

Enhanced Surveillance for Histoplasmosis

Request for OMB approval of a New Information Collection

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Supporting Statement A

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Table of Contents

Request for OMB approval of a New Information Collection.....	1
1. Authorizing Legislation.....	3
2. 60-Day FRN.....	3
3. Information Collection instrument: Case Report Form for Histoplasmosis Enhanced Surveillance. .	3
4. Non-research determination.....	3
1. Circumstances Making the Collection of Information Necessary.....	4
2. Purpose and Use of Information Collection.....	5
3. Use of Improved Information Technology and Burden Reduction.....	6
4. Efforts to Identify Duplication and Use of Similar Information.....	6
5. Impact on Small Businesses or Other Small Entities.....	6
6. Consequences of Collecting the Information Less Frequently.....	6
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	7
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency. 7	
9. Explanation of Any Payment or Gift to Respondents.....	7
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	7
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	7
12. Estimates of Annualized Burden Hours and Costs.....	7
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	9
14. Annualized Cost to the Government.....	9
15. Explanation for Program Changes or Adjustments.....	9
16. Plans for Tabulation and Publication and Project Time Schedule.....	9
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	9
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	10

Attachments

1. Authorizing Legislation
2. 60-Day FRN
3. Case Report Form for Histoplasmosis Enhanced Surveillance
4. Non-research determination
5. Project protocol

- **Goal of the study:** To better describe the epidemiological and clinical characteristics of reported histoplasmosis cases in states where it is reportable.
- **Intended use of the resulting data:** Data will be used to describe the features of histoplasmosis cases in at least one scientific publication, to help inform current routine surveillance practices, and to guide future awareness and educational efforts.
- **Methods to be used to collect:** State health department personnel will conduct telephone interviews with reported histoplasmosis 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.
- **The subpopulation to be studied:** Histoplasmosis cases meeting the [CSTE Standardized Surveillance Case Definition](#) in participating states.

PART A. JUSTIFICATION

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. 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 Foodborne, Waterborne, and Environmental Diseases requests approval for information collection from state and local health departments in states where histoplasmosis is reportable on patients with histoplasmosis. Histoplasmosis is an infectious disease caused by inhalation of the environmental fungus *Histoplasma capsulatum* (1). Histoplasmosis can range from asymptomatic or mild illness to severe disseminated disease, and it is often described as the most common endemic mycosis in North America. Most epidemiologic data about histoplasmosis is derived from outbreak investigations, yet outbreak-associated illnesses represent a small proportion of overall cases. Therefore, much still remains unknown about the epidemiology and patient burden of histoplasmosis in the United States (2-4).

Histoplasmosis is currently reportable in 11 states – Arkansas, Delaware, Illinois, Indiana, Kentucky, Louisiana, Michigan, Minnesota, Nebraska, Pennsylvania, and Wisconsin – but is not nationally notifiable. In June 2016, the Council of State and Territorial Epidemiologists (CSTE) passed a position statement to standardize the case definition for histoplasmosis, a first step towards more consistent surveillance methodology (5). Before this change, states used slightly different case definitions. A recent multistate analysis of histoplasmosis cases reported to public health during 2011–2014 also revealed variation in the data elements collected by each state, limiting inter-state comparability (6). In addition, data on possible exposures, underlying medical conditions, symptoms, and antifungal treatment was only collected in a few states. These types of data are often collected during outbreak investigations (4), and studies describing clinical features of histoplasmosis cases typically focus on specific high-risk groups such as patients with HIV/AIDS, patients taking TNF- α blocker therapy, transplant recipients,

and older adults (7-11). Furthermore, no multistate data exists about histoplasmosis cases identified using the newly-created CSTE case definition.

Primary prevention strategies for histoplasmosis can be challenging to implement. Public health efforts aimed at promoting awareness of histoplasmosis among healthcare providers and the general public 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, more detailed data about histoplasmosis cases detected during routine surveillance in the general population are needed to better understand the features of persons at risk, characterize the effects of histoplasmosis on patients (e.g., delays in diagnosis, symptom duration, and decreased productivity), understand patient awareness of histoplasmosis, and determine its true public health burden. This information will not only help inform routine surveillance practices, but also guide awareness efforts and appropriate prevention strategies.

2. Purpose and Use of Information Collection

Currently, very little information exists about histoplasmosis cases detected during routine surveillance in the general population in terms of patients' potential environmental exposures, healthcare-seeking behaviors, antifungal treatment, outcomes, and knowledge about the disease. These data are needed to help develop additional public health messages and strategies to prevent histoplasmosis. This information is also essential to guide future public health surveillance for histoplasmosis. Therefore, CDC and state health departments will use the information collected to:

- Describe patient burden, exposures, and laboratory diagnosis of cases in participating states
- Evaluate the new Council of State and Territorial Epidemiologists (CSTE) case definition and determine which data elements are most important to collect during routine histoplasmosis surveillance
- Identify opportunities for outreach efforts related to histoplasmosis awareness, education, and prevention

The project is open to participation from state and local health departments in states where histoplasmosis is reportable. Cases will be identified through routine histoplasmosis surveillance; cases meeting the CSTE definition of a confirmed or probable case are eligible to be interviewed. Interviews will be conducted by state or local 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 voluntary interview.

A standardized case report form (CRF) (Attachment 3) will be used to collect information on demographics, underlying medical conditions, exposures, symptom type and duration, healthcare seeking behaviors, diagnosis, treatment, outcomes, and awareness of histoplasmosis. Each interview is estimated to take approximately 15 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 histoplasmosis diagnosis

based on available information in states' reportable disease databases. No personally identifying information will be recorded on the CRF. Each case will be assigned a unique identifier containing the state postal code followed by a hyphen and sequential numbering (e.g., AR-01, AR-02, etc.). A parent or guardian should be interviewed for cases in persons under 13 years old. For cases in persons aged 13–17 years old, the adolescent can be interviewed if permission from the parent or guardian is obtained. For cases in persons who are deceased or incapacitated, a proxy such as a family member or caregiver can be interviewed on the patient's behalf. Health departments should use their existing processes for gaining voluntary participation from patients/guardians with reportable conditions.

Participating states can share completed CRFs with CDC via email or fax. This information will be stored electronically on secure CDC computers as password-protected files. CDC will enter the data into a password-protected Microsoft Access database and can provide a final copy of the completed database to each state containing only that state's cases. CDC will merge data from all states and import the data to SAS v. 9.4 for analysis. Proposed analyses include but are not limited to:

- Overall description of case demographic features, clinical presentation, healthcare use, exposures, and treatment and outcomes
- Descriptive analysis of laboratory methods used for histoplasmosis diagnosis; analysis of positive test types stratified by clinical syndrome and/or other relevant variables
- Analysis of factors potentially associated with length of time from symptom onset to diagnosis
- Comparison of case characteristics by demographic groups (age, sex, race/ethnicity) and severity

3. Use of Improved Information Technology and Burden Reduction

State health department personnel will interview participants via telephone using a standardized questionnaire which is designed to collect only the minimum amount of information required for this investigation.

Health department personnel will also complete a form, which is included with the patient interview form, about the types of laboratory tests used to diagnose histoplasmosis, using information extracted from their electronic reportable disease databases.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of the availability of any similar information.

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

Each case-patient will be contacted only once, for an interview lasting approximately 15 minutes. Case-patients will be contacted four to six weeks after the case is identified through routine public health surveillance. Accurate information about cases' symptoms, exposures, and outcomes is essential to this analysis. The form about the types of laboratory tests used to diagnose histoplasmosis to be completed

by health department personnel, is also a key aspect of this analysis and will be filled out for each case patient, which will be 30 times at each of the 10 health departments.

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 21, 2017, vol. 82, No. 244, pp. 60609 (Attachment 2). CDC did not receive public comments related to this notice.

B. The development of this project was a collaborative effort between CDC and state health departments in 10 of the 11 states that require reporting of histoplasmosis: Arkansas Department of Health, Delaware Division of Public Health, Indiana State Department of Health, Kentucky Department for Public Health, Louisiana Department of Health and Hospitals, Michigan Department of Community Health, Minnesota Department of Health, Nebraska Department of Health & Human Services, Pennsylvania Department of Health, and Wisconsin Division of Public Health.

9. Explanation of Any Payment or Gift to Respondents

No payments nor gifts will be provided to respondents.

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

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act does not apply. There is no collection of personal identifiable information.

Information will be stored electronically on secure CDC computers as password-protected files. MDB will enter the data into a password-protected Microsoft Access database and can provide a final copy of the completed database to each state containing only that state's cases.

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 (Attachment 4). IRB approval was not required.

Justification for Sensitive Questions

There are no planned sensitive questions. Respondents can choose to skip any questions they do not feel comfortable answering.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

In participating states where histoplasmosis is reportable, an average of approximately 600 total cases were reported during 2011–2014, the most recent years for which data are available. We estimate that approximately half of case-patients will be unable to be contacted, refuse participation, or will not be able to be interviewed for other reasons, resulting in an estimated 300 total interviewed patients. The range in cases reported by state might require different approaches to sampling to reduce the burden of interviews on health departments to which many histoplasmosis cases are routinely reported. For states in which <100 yearly cases are typically reported, attempting to interview every case is preferred. For states in which ≥100 yearly cases are typically reported, states could consider attempting to interview every other reported case. However, each state may participate to the extent possible, and no minimum proportion of interviewed cases will be established.

Each interview is estimated to take approximately 15 minutes. Laboratory test data extraction from state reportable disease databases is expected to take 15 minutes per case. With a maximum of 300 case-patients interviewed, the total annual burden is estimated to be 75 hours for patients and 75 hours for health department personnel.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Histoplasmosis cases	Case Report Form for Histoplasmosis Enhanced Surveillance (pages 1-6)	300	1	15/60	75
Health department personnel	Case Report Form for Histoplasmosis Enhanced Surveillance (page 7)	10	30	15/60	75
Total					150

B. Estimated Annualized Burden Costs

Case-patient interviews and retrieval of information about laboratory tests used to diagnose histoplasmosis will be conducted by state and local health department epidemiologists. The mean hourly wage for a patient is \$23.86 and the mean hourly wage for a state health department epidemiologist is \$32.69, according to the US Department of Labor (<https://www.bls.gov/oes/current/oes191041.htm>). The estimated total respondent cost is \$4,241.25.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Histoplasmosis	Case Report Form	75	\$23.86	\$1,789.50

cases	for Histoplasmosis Enhanced Surveillance (pages 1-6)			
Health department personnel	Case Report Form for Histoplasmosis Enhanced Surveillance (page 7)	75	\$32.69	\$2,451.75
Total				\$4,241.25

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 estimated annualized cost to the federal government includes one GS-12 Epidemiologist’s time spent communicating with state and local health departments by email and phone, conducting data entry, and performing data analysis and interpretation. These activities are estimated to take 200 hours (4 hours per week for 50 weeks per year), at an hourly wage of \$36.27, resulting in a total annualized cost of \$7,254.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
GS-12 Epidemiologist’s time	\$7,254

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The project will involve data collection from histoplasmosis cases reported to state health departments during a period of one year. Because cases will be interviewed 4 to 6 weeks after they are reported to public health, data collection will take at least 14 months. In our experience (and to allow for unforeseen circumstances), data collection could take a few additional months, so we are requesting OMB approval for a period of 24 months.

Project Time Schedule	
Activity	Time Schedule
Data/information collection	0–16 months after OMB approval
Data cleaning and analysis	16–18 months after OMB approval
Preparation of final report(s) / manuscript	18–24 months after OMB approval
Manuscript publication	30 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.

19. References

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