Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant Pseudomonas aeruginosa Infections Associated with Invasive Medical Procedures in Tijuana, Mexico

Request for OMB approval of a New Information Collection

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Supporting Statement A

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- **Goal of the study:** Identify infections among individuals in the U.S. who had surgery at Facility 1 in order to prevent spread of resistance in the U.S.
- **Intended use of the resulting data:** Prevent spread of resistance in the U.S. and improve messaging to stem the flow of U.S. patients to Facility 1.
- **Methods to be used to collect:** Contacting exposed individuals by telephone and conducting a standardized survey.
- **The subpopulation to be studied:** Individuals who had surgery at Facility 1 since January 1, 2019.
- **How data will be analyzed:** Frequencies of survey responses will be calculated and summarized; attack rates of infections will be calculated and risk factors associated with infections will be determined.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) requests an emergency 3-month approval for a New Information Collection, "Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico".

Verona integron-encoded metallo-β-lactamase–producing carbapenem-resistant *Pseudomonas aeruginosa* (VIM-CRPA) and other carbapenemase-producing organisms are an emerging U.S. public health threat due to their high levels of antibiotic resistance and potential for rapid spread in healthcare.

Beginning in September 2018, CDC received reports of VIM-CRPA from multiple states through the Antibiotic Resistance Laboratory Network (AR Lab Network). The initial public health investigation identified 23 patients who reported undergoing invasive medical procedures in Tijuana, Mexico in the month prior to their positive culture. Among these, 18 patients reported surgery at Tijuana Facility 1; surgery dates at Facility 1 ranged from September 7, 2018 to January 21, 2019. Most individuals who underwent surgery at Facility 1 reported booking their surgeries through Travel Agency A. Mexican authorities conducted an onsite infection control assessment on December 4, 2018 and identified poor infection control practices at the hospital, including failure to follow recommended practices for assuring the quality of sterilization of medical devices and instruments. These breaches increase risk for infections with the bloodborne pathogens, including hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV), in addition to bacterial infections.

To communicate the ongoing risks associated with Facility 1 to the public, on January 9, 2019, CDC issued an alert recommending that travelers to Tijuana, Mexico not have surgery at Facility 1 until further notice. As names of persons exposed to Facility 1 beyond those with known CRPA cases were not initially provided to U.S. public health officials, bacterial and bloodborne pathogen testing recommendations for persons who had surgery at Facility 1 during the outbreak period were posted on

the CDC website on January 15. Despite these communications, U.S. residents continued to undergo surgery at Facility 1.

On February 22, 2019, Travel Agency A issued a notification about the risk of bacterial and blood borne pathogens infections following surgery at Facility 1 to all individuals who had surgery on or after August 1, 2018. On March 5, 2019, Travel Agency A provided CDC with contact information for all individuals that had been referred to Facility 1 to facilitate a public health response. Overall, 741 U.S. residents from 43 states, the District of Columbia, and Puerto Rico were referred by Travel Agency A and had surgery at Facility 1 from August 1, 2018 to March 1, 2019. Among these, 197 had surgery since January 1, 2018 and are at highest risk for developing VIM-CRPA infection and/or receiving ongoing treatment for surgical site infection in the U.S. healthcare system.

The overall goals of this urgent investigation are to ensure that patients who develop infections get prompt and appropriate treatment and to prevent spread of this resistant organism in U.S. hospitals. Specifically, this public health response is designed to (1) notify the patients who remain at risk for infection regarding the risk of infection with highly resistant bacteria and recommend they discuss bloodborne pathogen testing with their primary care provider; (2) assess whether exposed patients have been hospitalized since their surgery in order to guide efforts to prevent transmission of these resistant organisms in the United States; and (3) ensure that prior public health messages about this investigation are reaching the intended population in order to inform additional response/communication needs.

If individuals are identified as having suspected or confirmed infection or as having been hospitalized in the U.S. following their surgery, public health responses in accordance with CDC's Interim Guidance to Contain Novel and Emerging Multidrug-Resistant Organisms will be conducted by state or local health departments.

2. Purpose and Use of Information Collection

The data collected from the investigation will be used to identify infections among individuals in the U.S. who had surgery at Facility 1 in order to prevent spread of resistance in the U.S. and to improve messaging to stem the flow of U.S. patients to Facility 1. This request is to obtain OMB approval for collection of patient-level data through interview of exposed individuals by CDC or state and local health departments.

CDC cannot reasonably comply with the normal clearance procedures due to the public harm that is reasonably likely to result if routine processing of this request is required, specifically life-threatening infections in patients exposed to Facility 1, with the potential for further spread and outbreaks in U.S. hospitals where they seek treatment. Therefore, CDC requests a 90-day emergency clearance to conduct national case-finding and data collection for similar patient events.

3. Use of Improved Information Technology and Burden Reduction

Information on individuals who underwent surgery at Facility 1 will be collected by telephone interview. CDC will ask state and local health departments to contact individuals who underwent surgery at Facility 1 after January 1, 2019 by telephone to notify them of the potential risk of bacterial and BBP infection and to use a standardized survey instrument to assess exposures (e.g., type of surgery), infections post-surgery, hospital re-admissions post-surgery, and receipt of prior public health messaging. CDC will perform notifications and surveys for jurisdictions that request assistance. Although not specifically requested by CDC, some jurisdictions may interview individuals who had surgery prior to January 1 in order to identify prior infections resulting in hospitalization and direct surveillance efforts to detect spread of the resistant *P. aeruginosa* in local hospitals.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of similar data regarding this particular type of event.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data 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. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation (Attachment 2).

B. The efforts to consult outside the agency are outlined below:

CDC has been working closely with health departments in 43 states, the District of Columbia, and Puerto Rico.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

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

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act applies.

Data collected during patient notification and survey will come from sources with identifiable information. For notifications and interviews conducted by CDC, paper call logs and telephone scripts will necessarily contain personal identifiers, including name and telephone numbers. All individuals contacted by CDC will be assigned a unique identification number. Interview data will be entered into in a RedCap database without personal identifiers. Electronic files (e.g., interview database) will be stored on the secure CDC Share Network. Worksheets, call logs, and paper surveys will be stored in locked files in a laboratory and/or office.

Descriptive data presented in final reports, presentations, and scientific publications will not include patient identifiers. There are no planned uses for the data beyond the public health investigation described above.

Privacy Impact Assessment Information

Interview data will be entered into in a RedCap database without personal identifiers. However, CDC will maintain the contact information of individuals referred to Facility 1 by Travel Agency A. Where applicable, these forms are maintained as a system of records under the Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems," last published in its entirety in the Federal Register, Vol. 57, No. 252, December 31, 1992, pp. 62812-62814, and updated December 29, 1993 and December 28, 1994.

CDC will treat information in a secure manner and will not disclose, unless otherwise compelled by law. Electronic files (e.g., interview database) will be stored on the secure CDC Share Network. Worksheets, call logs, and paper surveys will be stored in locked files in a laboratory and/or office. Any electronic database that maintains such information will be kept in secure computers accessible to only CDC staff.

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

Institutional Review Board (IRB)

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review was not required (Attachment 4).

Justification for Sensitive Questions

In this activity, no sensitive questions will be asked.

12. Estimates of Annualized Burden Hours and Costs

The estimated burden to respondents is summarized in Table 12-A and Table 12-B below. The survey takes an average 15-20 minutes to complete. It's estimated that 45 state or local health departments will survey 197 individuals.

Table 12-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.)
Individuals	Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico: Survey	197	1	20/60	66
Total					66

There will be no anticipated costs to respondents other than time. The 2017 U.S. median national hourly wage for all occupations in the U.S. is $18.12 (see https://www.bls.gov/oes/current/oes_nat.htm#00-0000); since we do not know occupations of all individuals, this was used to represent wages. This wage is assumed for general respondents because of the variety of types of occupations expected.

Table 12-B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individuals	Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico: Survey	66	$18.12	$1196
Total				$1196

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

None.

14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is $11,814,40. This figure encompasses 50% FTE of two GS-12 employees for 1 week doing data collection, 50% of two GS-12 employees doing data analysis for two weeks, and ancillary information collection costs. The average hourly rate was obtained from the Office of Personnel Management's website (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/). The hourly rate for a GS-12 in metro Atlanta is $36.92.

Estimated Annualized Cost to the Government per Activity and Total				
Activity	Time in hours required to perform activity	Number of employees performing activity	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost
Data collection	80	2	$36.92	$5,907.20
Data analysis	80	2	$36.92	$5,907.20
			Total	$11,814.40

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Data collection	1 week after OMB approval
Data analysis	1–2 months after OMB approval
Generation of report	6 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. Verona Integron-Encoded Metallo-β-Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico: Survey
2. 60-Day Federal Register Notice
3. Non-Research determination