

# **Chronic Q Fever in the United States: Enhanced Clinical Surveillance**

Request for OMB approval of a Revision Information Collection

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## **Supporting Statement A**

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- **Goal of the study:** To establish enhanced medical surveillance for chronic Q fever by gathering additional and more specific clinical data not otherwise collected during the course of routine public health surveillance for chronic Q fever. This information will allow for better characterization of the clinical presentation of, risk factors for, and response to treatment of chronic Q fever in the United States.
- **Intended use of the resulting data:** Summarized data will be used in at least one scientific publication. The results of this analysis are intended for physicians and medical researchers treating chronic Q fever. The results will help characterize an under-recognized disease and help educate physicians on identifying, diagnosing, and treating these patients.
- **Methods to be used to collect:** Passive surveillance; CDC staff will record requested information in a standardized REDCap electronic data form. No personally identifying information will be collected.
- **The subpopulation to be studied:** Chronic Q fever patients
- **How data will be analyzed:** Descriptive statistics (e.g. frequencies, means)

## 1. Circumstances Making the Collection of Information Necessary

This is a Revision Information Collection Request. We are requesting approval for a period of 3 years. This study is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector-borne Diseases requests approval for information collection from clinical healthcare providers who treated patients with chronic Q fever. Q fever is a worldwide zoonosis caused by *Coxiella burnetii* with acute and chronic disease presentations in humans. Acute infections are generally asymptomatic or subclinical but may result in non-specific febrile illness. Chronic Q fever occurs in fewer than 5% of patients with acute infection and can manifest months to years after the primary infection. Chronic Q fever has several clinical presentations, including endocarditis, chronic hepatitis, chronic vascular infections, osteomyelitis, and osteoarthritis. Endocarditis is the most common presentation of chronic Q fever, and patients at highest risk for developing this kind of infection are those with pre-existing valvular heart disease, vascular grafts, or aneurysms.

In the United States, Q fever cases are reported via the National Notifiable Disease Surveillance System (NNDSS), and supplementary clinical, laboratory, and demographic data are collected using a case report form (CRF) (Attachments 3 & 4) approved under OMB Control Number 0920-0728. Although chronic Q fever was recognized as a separate reportable disease entity in 2007, acute and chronic Q fever cases are still reported using the same CRF, with risk factor, exposure history, and clinical questions applied to both forms of the disease. This limits the amount and quality of data collected about chronic Q fever in particular, as its presentation differs from acute Q fever and different treatment strategies are required. Only endocarditis and hepatitis are listed as options for clinical manifestations on

the current CRF; data on osteomyelitis, osteoarthritis, central nervous system, or vascular infections are not collected systematically. It is unknown how frequently, or in what patients, these other chronic Q fever presentations occur in the United States. Data on outcomes other than death or hospitalizations are not collected by the current CRF. Patients with Q fever endocarditis are at risk for embolic strokes and infarcts, but the extent to which these two sequelae occur in Q fever patients is unknown. Although endocarditis is an option on the current CRF, no additional clinical data on endocarditis patients is collected. For example, we cannot describe which valve(s) is(are) more likely to be affected or what types of underlying valvular or cardiac disease may contribute to development of Q fever endocarditis — clinical data that may help physicians identify and diagnose cases. Additionally, response to treatment is not systematically collected, and understanding response to treatment would help improve clinical guidance provided by CDC to clinicians who reach out for guidance. Because of this lack of data, the true burden and proportion of cases exhibiting endocarditis and other forms of chronic Q fever in the United States is unknown.

## **2. Purpose and Use of Information Collection**

The purpose of this project is to obtain additional clinical and epidemiological information on cases of chronic Q fever. Medical management of chronic Q fever patients is complex, requiring several years of medical examinations and treatment for patients. Chronic Q fever is a very rare disease, with only 30–40 cases reported annually through national surveillance. Given the rarity of the disease and the complexity of the clinical care, health care providers often reach out to CDC for clinical consultation with Q fever subject matter experts. After assisting the clinician with his/her clinical management questions, a CDC staff member will verbally consent the clinician (Attachment 5) introducing the enhanced surveillance project and will enter information from a questionnaire (Attachment 6) into a REDCap database at the time of the initial consultation. Additional questionnaires (Attachment 7) will be administered at 6, 12, 18, and 24 months after the initial consult (twice annually for each respondent). Participation is voluntary.

RZB staff will enter data into a CDC REDCap database at the time of initial consult and at 6, 12, 18, and 24 months after the initial consult. 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. The majority of questions are multiple choice or select all that apply and open-ended questions are minimal. This will be a growing dataset with open enrollment; whenever staff identify an appropriate case, they will invite the clinician to participate in enhanced surveillance. This data collection tool collects different data than the standard NNDSS surveillance case report form and will not duplicate data collection efforts already in place.

## **3. Use of Improved Information Technology and Burden Reduction**

This study will consist of data collection using an initial questionnaire (Attachment 6) and follow-up questionnaires (Attachment 7) to collect and process data to reduce respondent burden and aid in data processing and reporting efficiency. Administering this survey during the initial consult will streamline data collection and reduce additional burden for consulting clinicians. Not all questions will be applicable for every patient, which reduces the overall time it takes to complete the survey.

The number of questions posed will be held to the minimum required in all information collections in order to elicit the necessary data.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

Existing national surveillance reported to CDC does not collect many important characteristics regarding the various clinical presentations, risk factors, and outcomes of chronic Q fever. CDC is not aware of the availability of any similar information in the United States.

#### **5. Impact on Small Businesses or Other Small Entities**

This data collection will not involve small businesses.

#### **6. Consequences of Collecting the Information Less Frequently**

This is a one-time information collection, unless a healthcare provider has multiple patients to report. Each patient is only reported on once for this surveillance system.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

#### **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. A 60-day Federal Register Notice was published in the *Federal Register* on June 27, 2023, vol. 88, No. 112, pp. 41629 (Attachment 2). CDC did not receive public comments related to this notice.

B. No consultations outside of CDC occurred.

#### **9. Explanation of Any Payment or Gift to Respondents**

No payments, gifts, or incentives will be provided for participation in this enhanced surveillance.

#### **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

Activities do not involve the collection of individually identifiable information.

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. Further information concerning the protection of privacy can be found in the attached Privacy Impact Assessment (Attachment 8).

#### **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

##### Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required (Attachment 9).

## Justification for Sensitive Questions

There are no planned sensitive questions for this surveillance system.

### **12. Estimates of Annualized Burden Hours and Costs**

**12.A** and **12.B** provide details about how this estimate was calculated, assuming 50 respondents a year. The initial questionnaire will take approximately 20 minutes per individual (17 burden hours), and the follow-up questionnaires will take approximately 10 minutes per individual (17 burden hours). The estimated annual cost burden to participants for information collection will be \$3,682.20.

#### A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Physician, Internist	Chronic Q fever enhanced surveillance report form	50	1	20/60	17
	Chronic Q fever enhanced surveillance report form: follow-up	50	2	10/60	17
<b>Total</b>					<b>34</b>

#### B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Physician, Internist	Chronic Q fever enhanced surveillance report form	17	\$108.30	\$1,841.10
	Chronic Q fever enhanced surveillance report form: follow-up	17	\$108.30	\$1841.10
<b>Total</b>				<b>\$3,682.20</b>

\* The United States Department of Labor, Bureau of Labor Statistics May 2022 <https://www.bls.gov/oes/current/oes291216.htm> data were used to estimate the hourly wage rate for physicians.

### **13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no costs to respondents other than their time to participate.

#### 14. Annualized Cost to the Government

The average annualized cost to the Federal Government to collect this information is \$5,000. The federal government personnel estimate is based on cost of the one CDC staff. Federal staff responsibilities include overall management and oversight of the project, provision of content matter expertise in the development of the research strategy and data collection instruments, data collection, analysis and reporting.

		Percent Time	Total (\$)
<b>Federal Government Personnel Costs</b>	CDC Epidemiologist (GS-13)	5%	5,000
<b>Total Annualized Cost to Government</b>			\$5,000

#### 15. Explanation for Program Changes or Adjustments

This is a revision of a currently approved collection. Recently, there has been an increased volume of clinical consultation requests. To reflect this, we are proposing an increase in the number of respondents to 50 each year. Additionally, the clinical course for these patients is often complex, and clinical relapse or prolonged infection has been reported. To capture these important clinical details, we propose increasing the number of total instruments to 2 (two), with a follow-up survey that will take five minutes each at 6, 12, 18, and 24 months from the date of the initial consult.

#### 16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Ongoing enrollment for medical surveillance	Any time after OMB approval
Data compiled for analysis	Five years after data collection begins
Analysis of first five-year results (descriptive statistics)	Within 2 months of data compilation
Draft manuscript completed	Within 6 months of analysis
Final manuscript submitted	Within 3 months of draft manuscript completion

Between 30 and 35 cases of chronic Q fever are reported each year in the United States through national surveillance. CDC provides consultation with medical providers on 20–30 patients a year. A minimum of five years of data collection will likely be necessary to obtain a sufficient sample size. Data collection

is anticipated to begin in as soon as OMB approval is obtained. After a period of five years, the data will be compiled for analysis. The analysis will focus on summary statistics of clinical characteristics and trend analysis. Individual cases will not be discussed singularly in the summary of analysis. Data will be analyzed in R. The results will be included in a manuscript and submitted for publication in the peer-reviewed literature. Results will also be used to develop clinical educational materials. The results of this analysis are intended for physicians and medical researchers studying chronic Q fever. The results will help characterize an under-recognized disease and help educate physicians on identifying, diagnosing, and treating these cases.

#### **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB Expiration date is appropriate.

#### **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

#### **Attachments**

1. Authorizing Legislation
2. Published 60-Day FRN
3. National Notifiable Disease Surveillance System Q fever case definition
4. Supplemental Q fever Case Report Form (CFR)
5. Consent Script
6. Chronic Q fever enhanced surveillance report form (PDF)
7. Chronic Q fever enhanced surveillance report form – Follow-up (PDF)
8. Privacy Impact Assessment
9. Human Subjects Determination Letter