Enhanced Surveillance of Respiratory Illness Among People Experiencing Homelessness in Anchorage, Alaska

Request for OMB approval of a New Information Collection

October 31, 2022

Supporting Statement A

Contact:
Thomas J. “Chip” Daymude
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Email: qkh7@cdc.gov

Table of Contents

- **Goal of the study:** To inform respiratory infection control and vaccination practices for SARS-CoV-2, influenza, respiratory syncytial virus (RSV), and other respiratory infections in facilities where people experiencing homelessness are provided a place to stay in Anchorage, Alaska.
- **Intended use of the resulting data:** The data from this respiratory surveillance project will contribute to identifying the needs of people experiencing homelessness in Anchorage, Alaska for public health officials.
- **Methods to be used to collect:** Trained personnel will interview people experiencing homelessness to obtain demographic information, to ascertain their specific symptoms, and vaccination status. Medically trained members will collect a nasopharyngeal (NP) swab from each consenting person. The NP specimen collected will be analyzed using a multiplex viral respiratory panel at CDC/AIP laboratory.
- **The subpopulation to be studied:** People with respiratory symptoms experiencing homelessness in congregate and non-congregate settings in Anchorage, Alaska.

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request. We are requesting approval for a period of 12 months. This project is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Preparedness and Emerging Infections (DPEI), Science Unit requests approval to collect information regarding respiratory symptoms and vaccine status, and to obtain a nasopharyngeal swab from people with respiratory symptoms experiencing homelessness in Anchorage, Alaska.

Residents of congregate living facilities, such as homeless shelters, may be housed in a high-density population with overcrowding and poor ventilation, have shared hygiene facilities, and incur a large turnover rate which puts individuals at an elevated risk for outbreaks of respiratory diseases. Moreover, the high turnover rate in homeless shelters allows the spread of respiratory diseases between facilities. The risk of COVID-19 in homeless shelters has been well described.[1-3] The point prevalence of SARS-CoV-2 in U.S. homeless shelters during outbreaks has been reported as high as 67%.[4] In a study assessing complications from COVID-19, persons experiencing homelessness were over twenty times more likely to be admitted to the hospital, over ten times more likely to require intensive care, and over five times more likely to die within twenty-one days of their first positive result.[3] Only a couple of studies have looked at other specific respiratory pathogens, influenza and RSV, in people experiencing homelessness[5-7]. Thus, the information on the true burden of respiratory illnesses in people experiencing homelessness is limited.[8]

Respiratory surveillance projects in congregate and non-congregate settings of people experiencing homelessness are needed in Anchorage, Alaska. The homeless population in these facilities includes approximately 2000 people, half of which live in Anchorage. The people experiencing homelessness in Anchorage have additional adverse factors confronting them. During the COVID-19 pandemic, up to 500 people experiencing homelessness were sheltered in the Sullivan center which then closed on June 30, 2022.[9] Additional facilities were not built, the current shelters were full, and thus, the individuals

were sent to a campsite at Centennial park. Winter is approaching with temperatures in Anchorage ranging from 5ºF to 41ºF, rarely falling below -8ºF. In this frigid climate, homelessness is particularly harmful, and individuals are even more prone to contract respiratory illnesses. The temporary site at Centennial park campground closed on October 1, 2022, at 5 pm and after long debates, 150 people experiencing homelessness were shuttled back to the Sullivan center.[10] The situation facing these people is dire and understanding the respiratory illnesses that may be occurring among people experiencing homelessness in Anchorage, Alaska is crucial.

2. Purpose and Use of Information Collection

The collection of information will allow us to understand the burden of respiratory diseases, to inform infection control, and to determine the vaccination status of people experiencing homelessness in Anchorage, Alaska. The burden of disease varies widely by pathogen. For this reason, the respiratory surveillance project will include a multiplex assay to test for viral respiratory pathogens, and perhaps bacterial pathogens as well.[11] The data will aid in developing additional public health messages and strategies to prevent respiratory illnesses among people experiencing homelessness in Anchorage, Alaska. This information is also essential to guide future public health surveillance for respiratory illnesses in this population. CDC and Anchorage Health Department will use the information obtained to:

- Determine which data elements are most important to collect during routine respiratory surveillance
- Calculate cumulative incidence of respiratory illness
- Determine pathogen specific infections from laboratory analysis of cases
- Ascertain risk factors for those who developed disease
- Identify opportunities for outreach efforts related to respiratory illnesses, education, and prevention

At homeless shelter locations, contractors who are supervised by CDC personnel will interview people with respiratory illness who are experiencing homelessness and who voluntarily consent to participate. (Attachment 6) These individuals are composed of symptomatic people at facility-based clinics, people who are experiencing respiratory symptoms at the time of COVID-19 screening, or people experiencing symptoms who access a respiratory infection testing kiosk at shelter sites. These participants are adults 18 years or older and are only interviewed once. The interviewer will ask the participant demographic information, symptoms, and vaccination history for COVID-19 and flu, and record the information which should take a maximum of 15 minutes. A medically trained contractor (i.e., nurse, nurse practitioner, nurses aid, etc.) will collect a nasopharyngeal swab from each participant.

Surveillance staff at each participating site will enter data from the case report form into the REDCap database and submit their data, stripped of identifiers, to the reporting database daily to weekly (Attachment 3). Data will be collected via-password protected device (i.e., tablet, laptop), and stored on a secure, HIPAA-compliant server through REDCap. Any laboratory samples sent for testing or data sent for statistical analysis will use only the project ID. The laboratory samples will be analyzed on a multiplex Illumina viral respiratory panel detecting 41 respiratory viruses.[11]

Left over samples will be banked, using the project ID, for the duration of the project and may be used to test for a broader array of pathogens, including Group A Streptococcus, or other respiratory pathogens not included in the initial panel. Left over samples will be destroyed at the end of the project.

The proposed analyses for the data collected may include:

- Descriptive analysis of demographic features, symptoms, and vaccination status
- Comparison of case characteristics by demographic groups (age, sex, race/ethnicity) and severity
- Descriptive analysis of laboratory methods used for detection of respiratory viral and bacterial pathogens
- Analysis of positive cases stratified by clinical syndrome, and if applicable by age, sex, and race/ethnicity

Without respiratory surveillance of this population, the risk of respiratory infections due to the extreme adverse conditions in Anchorage can be devastating. Determination of the specific pathogens in this population is needed to address the appropriate measures to prevent outbreaks in such a challenging environment. A timely project such as this proposed collection of information can garner valuable data for additional work to help reduce respiratory illnesses among people experiencing homelessness.

3. Use of Improved Information Technology and Burden Reduction

Trained contractors will interview participants at the facilities where people experiencing homelessness are located. The contractors will document the participants answers on the questionnaire which is designed to obtain only the minimum amount of data needed regarding demographics, symptoms, and vaccination status.

Data will be entered by contractors into REDCap database that follows the case report form at each participating site daily to weekly. The password protected device (i.e., tablet, laptop), will have the REDCap database, which is stored on a secure, HIPAA-compliant server.

The CDC AIP laboratory may use a multi-pathogen assay (Illumina viral panel) to detect respiratory pathogens or a respiratory TaqMan Array Card with real-time PCR may be used for detection. The multiplex assay can detect 41 respiratory viruses. Batched testing will be performed on a bi-weekly or monthly basis and findings would be provided in aggregate to the shelter, municipality, Anchorage Coalition to End Homelessness, Anchorage Health Department, and Alaska Department of Health and Social Services.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of the availability of any similar information.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection.

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 June 2nd, 2022, vol. 87, No. 106, pp. 33490 (Attachment 2). CDC did not receive public comments related to this notice.

B. No consultations outside of CDC occurred.

9. Explanation of Any Payment or Gift to Respondents

A token of appreciation in the form of a $25 gift card will be given to each participant. Persons experiencing homelessness in Anchorage, Alaska view a token of appreciation as a sign of respect for them and their time. Therefore, all interventions by state and local health officials involving persons experiencing homelessness in Anchorage, Alaska have involved the provision of incentives to thank them for their time and effort. Based on state and local health officials' strong recommendation that persons who participate in this activity are compensated for their time, and the discomfort a nasopharyngeal swab may entail, an incentive ($25 value) in the form of a gift card will be given as a token of appreciation.

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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act applies. The system will obtain the name and date of birth of each person who signs the consent form. The system is also using demographic information to include age, sex, and race/ethnicity. Privacy Impact Assessment attached (Attachment 7).

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

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects (Attachment 4). IRB approval is not required.

Justification for Sensitive Questions

There are no planned sensitive questions in this project.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Each person experiencing homelessness with respiratory symptoms will be interviewed once by a team member and asked questions regarding demographic information, symptoms, and COVID-19 and flu vaccination status. The responses will be documented by the interviewer. Based on the number of questions, the interview should take 15 minutes. After the interview, a nasopharyngeal (NP) swab will be collected from the participant. Preparation for the swab process, collecting the specimen, and final documentation should take a maximum of 15 minutes based on experience of performing this task

previously. The total number of participants will not exceed 1000 which means 500 hours is the maximum burden in hours.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Persons with Respiratory Symptoms Experiencing Homelessness	Enrollment in Symptom Screening	1000	1	0.5	500
Total					500

B. Estimated Annualized Burden Costs

There is no cost to respondents as it is a voluntary collection of information. The participants are receiving a token of appreciation which is a $25 gift card.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
People experiencing homelessness	Enrollment in Symptom Screening	500	0	0
Total				0

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The estimated annual cost to the government includes one CDC staff member, a health scientist/epidemiologist, who will implement a new project in the REDCap database, perform data analysis, and work with the contract staff and CDC team in Anchorage. These activities will cost an estimated $37.90 per hour, for a total of 80 hours, with an estimated annualized cost to the government of $3032.00, according to https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm.

The estimated hourly cost to the government for two medically trained individuals, as defined on the following site https://doh.wa.gov/sites/default/files/2022-09/ProvidersAuthorizedToCollectNasalSwabCOVID19.pdf, who will collect a nasopharyngeal swab from each participant, is at the rate of $23.11 per hour according to https://www.bls.gov/ooh/healthcare/licensed-practical-and-licensed-vocational-nurse. If the

two trained contractors work a combined total of 80 hours per week, for 20 weeks the estimated annual cost to the government for two medically trained individuals is $36,976.

Interviews of participants, and data entry from case report forms into REDCap database will be performed by a data entry member/contractor. At an hourly rate of $17.20, the activities described should take 40 hours per week, and the project will last until March 2023, 20 weeks. The estimated annual cost to the government is $13,760 and the hourly rate was determined from https://www.bls.gov/oes/current/oes439021.htm#nat.

Testing supplies will include specimen collection items: NP swabs, Viral transport media (3 ml) in sterile tubes, specimen sticker labels, cooler and ice packs, plastic bags with a pocket; PPE: N95masks, gloves, gowns, eye protection (goggles or disposable face shields that cover the front and sides of the face); cleaning and disinfection supplies; laboratory supplies; office supplies; non-contact digital thermometers with extra batteries; etc. The supplies for this project will generate an estimated annual cost to the government of $50,000 due to the laboratory analysis of the specimens and was determined from pricing of supplies through vendors and scientific companies.

Each participant will be given a $25 gift card. With a maximum of 1000 participants. The estimated annual cost to the government will be $25,000.

Category	Type of work/supplies	Hourly rate/supply cost /participant	Total Hours/total number participants
CDC staff hours?	Health scientist/epidemiologist-1	$37.90	80
Contractor staff	Practical nurse-2	$23.11	1600
	Data manager-1	$17.20	800
Testing supplies	Office, PPE, cleaning and disinfecting, specimen collection, and laboratory supplies	Based on government contracts	
Incentives		$25 per respondent	1000

E.g.:

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
CDC Staff hours	$3032
Contractor Staff hours -2 medical trained personnel	$36,976
1- Data entry	$13,760
Testing supplies	$50,000
Incentives	$25,000
Total	$128,768

15. Explanation for Program Changes or Adjustments

This is a new information collection

16. Plans for Tabulation and Publication and Project Time Schedule

The data will be obtained from the REDCap database which contains the information from the questionnaire filled out during the interview. Results from the multiplex respiratory viral panel will be in the REDCap database and links to files containing genomic sequences of a specific pathogen will be attached to individual case reports.

The incidence of respiratory illness and pathogen-specific infection will be calculated using monthly census counts of individuals staying in the facilities. Age-specific rates will be calculated using population denominators and facility census counts in the surveillance area.

Project Time Schedule	
Activity	Time Schedule
Data/information collection	0-6 months after OMB approval
Data cleaning/analysis	6-10 months after OMB approval
Laboratory testing of specimens	1-10 months after OMB approval
Laboratory/genomic analysis	10-12- months after OMB approval
Publication of results and reports to public health and shelters	18 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.

Attachments

1. Authorizing Legislation
2. 60-Day FRN
3. Case Report Form for Enhanced Surveillance of Respiratory Illness Among People Experiencing Homelessness in Anchorage, Alaska
4. Non-research determination
5. Project protocol
6. Consent form
7. Privacy Impact Assessment

References:

1. Rogers JH, Link AC, McCulloch D, et al. Characteristics of COVID-19 in Homeless Shelters : A Community-Based Surveillance Study. *Ann Intern Med*. Jan 2021;174(1):42-49. doi:10.7326/m20-3799
2. Tobolowsky FA, Gonzales E, Self JL, et al. COVID-19 Outbreak Among Three Affiliated Homeless Service Sites - King County, Washington, 2020. *MMWR Morb Mortal Wkly Rep*. May 1 2020;69(17):523-526. doi:10.15585/mmwr.mm6917e2
3. Richard L, Booth R, Rayner J, Clemens KK, Forchuk C, Shariff SZ. Testing, infection and complication rates of COVID-19 among people with a recent history of homelessness in Ontario, Canada: a retrospective cohort study. *CMAJ Open*. Jan-Mar 2021;9(1):E1-e9. doi:10.9778/cmajo.20200287
4. Imbert E, Kinley PM, Scarborough A, et al. Coronavirus Disease 2019 Outbreak in a San Francisco Homeless Shelter. *Clin Infect Dis*. Jul 15 2021;73(2):324-327. doi:10.1093/cid/ciaa1071
5. Miyawaki A, Hasegawa K, Tsugawa Y. Lessons from Influenza Outbreaks for Potential Impact of COVID-19 Outbreak on Hospitalizations, Ventilator Use, and Mortality Among Homeless Persons in New York State. *J Gen Intern Med*. Sep 2020;35(9):2781-2783. doi:10.1007/s11606-020-05876-1
6. Boonyaratanakornkit J, Ekici S, Magaret A, et al. Respiratory Syncytial Virus Infection in Homeless Populations, Washington, USA. *Emerg Infect Dis*. Jul 2019;25(7):1408-1411. doi:10.3201/eid2507.181261
7. Chu HY, Boeckh M, Englund JA, et al. The Seattle Flu Study: a multiarm community-based prospective study protocol for assessing influenza prevalence, transmission and genomic epidemiology. *BMJ Open*. Oct 7 2020;10(10):e037295. doi:10.1136/bmjopen-2020-037295
8. Gray L. Lessons from coronavirus surveillance at homeless shelters. *UW Medicine| Newsroom*. https://newsroom.uw.edu/news/lessons-coronavirus-surveillance-homeless-shelters
9. Goodykoontz E. City's plan to close Sullivan Arena homeless shelter before July faces big challenges. *Anchorage Daily News*. February 19, 2022. https://www.adn.com/alaska-news/anchorage/2022/02/19/citys-plan-to-close-sullivan-arena-homeless-shelter-before-july-faces-big-challenges/
10. Fernandez G. Campers say goodbye to temporary home as Centennial Campground closes. *Alaska News Source*. October 1, 2022. https://www.alaskasnewssource.com/2022/10/01/campers-say-goodbye-temporary-home-centennial-campground-closes-tonight/