Any Payment or Gift to Respondents**

There will be no gifts or payments to respondents.

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

Information discussed by the participants during the KIIs will remain de-identified, anonymous and will be used to better inform the survey. All participants will be assigned a random identifier which will be stored temporarily and within 90–120 days of project completion, will be deleted and permanently removed. The discussion recordings (audio only) will be erased once all interviews are summarized. The summary notes will be stored in a database and managed by the co-investigators.

Data collection surveys and key informant interview questionnaires will be analyzed and de-identified to create publicly available aggregate data in the form of a manuscript and presentation. Individual level data will be stored securely and accessible only to team members for the duration of the project. Data will be permanently deleted twelve months after the study period. Data will be kept private to the extent allowed by law.

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

There are no sensitive questions. This activity has been determined to be non-research. IRB Approval is not required.

**A.12. Estimates of Annualized Burden Hours and Costs**

The annualized response burden for this GenIC is estimated at 111 hours.

**Exhibit A.12.A Annualized Burden Hours**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category of Respondent**  | **Form Name** | **No. of Respondents** | **Participation Time (minutes)** | **Burden in Hours** |
| Key informant interview (State Public Health Emergency Preparedness Directors, State Animal Health Officials, State Public Health Veterinarians) | Key Informant Interview Questionnaire | 15 | 45  | 11 hours |
| Survey (State Public Health Emergency Preparedness Directors (PHEP), with inputs from State Animal Health Officials (SAHO), State Public Health Veterinarians (SPHV) and other relevant staff) | Online Survey Questionnaire | 50  | 120  | 100 hours |
| **Totals** |  |  |  | **111 hours** |

**A.12.B Estimated Annualized Costs**

Collections by health jurisdictions are generally funded through cooperative grants and these will be noted in the specific collection requests. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Department of Labor, Bureau of Labor Statistics, May, 2023 <http://www.bls.gov/oes/current/oes_nat.htm>.) was used for the mean hourly wage for PHEP cooperative agreement recipients, classified as Emergency Management Directors, is $45.05.

Exhibit A.12.B. Annualized Cost to Respondents

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Cost** |
| Data collection  | 111 | $45.05 | $5,000.55 |

**A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

There are no other costs to respondents other than their time

**A.14**. **Annualized Costs to the Government**

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one CDC project officer (GS-12, 13 or 14 levels) who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote technical assistance to the local areas implementing the data collection. In some cases, a CDC data manager’s (typically a contractor equivalent to GS-9) time may also be required. An estimated average cost per individual activity is listed below, but detailed costs will be submitted with each individual collection request.

|  |  |  |
| --- | --- | --- |
| **Expense Type** | **Expense Explanation** | **Annual Costs (dollars)** |
| Direct Costs to the Federal Government |  |  |
|  | CDC Project Officer (GS-12/13, 0.5 FTE) | $40,641 |
|  | CDC Data Manager (GS-9/10, 0.25 FTE) | $13,450 |
|  | Subtotal, Direct costs | $54,091 |
|  | TOTAL COST TO THE GOVERNMENT | $54,091 |

**A.15. Explanation for Program Changes or Adjustments**

N/A

**A.16. Plans for Tabulation and Publication and Project Time Schedule**

|  |  |
| --- | --- |
| **Milestones** | **Schedule** |
| Key Informant Interview  | Immediately following OMB Approval |
| KII Analysis and Survey Modification | 4 weeks after OMB Approval |
| Survey Deployment and Data Collection | 2 months after OMB Approval |
| Analysis and Reporting | 1 year after OMB Approval |

Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases of individual interviews conducted during pilot testing of interventions where respondents may have to be approached more than once on the same or similar topic under evaluation. No single data collection activity will take longer than 1 year to complete from inception of information collection to the first report of findings. Proposed timelines will be submitted for each individual data collection activity.

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

The display of the OMB expiration date is not inappropriate.

**A.18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

**Attachments**

Attachment 1 - Authorizing Legislation

Attachment 2 - 60-Day Federal Register Notice

Attachment 3 - GenIC Template

Attachment 4 – Key Informant Interviews

Attachment 5 – Draft Online Survey

Attachment 6- Non-Research Determination