Long-term sequela of Rocky Mountain spotted fever (RMSF)

Request for OMB approval of a New Information Collection

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Supporting Statement B

Contact:
Lee Samuel
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: llj3@cdc.gov

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1. Respondent Universe and Sampling Methods

This study uses a cohort of individuals already diagnosed with RMSF. No sampling will be undertaken, however some individuals may chose not to participate.

This investigation includes three components of data collection: 1. Review of medical charts for study patients, 2. Patient screening questionnaires, and 3. Neurological exam. We have selected to look at only hospitalized cases of RMSF between 2002-2017 in Arizona tribal communities. Hospitalized cases are more likely to have confirmatory laboratory criteria, and selects more severe cases which are more likely to express neurologic sequela from advanced vascular damage. We will attempt to contact all living individuals within this cohort to participate in the patient questionnaire. Only individuals who are determined to have possible long term sequela based on the survey responses and medical history will be eligible for the neurological exam.

Based on available surveillance data we believe that as many as 270 individuals will have been hospitalized for RMSF between 2002-2017. We anticipate some loss to follow-up and individuals who are unwilling to participate in the study and estimate a maximum samples size of 250 individuals to participate in the patient interview. We estimate that roughly half (125) of these individuals may warrant a neurological exam. This study is largely descriptive in nature and is not designed to compare neurological sequelae incidence in cases of RMSF compared to control populations. As such, few inferential statistics will be used. Standardized neurological assessments including the Montreal Cognitive Assessment (MoCA)[1] can be compared to reference standards in the overall population. Modified Rankin scales have been used in cases of stroke an in acute rehabilitation settings to predict recovery. [2] Based on scores of these standard test in normative populations and what would be considered abnormal, the same size for the neurological exam needs to exceed 30 persons to be sufficiently powered.

2. Procedures for the Collection of Information

[1] https://www.verywell.com/alzheimers-and-montreal-cognitive-assessment-moca-98617
[2] https://www.ncbi.nlm.nih.gov/pubmed/17272767

Data will be collected on paper forms for all three collection activities. Data will then be entered into Microsoft Access databases at CDC headquarters on CDC computers. Data will be stored on an encrypted SQL server.

Medical charts will be abstracted on site and recorded on chart abstraction forms. Medical chart abstraction forms will be transported to CDC facilities in Atlanta through certified mail, secured fax, or personal transportation. A coversheet, documenting patient name, date of birth, community, and patient ID, will be recorded on each data collection form at the time of abstraction or exam. The top sheet will then be separated from responses by the PIs and all patient data, exam results, and responses will be connected only by patient ID. PIs will maintain coversheets in a locked room at the CDC Rickettsial Zoonoses Branch office, separate from the original documents, until the completion of the study. A key linking unique identifiers with personal information will be kept with study investigators in a password protected file. All printed copies of data collection forms will be secured in a locked room at the CDC Rickettsial Zoonoses Branch office in a double locked facility for ten years as per CDC records management guidelines.

Data abstractors (members of CDC, IHS, state, county and tribal health departments) will be trained prior to study commencement in standard data collection practices and how to correctly use the data abstraction tool to minimize rater errors and biases. A second training will be used for individuals administering the questionnaire to provide adequate informed consent and to train individuals in completing a non-leading survey. Only a handful of practitioners (all study co-PIs) will be relied upon to perform neurological examinations so that it minimized rater-reliability issues. All practitioners will be trained and supervised by the neuro-epidemiologist from the CDC team. We will not perform double data collection verification. However, each data collection instrument will be evaluated by the site supervisor at the conclusion of each day to ensure all abstractions, surveys and exams are being performed consistently. Neurological exams will be scheduled to accommodate specialist and patient availability.

3. Methods to maximize Response Rates and Deal with No Response

Every effort will be made to find all medical charts of individuals meeting our initial case criteria to evaluate the clinical evidence of RMSF illness in order to be considered for the patient survey. Patient contact will be initiated by members of the Tribal health department who are working with the CDC study team. Tribal staff will have most up to date contact information for individuals and we believe will be the most culturally sensitive, respectful of patient privacy and best able to advocate for the reasons for participation. Patient interviews will be supervised by study staff. Tribal staff will make up to three attempts to contact an individual for participation. No incentive will be given for participating in the questionnaire. Only a small incentive ($10 gift card) will be provided for individuals participating in the neurological exam.

4. Tests of Procedures or Methods to be undertaken

During the development process data collection tools were piloted by study designers to ensure that questions were easily understood and locally appropriate. Collaboration with local community-based

organizations and leaders will help ensure that data collection activities are conducted in a culturally and linguistically appropriate manner, and will also enhance participation from community members, which will reduce non-response bias. Certified translators associated with the Tribal health department will also be available if preferred by the respondent. No further pre-tests are planned.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

All individuals consulted for statistical and data analysis aspects of the study work for the Centers for Disease Control and Prevention		
Naomi Drexler	Epidemiologist, Rickettsial Zoonoses Branch	isj3@cdc.gov, (404) 718-4669
Paige Armstrong	Medical Epidemiologist, Rickettsial Zoonoses Branch	Yzu9@cdc.gov, (404) 639-8450
Daniel Pastula	Neurologist and Medical Epidemiologist, Division of Vector Borne Diseases University of Colorado, Departments of Neurology, Medicine (Infectious Diseases), and Epidemiology	DPastula@cdc.gov, (908) 447-9360
Amy Peterson	Epidemiology Team Lead, Rickettsial Zoonoses Branch	Amp7@cdc.gov, (404) 718-4674
Brad Biggerstaff	Statistician, Division of Vector Borne Diseases (will be engaged in data analysis)	bkb5@cdc.gov, (970) 221-6473

Members of the Rickettsial Zoonoses Branch, Indian Health Service, Arizona Department of Health Services, and Tribal health departments may be involved in the design, collection, and reporting of the data collected using this activity.