

# **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**

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## 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 that reach out to consult with CDC’s Rickettsial Zoonoses.

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. Chronic Q fever is a very challenging diseases to medically manage and patients are on treatment for years and require frequent examination from their healthcare providers. Any U.S. medical provider that treats Q fever patients has the ability to reach out to CDC’s Rickettsial Zoonoses Branch to request a clinical consult. On average, CDC provides consultation with 5–12 medical providers a year. After case management consultation, we will invite the clinicians to participate in our enhanced clinical surveillance system via an introductory email (Attachment 5) that includes a URL link to an anonymous REDCap survey (Attachment 6). Our sampling strategy is passive in nature, relying on clinician reports to CDC. Given the busy nature of clinical practice, we do not expect that all clinician will participate; we anticipate high participation rates (50-75%) because of the long-term involvement the healthcare providers have in the management of these difficult cases. We aim to have information collected for 50 cases.

#### 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 a healthcare provider contacts the Rickettsial Zoonoses Branch staff for consultation. The Chronic Q fever enhanced surveillance report form (Attachment 6 & 7) collects different data than the National Notifiable Disease Surveillance System (NNDSS) (OMB 0920-0009) or supplement case report form for Q fever (Attachment 4) and will not duplicate data collection efforts already in place. After assisting the clinician with his/her clinical management questions, a CDC Rickettsial Zoonoses Branch staff member will send a separate email (Attachment 5) introducing the enhanced surveillance project and provide a URL link to an anonymous REDCap survey (Attachment 6). Participation is not required and the healthcare provider can still receive clinical consultations regardless of their participation.

Participating clinicians will enter the requested data into the Chronic Q fever enhanced surveillance report form accessed via an anonymous CDC REDCap web survey (Attachment 6). 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 the enhanced surveillance component.

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

## **2. 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 (Attachment 5).

The Chronic Q fever enhanced surveillance report form was designed to be administered in 20 minutes, so the burden on participants should be sufficiently low to maximize response rates. Through the language of the introductory email (Attachment 5), 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. We will send one reminder email one week after the initial request.

## **3. Tests of Procedures or Methods to be undertaken**

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

## **4. 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](mailto:bkb5@cdc.gov); statistical support.

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

- Cara Cherry, Epidemiologist, Rickettsial Zoonoses Branch, National Center for Emerging & Zoonotic Infectious Diseases; (404) 718-5401; [imv5@cdc.gov](mailto:imv5@cdc.gov); POC for data collection and analysis; project design.
- Paige Armstrong, Epidemiology Team Lead, Rickettsial Zoonoses Branch, National Center for Emerging & Zoonotic Infectious Diseases; (404) 639-8450; [yzu9@cdc.gov](mailto:yzu9@cdc.gov); data collection and project design.