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 A

Contact:
Amy McMillen
Office of Policy, Analysis and Strategy
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS H16-5
Atlanta, Georgia 30329-4027
Phone: (404 639-1045
Email: auh1@cdc.gov

Table of Contents

1. Circumstances Making the Collection of Information Necessary....3
2. Purpose and Use of Information Collection....3
3. Use of Improved Information Technology and Burden Reduction....3
4. Efforts to Identify Duplication and Use of Similar Information....4
5. Impact on Small Businesses or Other Small Entities....4
6. Consequences of Collecting the Information Less Frequently....4
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5....4
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency. 4
9. Explanation of Any Payment or Gift to Respondents....4
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents....5
11. Institutional Review Board (IRB) and Justification for Sensitive Questions....5
12. Estimates of Annualized Burden Hours and Costs....5
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers....6
14. Annualized Cost to the Government....6
15. Explanation for Program Changes or Adjustments....6
16. Plans for Tabulation and Publication and Project Time Schedule....6
17. Reason(s) Display of OMB Expiration Date is Inappropriate....7
18. Exceptions to Certification for Paperwork Reduction Act Submissions....7

Attachments....7

- **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 and risk factors 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 and diagnosis these cases.
- **Methods to be used to collect:** Passive surveillance; participating clinicians 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 new 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. Acute infections are generally asymptomatic or subclinical, but may result in non-specific febrile illness. Chronic Q fever can manifest months to years after the primary infection and is rare, occurring in <5% of persons with an acute infection. Chronic Q fever can take on several clinical forms, 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) (OMB 0920-0009), and supplementary clinical, laboratory, and demographic data are collected using a case report form (CRF) (Attachments 3 & 4). 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, since its presentation is very different from acute Q fever. Only endocarditis and hepatitis are listed as options for clinical manifestations on the current CRF; data on osteomyelitis, osteoarthritis, or vascular infections are not systematically collected. 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. 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 (average of 5 to 12 year) 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 send a separate email (Attachment 5) introducing the enhanced surveillance project and provide a URL link to an anonymous REDCap survey (Attachments 6 & 7). Participation is not required.

Participating clinicians will complete the Chronic Q fever enhanced surveillance report form by entering the requested data into 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. 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 through the use of a one-time electronic survey (Attachment 6) to collect and process data to reduce respondent burden and aid in data processing and reporting efficiency. This survey makes use of extensive skip-logic patterns, so that entire sections of questions are hidden unless the participant indicates that a certain disease characteristic is present. An online survey format is easier for the participant to follow than printed skip logic instructions on a paper form. Not applicable questions been hidden also reduces the overall time it takes to complete the survey.

Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. 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 December 23, 2019, vol. 84, No. 246, pp. 70,552 (Attachment 2). CDC received one non-substantive public comment related to this notice and replied with a standard CDC response (Attachment 2a).

B. CDC consults included:

Gil Kersh, PhD
Q fever laboratory team lead and Rickettsial Zoonoses Branch Chief
CDC, Atlanta, GA 30029
404.639.1028; hws7@cdc.gov

Chris Paddock, MD
Medical Officer, Rickettsial Zoonoses Branch
CDC, Atlanta, GA 30029
404.639.1309; cdp9@cdc.gov

Outside CDC consultation included:

Aldon Li, MD | Physician In Charge
Division of Infectious Disease – Riverside / Moreno Valley
Volunteer Assistant Clinical Professor, UCR School of Medicine

Zanthia Wiley, MD
Assistant Professor of Medicine
Division of Infectious Diseases
Associate Director of Antimicrobial Stewardship

Emory University Hospital Midtown

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

This information collection request has been reviewed by the CDC National Center for Emerging and Zoonotic Diseases (NCEZID). NCEZID has determined that the Privacy Act does not apply to this information collection request. A Privacy Impact Assessment is included as part of this submission (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 15 respondents a year. The survey will take approximately 20 minutes per individual (5 burden hours). The estimated annual cost burden to participants for information collection will be $472.

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	15	1	20/60	5
Total					

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	5	$94.47	472.35
Total				

* The United States Department of Labor, Bureau of Labor Statistics May 2018 https://www.bls.gov/oes/current/oes291063.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 ($)**
Federal Government Personnel Costs	CDC Epidemiologist (GS-13)	5%	5,000
Total Annualized Cost to Government			$5,000

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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 5–10 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 SAS. The results will be included in a manuscript and submitted for publication in the peer-reviewed literature. 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 and diagnosing 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
   2a. Public Comment
3. National Notifiable Disease Surveillance System Q fever case definition
4. Supplemental Q fever Case Report Form
5. Survey invitation e-mail
6. Screenshots of REDCap online survey module of the Chronic Q fever enhanced surveillance report form(Information Collection instrument)
7. PDF Information Collection instrument (the Chronic Q fever enhanced surveillance report form)
8. Privacy Impact Assessment
9. Human subjects determination letter