Chronic Q Fever in the United States: Enhanced Clinical Surveillance

Request for OMB approval of a New Information Collection

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Supporting Statement B

Contact:
Johanna Salzer, DVM, PhD
MS H12-24
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30329
Phone: (404) 639-5176
Email: hio7@cdc.gov

Table of Contents

1. Respondent Universe and Sampling Methods..2
2. Procedures for the Collection of Information..2
3. Methods to maximize Response Rates and Deal with No Response...3
4. Tests of Procedures or Methods to be Undertaken...3
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data......3

1. Respondent Universe and Sampling Methods

This enhanced surveillance system is open to participation from clinicians managing the medical care of chronic Q fever patients.

Between 30 and 35 new cases of chronic Q fever are reported each year in the United States through the National Notifiable Diseases Surveillance System at CDC. CDC provides consultation with medical providers on 20–30 patients with chronic Q fever annually. As part of the case management consultation, we will enter clinical and epidemiologic information obtained from consenting clinicians into a secure online database as part of this enhanced clinical surveillance system. Our sampling strategy is passive in nature, relying on clinician reports to CDC. Given the busy nature of clinical practice, we do not anticipate that all clinician will participate. Therefore, it is likely that a minimum of five years of data collection will be necessary to obtain a sufficient sample size.

2. Procedures for the Collection of Information

The purpose of this project is to obtain additional clinical and epidemiological information on cases of chronic Q fever for which RZB staff is consulted by the provider. After assisting the clinician with his/her clinical management questions, a CDC Rickettsial Zoonoses Branch staff member will obtain clinical and epidemiologic information from the provider and enter this information into a REDCap database (Attachment 5). The Chronic Q Fever Case Initial Investigation Form collects different data than the standard surveillance case report form (Attachment 3) and will not duplicate data collection efforts already in place. Chronic Q fever cases are defined as those patients who meet the clinical and laboratory criteria defined by the Council for State and Territorial Epidemiologists (CSTE) for a chronic Q fever case (Attachment 2).

CDC Rickettsial Zoonoses Branch staff members will enter data into a CDC REDCap database. Data collection topics will include basic demographics, previous Q fever history, patient risk factors, clinical findings, laboratory and other diagnostic data, treatment information, and case outcome. Personally identifiable information for either the healthcare provider or the patient will not be collected or included in the electronic data used for analysis. This is a growing dataset with open enrollment; whenever CDC staff identify an appropriate case, we will invite the clinician to participate in this enhanced surveillance component.

CDC Rickettsial Zoonoses Branch staff members will contact the clinician at intervals of 6, 12, 18, and 24 months after the date of initial consult to obtain additional clinical information related to response to treatment using a standardized questionnaire (Attachment 6). Responses from this questionnaire will be entered into a CDC REDCap database. Participation in these follow-up surveys is optional and clinicians may refuse to participate in further data collection at any point.

General descriptive statistics (frequency, medians, etc.) will be used to summarize the data. The data are not generalizable beyond the particular respondents.

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

As with other infectious diseases reporting systems, this enhanced clinical surveillance system is a type of passive surveillance. The system relies on the receipt of case reports from healthcare providers. By sampling healthcare providers that reach out for clinical consultation with CDC subject matter experts, we hope that establishing a relationship with a clinician will ensure a higher response rate. We believe that clinicians will have a greater motivation to participate when we explain how the information learned from their experience managing a chronic Q fever patient will improve the overall understanding of this rare, but complex, disease.

Questionnaires will be designed to be administered in 20 minutes for the initial questionnaire and 5 minutes for each follow-up questionnaire, so the burden on participants should be sufficiently low to maximize response rates. We will inform respondents of what the project is asking, why it is being asked, who will see the results, and how the results will be used, as well as discussing how respondents will benefit from the results and how the findings will be put into action. Respondents will be informed of the time it will take to complete the survey, how their answers will be used, and will address data security and anonymity with respondents.

4. Tests of Procedures or Methods to be undertaken

We implemented strategies, e.g. pre-testing, key informant interviews, to ensure that the questionnaire collects the appropriate information and is not overly burdensome to complete. We invited three clinicians that had previously consulted on chronic Q fever cases to complete the questionnaire and provide feedback. Feedback received regarding the questionnaire included: “Overall, very easy to use and questions were very clear.” Clinicians piloting the initial questionnaire also were asked to record the amount of time it took to complete the survey to estimate the burden for administering the initial questionnaire. In this way, the burden estimate should most closely resemble a maximum average burden.

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

Statistical support is available to staff in the Division of Vector-borne Diseases, through Brad Biggerstaff and his team.

- Brad Biggerstaff, Statistician, Division of Vector-borne Diseases, National Center for Emerging & Zoonotic Infectious Diseases; (970) 221-6473; bkb5@cdc.gov; statistical support.

Data collection and analysis will be conducted by staff from the Epidemiology Team of the Rickettsial Zoonoses Branch.

- David McCormick, Medical Epidemiologist, Rickettsial Zoonoses Branch, National Center for Emerging & Zoonotic Infectious Diseases; (970) 787-5036; yup1@cdc.gov; POC for data collection and analysis; project design.
- Johanna Salzer, Epidemiology Team Lead, Rickettsial Zoonoses Branch, National Center for Emerging & Zoonotic Infectious Diseases; (404) 639-8450; hio7@cdc.gov; data collection and project design.
- Marissa Taylor, Epidemiologist, Rickettsial Zoonoses Branch, National Center for Emerging & Zoonotic Infectious Diseases; (404) 956-3781; njr2@cdc.gov; data collection.
- Nicolette Bestul, Epidemiologist, Rickettsial Zoonoses Branch, National Center for Emerging & Zoonotic Infectious Diseases; (678) 428-0379; pue8@cdc.gov; data collection.