U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/13/19

Title:	Verona Integron-Encoded Metallo--Lactamase (VIM)-Producing Carbapenem-Resistant Pseudomonas aeruginosa Infections Associated with Invasive Medical Procedures in Tijuana, Mexico
Project Id:	0900f3eb81939d8f
Project Contact:	Epstein_Lauren (xdd0)
Organization:	NCEZID/DHQP/PRB/AREP
Status:	**Pending OADS Clearance**
Intended Use:	**Project Determination**
Estimated Start Date:	03/12/2019
Estimated Completion Date:	07/01/2019
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control#:	

Determinations

Determination	Justification	Completed	Entered By & Role
Does NOT Require OADS HRPO Review	Not Research	Tue Mar 12 07:30:19 EDT 2019	Peterson_James M. (iyr1) CIO HSC
Paperwork Reduction Act does apply		Tue Mar 12 15:46:37 EDT 2019	McMillen_Amy H. (auh1) OMB / PRA

Description & Funding

Description

Priority:	Standard
Determination Start Date:	03/11/19
Description:	DHQP is investigating an outbreak of highly resistant Pseudomonas aeruginosa infections associated with bariatric surgery at a hospital in Tijuana, Mexico. Approximately 750 Americans from 45 states have had surgery at this facility since August 1, 2018, the beginning of the outbreak period. Among these, approximately 200 had surgery since January 1, 2018, and are still at risk for developing infection and/or having infections that are still being treated in the U.S. healthcare system. CDC recently received the contact information for these exposed individuals to enable public health response. To help prevent spread of this resistant organism in U.S. hospitals and to ensure that patients who develop infection get prompt and appropriate treatment, CDC is recommending that states reach out to individuals to assess whether they developed infections and whether they have been hospitalized since their surgery in Mexico.
Goals/Purpose	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.
Objective:	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) ensuring that prior public health messages about this investigation are reaching the intended population in order to inform additional response/communication needs.
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other
Tags/Keywords:	Disease Notification, Disease Outbreaks, Mexico

Tags/ Keywords:	Disease Notification, Disease Outbreaks, Mexico
CDC's Role:	Other
Method Categories:	Outbreak Investigation, Public Health Assessment, Technical Assistance
Methods:	Telephone survey 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 (Appendix I). CDC will perform notifications and surveys for jurisdictions that request assistance. Some state health departments might choose to additionally notify and interview individuals who underwent surgery at Facility 1 prior to January 1, 2019, in order to identify cases who might have sought healthcare in their region, assess potential spread, and initiate prevention measures. For jurisdictions conducting the notifications, CDC will share contact information securely via encrypted Epi-X messaging. Colonization screening Individuals exposed to Facility 1 will be offered screening for carbapenemase-producing organisms carriage at the discretion of the state health department. Screening is used routinely in public health investigations of emerging multidrug-resistant organisms to identify asymptomatically colonized individuals and present spread in healthcare settings; screening recommendations are described in the CDC Interim Guidance for a Public Health Response to Contain Novel or Targeted Multidrug-resistant Organisms (MDROs) [https://www.cdc.gov/hai/containment/guidelines.html] and the February 14, 2013 HAN: New Carbapenem-Resistant Enterobacteriaceae Warrant Additional Action by Healthcare Providers. In this investigation, CDC recommends that states conduct screening for individuals at highest risk of transmitting VIM-CRPA in U.S. healthcare settings (e.g., those who had recent (since January 1, 2019) surgery at Facility 1, or who have been hospitalized in the U.S. following surgery at Facility 1 and whose VIM-CRPA carriage status is unknown). Screening for carbapenemase-producing organisms such as VIM-CRPA is conducted via rectal swab. Individuals approached for screening will be asked for consent for rectal swab collection (Appendix 2). Testing will be performed under CLIA guidelines through CDC's Antimicrobial Resistance Laboratory Network. Notifications by U.S. mail All individuals with surgery at Facility 1 prior to February 22, 2019 were provided an electronic notification by Travel Agency A about risks of bacterial and bloodborne pathogen infection. It is unknown whether this electronic notification was accessed by recipients and whether individuals undergoing surgery more recently also received a notification. CDC will therefore ask states to send two documents by U.S. mail to each individual who was exposed to Facility 1 after January 1, 2019: a notification regarding the risk of bacterial and blood-borne pathogen infections

	January 1, 2019: a notification regarding the risk of bacterial and blood borne pathogen infections and a letter to present to health providers if individuals are admitted to the hospital. The latter document will contain instructions for healthcare providers regarding transmission-based precautions and colonization screening. States may also elect to notify by mail individuals at lower risk of developing bacterial infections. Some states may ask individuals who have developed infections to contact the state health department.
Collection of Info, Data or Biospecimen:	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.
Expected Use of Findings/Results:	Survey and colonization screening findings will be shared with state health departments. Colonization screening findings will be shared with healthcare providers. Depending on the results of the investigation, findings may be reported at national conferences, as well as in a peer-reviewed manuscript.
Will PII be captured?	Yes
Does CDC have access to the identifiers?	Yes
Is a certificate or assurance of confidentiality in place or planned?	No
Is a nondisclosure agreement in place?	No

Funding

Funding yet to be added .....

Review Attributes

Non-Epi Aids Investigations

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT	Staff Type	Email	Phone	Organization
David Ham	SIQT1000575648	Principal Investigator	ink4@cdc.gov	404-639-2038	Antimicrobial Resistance and Emerging Pathogens Team
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Maroya Walters	SIQT1001441209	Principal Investigator	vii0@cdc.gov	404-639-3539	PREVENTION AND RESPONSE BRANCH

Data

DMP

Proposed Data Collection Start Date:	3/15/19
Proposed Data Collection End Date:	4/12/19
Public Access Level:	Restricted
Data Use Type:	Other - Data are covered under the Privacy Act.
Data Use URL:	
Data Use Contact:	

Spatiality

Country	State/Province	County/Region
United States		

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