Enhanced Surveillance of Coccidioidomycosis in Low- and Non-Endemic States

New submission

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Enhanced Surveillance of Coccidioidomycosis in Low- and Non-Endemic States

Goal of study: The goal of this project is to better describe the epidemiological and clinical characteristics of coccidioidomycosis cases in low- and non-endemic states.

Intended use of data: Data will be used to describe the features of coccidioidomycosis cases in low- and non-endemic states in at least one scientific publication, to help inform current routine surveillance practices, and to guide future awareness and educational efforts in these areas.

Methods used: For one calendar year, state health department personnel will conduct telephone interviews with reported coccidioidomycosis cases and will record responses on a standardized form. Completed forms containing no personally-identifying information will be sent to CDC's Mycotic Diseases Branch by secure email or fax.

Subpopulation studied: Coccidioidomycosis cases meeting the CSTE case definition in participating low- and non-endemic states.

How data analyzed: CDC will enter and merge data from participating states in Microsoft Access and import the data to SAS v. 9.3 for descriptive analyses.

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request. We are requesting approval for a period of 24 months.

Background

Coccidioidomycosis, also called "Valley fever," is a nationally notifiable fungal infection caused by inhalation of soil-dwelling *Coccidioides* spp. arthroconidia. Symptomatic infection occurs in approximately 40% of cases and usually presents as a self-limiting influenza-like illness, but a small proportion of patients develop life-threatening severe pulmonary or disseminated disease.[1,2] In the United States, coccidioidomycosis is known to be endemic in the southwestern states, with hyperendemic foci in Arizona's Sonoran Desert and California's southern San Joaquin Valley.[3] Nevada, New Mexico, Utah, and western Texas (coccidioidomycosis is not reportable statewide in Texas) are also known to be endemic but have a much lower reported incidence. The endemic areas in the U.S. were established using large-scale skin test surveys conducted during the mid-1940s to early 1950s.[3] There is now evidence to suggest that the true endemic areas may be broader than previously recognized. For example, *Coccidioides* was recently found in soil in south-central Washington State, far north of the known endemic areas.[4,5] Because cases are reported according to state of residence (which is not necessarily the state where exposure occurred), accurate information on a case's travel history is essential for describing where the infection was likely acquired.

Coccidioidomycosis is currently reportable in 19 states. Approximately 10,000 coccidioidomycosis cases are reported in the U.S. each year to CDC through the Nationally Notifiable Diseases Surveillance System (NNDSS). More than 65% of reported coccidioidomycosis cases occur in Arizona, and more than 30% occur in California.[6] The epidemiology of this disease in Arizona and California has been relatively well-described;[7-9] however, the features of reported cases in other states have not been assessed systematically. NNDSS data indicate that the number of reported coccidioidomycosis cases in known low-endemic (New Mexico, Nevada, and Utah) and non-endemic states has increased overall during the past decade, indicating that this disease remains an important public health problem on a national scale. Data reported to NNDSS are essentially limited to state and county of residence, date reported, age, sex, race, and ethnicity. A few states collect additional information that is not transmitted to NNDSS; however, states that do so may capture different data elements or capture the same

elements in different ways, so the additional information gathered during surveillance is not always comparable between states.

In addition to determining which information is most important to collect during routine surveillance in non-hyperendemic states, the suitability of the Council of State and Territorial Epidemiologists (CSTE) case definition has not been assessed in these areas. The CSTE definition for coccidioidomycosis includes both clinical and laboratory criteria and has undergone several revisions since its creation in 1995. Most recently, the laboratory component of the case definition was changed in 2008 to include cases with a single positive test result; previously, documentation of a rising IgG titer was required. Serologic tests are commonly used in the diagnosis of coccidioidomycosis, and the coccidioidal enzyme immunoassay (EIA) is widely used because of its rapid turnaround time; however, one commercially-available EIA (Meridian Bioscience) had been described to have high rates of false positivity for isolated IgM results in some instances.[10,11] In addition, the CSTE case definition does not incorporate exposure to known endemic areas. Therefore, in areas with undefined endemicity or in areas not known to be endemic, interpretation of a single positive serologic test result for coccidioidomycosis can be challenging in the absence of clinical symptoms, if the patient's travel history cannot be obtained, or if there is laboratory evidence of an additional pathogen that better explains the etiology of the infection.

Primary prevention strategies for coccidioidomycosis have not yet been proven to be effective. Without these types of evidence-based prevention methods, public health efforts may be best aimed at promoting awareness of coccidioidomycosis among healthcare providers and the general public, which could potentially lead to earlier diagnoses and possibly better outcomes for patients. Improved surveillance data are essential for identifying such opportunities to promote awareness about this disease and for determining its true public health burden. Therefore, a better description of the epidemiology, clinical features, diagnosis, treatment, and outcomes of coccidioidomycosis cases in low- and non-endemic states will not only help inform current routine surveillance practices, but also to guide future awareness and educational efforts in these areas.

This study is authorized under the Public Health Service Act, (42 USC 241) Section 301. A copy is included in the attachments (Attachment 1).

Privacy Impact Assessment

State health departments will have access to personal identifiers as part of their routine public health follow-up, but no identifiable information will be transmitted to CDC.

Overview of data collection system

Cases will be identified through routine state-based coccidioidomycosis surveillance; cases meeting the CSTE definition of a confirmed case are eligible to be interviewed by state health department personnel. All cases reported in the year following the project start date will be contacted by telephone and invited to participate in the interview. Ideally, cases should be contacted within four to six weeks after they are first identified as meeting the CSTE case definition. A log will be provided to record phone call attempts. A total of five attempts should be made for each valid phone number. At least one attempt should be made in the morning (8 am – 12 pm) and one in the afternoon (12 – 5 pm) on weekdays. If there is no response after three attempts during the day, at least one attempt should be made on a weekday evening (5 – 8 pm), and at least one attempt should be made on a weekend (Saturday or Sunday, 10 am – 9 pm). A parent or guardian will be interviewed for cases under 13 years old. For cases aged 13–17 years old, the adolescent can be interviewed if permission from the parent or guardian is obtained. State health departments routinely contact patients and their caregivers to collect information about reportable diseases such as coccidioidomycosis. Therefore, each state health department will use their existing processes for gaining voluntary participation from patients with reportable conditions (or their guardians).

Participating states (Louisiana, Michigan, Minnesota, Missouri, Montana, Nevada, New Mexico, North Dakota, Ohio, Oregon, Pennsylvania, Utah, and Wyoming) may choose to take a retrospective approach instead of or in addition to the prospective approach described above. With the retrospective approach, cases reported in the year preceding the project start date meeting the CSTE case definition will be contacted by telephone and invited to complete the interview by telephone. Interviews will be conducted using the same methods described in the prospective approach.

Data collection partners are any interested state where coccidioidomycosis is low- or non-endemic and is a reportable condition.

Description of the information to be collected

A standardized case report form to will be used to collect information on demographics, underlying medical conditions, travel history, symptom type and duration, healthcare-seeking behaviors, diagnosis, treatment, and outcomes. The interview is expected to take approximately 20 minutes. The last page of the CRF will not be used during the interview but will collect information about the laboratory method(s) used for coccidioidomycosis diagnosis, if that information is available from states' reportable disease databases.

State health departments will have access to personal identifiers as part of their routine public health follow-up, but no identifiable information will be recorded on the CRF or transmitted to CDC. CDC's Mycotic Diseases Branch (MDB) will enter the CRF data into a password-protected Microsoft Access 2010 database. MDB will merge data from all states and import the data to SAS v. 9.3 for analysis.

References

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2. Purpose and Use of Information Collection

Currently, little to no information exists about the appropriateness of existing coccidioidomycosis surveillance strategies or about the epidemiology of coccidioidomycosis in states where the disease is not highly endemic. CDC and state health departments will use the information collected to:

- Determine which data elements are most important to collect during routine coccidioidomycosis surveillance,

- Assess the applicability of the current Council of State and Territorial Epidemiologists (CSTE) case definition for coccidioidomycosis cases reported from non-hyperendemic areas,
- Describe the characteristics, exposure risk factors, and diagnostic and treatment practices of cases within and across participating states, and
- Identify areas and opportunities for future efforts related to coccidioidomycosis awareness and education.

3. Use of Improved Information Technology and Burden Reduction

State health department personnel will interview participants via telephone using a standardized questionnaire. Completed forms containing no personal identifiers will be sent to MDB and entered into a secure Microsoft Access database. No identifiable information will be recorded on the questionnaire or transmitted to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

Basic data on coccidioidomycosis are collected through NNDSS; however, the data are essentially limited to state and county of residence, date reported, age, sex, race, and ethnicity. A few states collect additional information, which varies by state and is not transmitted to NNDSS; however, none of the states participating in this project currently collect the type of detailed epidemiologic information proposed in this surveillance project.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences if Information Collected Less Frequently

Data collection will occur in the four to six weeks following the date the case is identified through routine public health surveillance. Respondents will respond to the data collection only once. Less frequent data collection could result in recall bias. Accurate information about cases' potential locations, timeframes, and activities related to exposure(s) is essential to this analysis.

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

The information collection activity fully complies with the Guidelines 5 CFR 1320.5.

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

A. A 60 day notice was published in the Federal Register on Friday, March 27, 2015, Volume 80, No. 59, p. 16397. No public comments were received.

B. The development of this project was a collaborative effort by MDB and the following state health departments: Louisiana Department of Health and Hospitals, Michigan Department of Community Health, Minnesota Department of Health, Missouri Department of Health & Senior Services , Montana Department of Public Health & Human Services, New Mexico Department of Health, Nevada Department of Health and Human Services, North Dakota Department of Health, Ohio Department of Health, Pennsylvania Department of Health, Utah Department of Health, and Wyoming Department of Health.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is to be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection request has been reviewed by NCEZID and it has determined that the Privacy Act does not apply.

State health departments will have access to personal identifiers as part of their routine public health follow-up, but no identifiable information will be recorded on the case report form or transmitted to CDC. State health department personnel who conduct the interviews will assign each interviewed case a unique identifier containing the state postal code followed by a hyphen and sequential numbering (e.g., LA-01, LA-02, etc.) and record this at the top of each page of the case report form. The assignment of a unique state identification number permits the removal of all personal identifiers and ensures security of the data sent to CDC. State health departments will determine how the linking information will be stored and for how long it will be maintained.

Potential respondents will be informed that their participation is completely voluntary and they may choose to not to participate or to not answer any questions that they consider to be of a sensitive nature. There are no penalties for not participating. There is also no risk to the subject beyond the unlikely risk of loss of security regarding non-sensitive questions. Participants may refuse to answer any of the questions or to discontinue the survey at any time.

IRB Approval

This study has been determined to be an exempt category of research involving human subjects. A copy of the exemption determination is attached (Attachment 3).

Privacy Impact Assessment Information

1. Individuals will be informed that providing the information is voluntary.
2. Because this project is part of routine public health surveillance for a reportable disease, formal consent to participate in the surveillance not required. However, cases may choose not to participate and may choose not to answer any question they do not wish to answer.
3. Information collected will not contain personal identifiers and will be stored on a secure network in a password-protected database.
4. This information collection request has been reviewed by NCEZID and it has determined that the Privacy Act does not apply.

11. Justification for Sensitive Questions

We do not believe that the proposed questions are sensitive in nature. Cases may decline to participate in the enhanced surveillance, and participants may choose not any answer any question(s) they feel are sensitive.

12. Estimates of Annualized Burden Hours and Costs

A. There were 291 confirmed coccidioidomycosis reported from participating states in 2013, the most recent year for which complete NNDSS data are available. Assuming a 50% response rate, we estimate enrollment of approximately 145 participants in one year. We estimate that it will take state health department personnel 20 minutes to administer the questionnaire and 10 minutes to retrieve and record the diagnostic information from their state reportable disease database. This results in an estimated annual burden to the public of 48 hours.

Estimated annual burden hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours
Cases	Case Report Form for Coccidioidomycosis (Valley Fever) Enhanced Surveillance	145	1	20/60	**48**

B. Case interviews will be conducted by epidemiologists at state health departments. The mean hourly wage for epidemiologists at state health departments is $29.73, according to the US Department of Labor (http://www.bls.gov/oes/2012/may/oes191041.htm). Estimated total respondent costs (48 burden hours * $29.73 per hour) is $1427.04.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Cases	Case Report Form for Coccidioidomycosis (Valley Fever) Enhanced Surveillance	48	$29.73	$1427.04
Total				1427.04

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

None

14. Annualized Cost to the Government

The estimated cost to the Federal government includes emailing, data entry, and data analysis performed by a GS-11 Epidemiologist.

Expense item	Estimated hours	Hourly Wage Rate	Cost
Epidemiologist (GS-11)	400 (8 hrs/wk for 50 weeks per year)	$29.32	$11,728.00

Total	**400**		**$11,728.00**

15. Explanations for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be complied, cleaned, and analyzed 15 to 18 months after OMB approval. Descriptive statistics will be used to analyze the data. CDC and state partners will publish the results in peer-reviewed journals.

Activity	**Time schedule**
Data collection	0 – 15 months after OMB approval
Final data cleaning and analysis	15 – 18 months after OMB approval
Preparation of final report(s)	18 – 24 months after OMB approval

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

1. Authorizing Legislation
2. 60 Day Federal Register Notice
3. Non-research determination
4. Case questionnaire
5. IRB determination