B. multivorans Ice Machine Multistate Investigation

Request for OMB approval of an Extension

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Supporting Statement A

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- **Goal of the study:** This is an outbreak investigation which aims to evaluate the associations between *Burkholderia multivorans* infections among hospitalized patients and potential exposures to nonsterile ice and water from ice machines to help inform measures to prevent ongoing transmission.
- **Intended use of the resulting data:** The Centers for Disease Control and Prevention will share findings and recommendations with public health and healthcare partners to prevent further spread of *B. multivorans* infections; findings may also be shared with other relevant stakeholders and/or published in scientific journals to disseminate investigation outcomes.
- **Methods to be used to collect:** A case report form will be shared with jurisdictions reporting cases so that they can conduct medical chart abstraction and informal interviews with hospital staff. The information collected will be analyzed by CDC to evaluate risk factors and identify opportunities to interrupt transmission.
- **The subpopulation to be studied:** Patients with a new diagnosis of infection or colonization by *B. multivorans* (isolated from any body site) who had a hospital admission lasting at least 48 hours in the 14 days prior to the index specimen collection.
- **How data will be analyzed:** Epidemiologic data will be analyzed and interpreted in the context of clinical and laboratory findings analyses to characterize *B. multivorans* risk factors, and assess potential sources of *B. multivorans,* including ice machines and other products used in conjunction with ice machines.

1. Circumstances Making the Collection of Information Necessary

This is an Extension Information Collection Request. CDC is requesting approval for a period of 3 years.

CDC has been assisting state and local jurisdictions investigate clusters of *Burkholderia multivorans* infections among patients admitted across four hospitals in two non-contiguous states. The outbreak strain of the bacteria has been identified in environmental samples from ice machines. Molecular analysis has shown that the bacterial strain identified in ice machines is genetically highly similar to the patient isolates. Further investigation revealed that the same brand of ice machine and the same filters, descaling/cleaning, and sanitizing products were used by the four hospitals. Epidemiologic and laboratory evidence suggest the possibility of contaminated nonsterile ice and water from the same brand of ice machines as a common source of exposure.

Further investigation is needed to identify the scope of the outbreak and the source of the ice machine contamination. CDC has deemed it necessary to conduct a national call for cases requesting that public health authorities report cases and clusters of *B. multivorans*. A case report form was developed by CDC to assist jurisdictions in this effort. Jurisdictions will gather information using this case report form to assist in determining epidemiologic characteristics and risk factors of patients with *B. multivorans* as well as potential source(s) of *B. multivorans,* including ice machines and ice machine-related products (e.g., cleaning solutions).

Prior to launching this expanded investigation, there was no pre-existing approved information collection form that could be used for this type of outbreak. Therefore, as these non-research public health response activities, which required the use of a new data collection instrument, are specified in the Code of Federal Regulations [45 CFR 46.102(I)(2)] and in Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1), we originally requested and obtained approval for data collection until September 30, 2024, through an emergency information collection request. Since this non-research public health response remains active, we are requesting continued information collection request for a period of 3 years.

2. Purpose and Use of Information Collection

Jurisdictions will use a standardized case report form to gather information on case-patients via medical record abstraction, interviews with hospital staff, and direct observations (Attachment 3). The jurisdictions will gather this information only once upon identifying each individual patient with the infection. Each jurisdiction will identify a staff member from its Healthcare-Associated Infections/Antimicrobial Resistance (HAI/AR) Program to complete the case report form.

The information collected in the case report form has been used to assess individual case-patients' past medical history and recent healthcare exposures, including inpatient admissions, invasive devices, and surgeries. The case report form has permitted systematic collection of information pertaining to each affected hospital as relates to its use of nonsterile ice and water from ice machines for clinical care activities and their maintenance of ice machines. Preliminary findings of the information that has been collected to date show that nonsterile ice and water from ice machines are often used by physical therapists and occupational therapists during patient assessments (e.g., swallow clinical assessments) and clinical care activities (e.g., ice/cold therapy for pain relief). Also, an additional patient has been identified with the *B. multivorans* outbreak strain.

Epidemiological analyses of this information will continue to be conducted and interpreted in the context of clinical and laboratory findings in order to: characterize *B. multivorans* risk factors of patients with *B. multivorans*, understand how the use of nonsterile ice and water ice machines are potentially contributing to transmission, and assess potential sources of *B. multivorans,* including ice machines and other products used in conjunction with ice machines. This will enable CDC to better ascertain risk factors for transmission, potential source(s) of ice machine contamination, and develop targeted infection prevention and control recommendations to stop the transmission of the bacteria.

Absent permission and authority to proceed with this information collection, given that without it CDC will not be in a position to define the scope of the outbreak in the United States, clarify the sources of *B. multivorans*, and advise on implementation of mitigation measures to prevent further spread.

3. Use of Improved Information Technology and Burden Reduction

The case report form has been built in REDCap, which will enable the designated staff at each jurisdiction to electronically access, document, and submit the information collected. The REDCap form can only be accessed by staff authorized to use CDC's Secure Access Management Services (SAMS).

SAMS is a federal information technology (IT) system that gives authorized personnel secure access to non-public CDC applications.

Additionally, access to project records will be limited by REDCap data access groups. Data access groups are based on a user's jurisdiction, meaning that a user from one jurisdiction will not be able to access another jurisdiction's data. Thus, by having the case report form in REDCap, CDC will provide a secure way for the collection of the information. Since most, if not all, jurisdictions have at least one HAI/AR Program staff authorized to use CDC's SAMS, it is very likely that most of the collection of information will be done electronically with REDCap.

In the event that a jurisdiction is unable to use REDCap, a PDF version of the case report form will be shared so that they can manually collect the information. Case report forms that are manually completed will be shared electronically using encryption. If this occurs, it is likely that only a small proportion of jurisdictions will use this method. Personally identifiable information will not be included in the case report form, regardless of whether it is completed manually or via REDCap.

4. Efforts to Identify Duplication and Use of Similar Information

Burkholderia multivorans is not a notifiable disease in the United States and it is rare among the general population. CDC is not aware of the availability of any similar information or parallel investigation into this public health issue.

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 Federal Register Notice was published on April 12, 2024, Vol. 89, No. 72, pages 25875 – 25876 and no comments were received during the 60-day comment period. (Attachment 2).

B. As this is a multistate public health response identified by CDC, no consultations outside of CDC occurred.

9. Explanation of Any Payment or Gift to Respondents

There will not be any incentive to respondents. Staff from the HAI/AR programs in jurisdictions will gather information on case-patients via medical record abstraction, interviews with hospital staff, and direct observations, as part of their normal health department functions and duties.

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

NCEZID's Information Systems Security Officer (ISSO) reviewed this submission and determined that PII is collected and the Privacy Act applies. All PII will be collected using REDCap. A Privacy Impact Assessment is included as part of this submission (attachment 4).

Data will be kept private to the extent allowed by law.

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. IRB approval is not required (Attachment 5).

Justification for Sensitive Questions

There are no planned sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12.A and **12.B** provide details about how this estimate was calculated, assuming 40 respondents a year. The case report form will take approximately 3 hours per respondent (120 annual burden hours). The estimated annual cost burden to respondents will be $4,560.

A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
HAI/AR Program staff	*Burkholderia multivorans* outbreak investigation case report form	40	1	3	120
Total					120

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
HAI/AR Program staff	*Burkholderia multivorans* outbreak investigation case report form	120	$38	$4,560
Total				$4,560

* The United States Department of Labor, Bureau of Labor Statistics May 2022 National Occupational Employment and Wage Estimates (bls.gov) data were used to estimate the hourly wage rate for epidemiologists.

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

This collection of information is part of an outbreak response led by CDC staff whose duties are to respond to outbreaks in healthcare settings. This activity aligns with routine staff duties. Personnel costs for collection and analysis of the information include:

GS-13 FTE (1) + GS-15 FTE (1) = $281,423

15. Explanation for Program Changes or Adjustments

This is a 3-year extension request for an existing information collection. There are no proposed changes to the current information collection instrument.

16. Plans for Tabulation and Publication and Project Time Schedule

Since this is part of an outbreak investigation, preliminary review and analyses of the data/information collected will be done routinely to inform a timely public health response and the implementation of mitigation measures to prevent further spread. Therefore, the project time schedule outlined below is only an estimation for publication purposes only.

Project Time Schedule	
Activity	Time Schedule
Data/information collection	1–6 months after OMB approval.
Validation	7–8 months after OMB approval.
Analyses	9–10 months after OMB approval.
Publication	11–12 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. Information Collection instrument
4. Privacy Impact Assessment
5. Human Subjects Determination