Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2018001-XXX
EPI AID No. (if applicable):	
Requesting entity (e.g., jurisdiction):	Arizona Department of Health Services
Title of Investigation:	Undetermined risk factors for long term sequela resulting from Rocky Mountain spotted fever—Arizona, 2018
Purpose of Investigation: (Use as much space as necessary)	Rocky Mountain spotted fever (RMSF), a life-threatening and rapidly progressive tickborne disease, is caused by infection with the bacterium *Rickettsia rickettsii*. RMSF is an emerging threat to Arizona tribal communities. In 2018, cases have more than doubled in number compared to what was reported last year at this time. We conducted an investigation to understand the risk factors associated with developing neurological dysfunction and long-term disability after hospitalization with RMSF. In order to provide answer to assist patients and providers, we conducted: • Medical Chart abstraction of 126 charts (OMB exempted activity) • Conducted 22 screening interviews for inclusion in neurologic exams • Performed 9 neurologic exams Chart reviews were performed on two tribal reservations, and interviews and exams conducted on one. The data from the investigation are being entered into a database for analysis. Preliminary data suggest that long-term sequela are present in patients, including, but not limited to decreased mobility, difficulty with concentration and focus, and sensory impairments. Analysis is ongoing.
Duration of Data Collection:	
Date Began:	7/23/2018
Date Ended:	10/19/2018
Lead Investigator	
Name:	Naomi Drexler
CIO/Division/Branch:	NCEZID/DVBD/RZB

Complete the following for <u>each</u> instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Patient screening questionnaire

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☒ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)

☐ Descriptive Study (describe):

☐ Cross-sectional Study (describe):

- ☒ Cohort Study (describe): This investigation will evaluated a cohort of persons hospitalized with RMSF between 2002–2017.
- ☐ Case-Control Study (describe):
- ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☒ Survey Mode (indicate which mode(s) below):
  - ☒ Face-to-face Interview (describe): In person interview for patients hospitalized for RMSF between 2002-2017 to screen for neurologic exams
  - ☐ Telephone Interview (describe):
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	22
Total No. Sampled/Eligible to Respond (B):	126
Response Rate (A/B):	17%

Data Collection Instrument 2

Name of Data Collection Instrument: Neurological Examination form

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☒ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

- ☒ Epidemiologic Study (indicate which type(s) below)
  - ☐ Descriptive Study (describe):
  - ☐ Cross-sectional Study (describe):
  - ☒ Cohort Study (describe): This investigation evaluated a cohort of persons hospitalized with RMSF between 2002–2017.
  - ☐ Case-Control Study (describe):
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

☒ Survey Mode (indicate which mode(s) below):
- ☒ Face-to-face Interview (describe): Neurologic exam was performed in person by a federal staff person who is a licensed medical provider. The Exam form documents the observed neurological signs and responses relating to the exam.
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):
☐ Biological Specimen Sample
☐ Environmental Sample
☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	9
Total No. Sampled/Eligible to Respond (B):	16
Response Rate (A/B):	50%

Data Collection Instrument 3

Name of Data Collection Instrument:

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff
☐ Other (describe):

Data Collection Methods (check all that apply)

☐ Epidemiologic Study (indicate which type(s) below)
- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):
☐ Laboratory Testing (describe):
☐ Other (describe):

Data Collection Mode (check all that apply)

☐ Survey Mode (indicate which mode(s) below):
- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

- Total No. Responded (A):
- Total No. Sampled/Eligible to Respond (B):
- Response Rate (A/B):

(Additional Data Collection Instrument sections may be added if necessary.)

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Screening questionnaire	Patient	22	1	10	4
Neurological examination form	Patient	9	1	40	6

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
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Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2018002-XXX
EPI AID No. (if applicable):	
Requesting entity (e.g., jurisdiction):	NYC Department of Health and Mental Hygiene
Title of Investigation:	Multistate outbreak of coccidioidomycosis (Valley fever) in U.S. students and adults who traveled to Tijuana area, Mexico
Purpose of Investigation: (Use as much space as necessary)	Valley fever or coccidioidomycosis, is a respiratory fungal disease acquired by inhalation of the microscopic fungal spores which have been aerosolized through soil-disturbing activities such as digging. Untreated, coccidioidomycosis causes an illness lasting weeks to months. Antifungal medication reduces the duration and severity of symptoms. Appropriate medications, however, are often not prescribed because the infection is misdiagnosed as being of viral or bacterial etiology. People with compromised immune systems are at risk for life-threatening systemic infection from the fungus. CDC received notification from New York City (NYC) Department of Health and Mental Hygiene (DOHMH) on August 8, 2018, that two high school students (Patient 1 and 2) were hospitalized with pneumonia and persistent fevers following a service trip to Tijuana, Mexico. Students were in an area endemic for coccidioidomycosis and worked on housing projects that involved moving large amounts of soil. Both patients had a rash affecting the back, axilla, and groin. The illnesses were unresponsive to antibacterial medications, and a respiratory PCR panel (Biofire) was negative for a range of respiratory viruses, as were *Legionella* urinary antigen, blood cultures, and influenza testing. Both patients had chest X-rays showing bilateral patchy infiltrates that did not improve despite antibiotic treatment (the duration of antibiotic treatment is unknown). These findings are consistent with a fungal pneumonia. Patient 1 traveled to the Tijuana area during July 8–15, 2018 as part of a group of 54 people from the same high school in NYC and ~10–15 people from Seattle, Washington. Patient 2 traveled to the area during July 15–22, 2018, with 22 people from the same high school as Patients 1 and 2 in NYC and ~30 people from Kansas City, Missouri. In response to these illnesses, the NYC high school of Patient 1 and 2 notified the families in early August 2018 that students on the trip became ill with pneumonia and they should seek appropriate health care if any student or adult on the trip is experiencing any symptoms not restricted to Valley fever. After that notification, NYC DOHMH heard of two additional patients (Patients 3 and 4) with respiratory symptoms who both visited emergency departments but were not hospitalized. All four illnesses were confirmed as caused by Valley fever by serologic testing, suggesting that an outbreak occurred, given shared exposure to dust-activities at the same site. Based on the severity of illness, high inoculum exposure is likely. The Missouri Health Department recently reported that a student from a Kansas City high school (a Kansas State resident) who traveled to Tijuana area in July 16–20, 2018 also tested positive for coccidioidomycosis. All the members of all the known groups who participated in this service trip during July 16–20, 2018 have been notified that some of the people have been hospitalized with Valley fever, and additional case finding is underway. To date, service trip volunteers have been identified in 4 states (NY, MO, KS, WA). In addition, we completed a binational notification to Mexico and the Mexican state of Baja California through the CDC US-Mexico Unit. It is important to ensure that all travelers at risk of coccidioidomycosis from exposure at this site have been promptly notified to improve chances of timely proper diagnosis and treatment of infected persons. Better understanding the specific source of this outbreak could help protect future travelers to this area, as well as local residents, and prevent

	additional illnesses. The cases of coccidioidomycosis reported to date are of special concern because they manifested as severe illness in young, otherwise healthy people, suggesting that travelers were either exposed to massive doses of the pathogen, or infected by an unusually virulent strain. CDC assistance with this investigation was requested to determine the scope and extent of the current cluster of Valley fever infections, identify potential common factors or risk factors among cases, and develop recommendations to potentially reduce the risk of additional cases. OMB approved a questionnaire (Appendix 1) to identify risk factors for and the source of infection. This information will be used to recommend potential prevention and control measures.
Duration of Data Collection:	
Date Began:	10/23/2018
Date Ended:	11/27/2018
Lead Investigator	
Name:	Mitsuru Toda, MS, PhD
CIO/Division/Branch:	NCEZID/DFWED/MDB

Complete the following for <u>each</u> instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Survey

Type of Respondent

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☒ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☒ Cohort Study (describe): This is a cohort study to systematically collect information about clinical illness and potential exposures associated with Valley fever in order to identify cases and risk factors for and the source of infection.
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

☒ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☒ Self-administered Paper-and-Pencil Questionnaire (describe): We contacted service trip volunteers who traveled to Tijuana area, Mexico in July 2018 to complete the questionnaire (Appendix 1).
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	93
Total No. Sampled/Eligible to Respond (B):	130
Response Rate (A/B):	72%

Data Collection Instrument 2

Name of Data Collection Instrument:

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

- ☐ Epidemiologic Study (indicate which type(s) below)
  - ☐ Descriptive Study (describe):
  - ☐ Cross-sectional Study (describe):
  - ☐ Cohort Study (describe):
  - ☐ Case-Control Study (describe):
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ Telephone Interview (describe):
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	
Total No. Sampled/Eligible to Respond (B):	
Response Rate (A/B):	

Data Collection Instrument 3

Name of Data Collection Instrument:

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

☐ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

☐ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):

Total No. Sampled/Eligible to Respond (B):

Response Rate (A/B):

(Additional Data Collection Instrument sections may be added if necessary.)

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Questionnaire	General public	93	1	20	31

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:
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