Characteristics of Cases of Priority Fungal Diseases

Request for OMB approval of a Revision of a Currently Approved Collection
OMB Control Number 0920-1385

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Supporting Statement A

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- **Goal of the study:** We plan to enhance surveillance of high priority fungal diseases across the United States to better characterize factors such as disease burden, geographic scope, patient risk factors, health disparities, healthcare utilization, outcomes, and emerging trends.
- **Intended use of the resulting data:** Findings will help identify populations at higher risk of high priority fungal diseases, detect emerging epidemiologic trends, and guide prevention and response efforts. They can also help better focus public and healthcare provider outreach, inform efforts to contain or mitigate spread, and influence health policy and research on prevention and treatment.
- **Methods to be used to collect:** We plan to use standardized case report forms (CRF) to collect public health surveillance data for cases of these diseases regarding demographics (e.g., age, sex, race/ethnicity, location of residence), underlying medical conditions, diagnosis (e.g., clinical presentation, laboratory testing), treatments, and outcomes (e.g., hospitalization, vital status). The corresponding CRF would be filled out voluntarily by state, local or tribal health departments, federal agencies, and members of the private sector (e.g., academic institutions) and contains a section for medical chart review and an optional supplemental interview (including data on potential occupational or environmental exposures) of the patient or their representative.
- **The subpopulation to be studied:** Patients receiving care at U.S. healthcare facilities and who involve at least one of the priority fungal diseases.
- **How data will be analyzed:** Descriptive analyses will be used to analyze the data.

1. Circumstances Making the Collection of Information Necessary

This is a revision of a currently approved collection, Characteristics of Cases of Priority Fungal Diseases (OMB Control No. 0920-1385). The Revision will expand the number of fungal diseases for which data may be collected. In addition to triazole-resistant *A. fumigatus* infections, coccidioidomycosis, histoplasmosis, blastomycosis, *C. auris*, and antifungal-resistant dermatophytosis, Case Report Forms (CRFs) have also been developed for chromoblastomycosis, mycetoma, and sporotrichosis. The request is to approve 3 years of information collection from date of approval.

Fungal diseases cause substantial illness, ranging from mild infection to severe or life-threatening invasive disease. They also constitute a considerable financial burden on patients and healthcare systems. Awareness of fungal diseases is low, and data collection has historically been limited in size, scope, and coordination, which has hindered our understanding of these diseases. Detailed epidemiologic and clinical data are critical to inform appropriate public health responses.

Authorizing legislation: Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of Information Collection

We plan to enhance surveillance of high priority fungal diseases across the United States to better characterize factors such as disease burden, geographic scope, patient risk factors, health disparities, healthcare utilization, outcomes, and emerging trends. Findings can help identify populations at higher risk of these diseases, detect emerging epidemiologic trends, and guide prevention and response efforts.

They can also help better focus public and healthcare provider outreach, inform efforts to contain or mitigate spread, and influence health policy and research on prevention and treatment.

As we are in the initial phase of the program, data collection and submission for FungiSurv has begun in collaboration with state and local health departments. Initial data quality is strong and allows for preliminary insights into key variables associated with disease burden, geographic scope, patient risk factors, and outcomes.

3. Use of Improved Information Technology and Burden Reduction

The collection of all information will occur using an electronic case report form that can be electronically submitted to CDC. The electronic case report is designed to ask as few questions as possible while providing the necessary relevant clinical and demographic information about involved patients. Data will be stored in a secure REDCap platform. Data sent to CDC will not contain personally identifiable information.

4. Efforts to Identify Duplication and Use of Similar Information

To avoid duplicative efforts, FungiSurv leverages data that jurisdictions are already collecting through other systems. When similar information is available, we coordinate with jurisdictions to access and utilize existing data, ensuring that additional data collection is not redundant. FungiSurv focuses on collecting supplementary information, such as demographics (e.g., age, sex, race/ethnicity, location of residence), underlying medical conditions, diagnosis (e.g., clinical presentation, laboratory testing), treatments, and outcomes (e.g., hospitalization, vital status), which is not fully captured through other systems, providing a more complete understanding of fungal disease cases.

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

Fungal diseases are a growing public health threat to the United States; case counts are rising, but diagnosis is challenging, and treatment may be hindered by limited access to effective therapies as well as the emergence of antifungal resistance. The data collection instruments collect critical information needed from public health officials to improve knowledge and inform messaging and prevention efforts. Not collecting this information or collecting it less frequently might permit the spread and impact of fungal diseases and associated antifungal resistance patterns to go unnoticed and unaddressed.

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 11, 2023, vol. 88, No. 236, pp. 85887-8 (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

CDC will not provide remuneration or incentives to participants.

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

No PII is being collected. CDC's Information Systems Security Officer reviewed this submission and determined that there are no changes to the Privacy aspects of this package. The Privacy Act applies (Attachment 5).

Data will be kept private to the extent allowed by law.

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 4).

The project was determined to be non-research public health surveillance.

Justification for Sensitive Questions

No sensitive questions are asked.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

For each form, respondents will include state, local or tribal health departments. For the triazole-resistant A. fumigatus form, we estimate 15 respondents, 15 responses per respondent, and 113 annual burden hours. For coccidioidomycosis, histoplasmosis, and blastomycosis forms, we estimate approximately 10 respondents each and 25 responses per respondent, resulting in 250 annual burden hours for each form. For the C. auris form, we estimate 15 respondents, 20 responses per respondent, and 225 annual burden hours. For the antifungal-resistant dermatophytosis form, we estimate 10 respondents, 10 responses per respondent, and 50 annual burden hours.

In addition to state, local, or tribal health departments, respondents will include members of the private sector (e.g., academic institutions). For coccidioidomycosis, histoplasmosis, and blastomycosis forms, we estimate approximately 3 respondents each and 10 responses per respondent, resulting in 30 annual burden hours for each form. For the C. auris form, we estimate 3 respondents, 10 responses per respondent, and 23 annual burden hours. For chromoblastomycosis and sporotrichosis forms, we estimate approximately 25 respondents each and 10 responses per respondent, resulting in 125 annual burden hours for each form. For the eumycetoma form, we estimate 25 respondents, 5 responses per respondent, and 62.5 annual burden hours.

In addition to state, local, or tribal health departments and members of the private sector, respondents will include federal government agencies. The Federal Bureau of Prisons will provide CDC with data that they are already collecting. Respondents may overlap across forms.

Burden hours were estimated by approximating the amount of time it will take state, local or tribal health departments, federal agencies, and the members of the private sector (e.g., academic institutions) to collect and enter data requested from the case report forms.

Form Name	Type of Respondent	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Triazole-resistant Aspergillus fumigatus Case Report Form (Attachment 3a)	State and Local Health Departments	15	15	0.5	113
Coccidioidomycosis Case Report Form	State and Local Health Departments	10	25	1.0	250
(Attachment 3b)	Private Sectors	3	10	1.0	30
Histoplasmosis Case Report Form	State and Local Health Departments	10	25	1.0	250
(Attachment 3c)	Private Sectors	3	10	1.0	30
Blastomycosis Case Report Form	State and Local Health Departments	10	25	1.0	250
(Attachment 3d)	Private Sectors	3	10	1.0	30
Candida auris Case Report Form	State and Local Health Departments	15	20	0.75	225
(Attachment 3e)	Private Sectors	3	10	0.75	23
Antifungal-resistant dermatophytosis case report form (Attachment 3f)	State and Local Health Departments	10	10	0.5	50

Chromoblastomycosis case report form (Attachment 3g)	Private Sectors	25	10	0.5	125
Mycetoma case report form (Attachment 3h)	Private Sectors	25	5	0.5	63
Sporotrichosis case report form (Attachment 3i)	Private Sectors	25	10	0.5	125
Total					1,564

B. Estimated Annualized Burden Costs

We estimate a total annualized cost of $67,937.50 to respondents. The hourly wage rate was obtained from the Department of Labor website, using the 19-1014 occupation code for epidemiologists (mean hourly wage of $43.48).

Form Name	Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Triazole-resistant Aspergillus fumigatus Case Report Form (Attachment 3a)	State and Local Health Departments	113	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$4,891.50
Coccidioidomycosis Case Report Form (Attachment 3b)	State and Local Health Departments	250	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$10,870.00

	Private Sectors	30	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$1,304.40
Histoplasmosis Case Report Form (Attachment 3c)	State and Local Health Departments	250	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$10,870.00
	Private Sectors	30	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$1,304.40
Blastomycosis Case Report Form (Attachment 3d)	State and Local Health Departments	250	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$10,870.00
	Private Sectors	30	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$1,304.40
Candida auris Case Report Form (Attachment 3e)	State and Local Health Departments	225	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$9,783.00

	Private Sectors	23	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$978.30
Antifungal-resistant dermatophytosis case report form (Attachment 3f)	State and Local Health Departments	50	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$2,174.00
Chromoblastomycosis case report form (Attachment 3g)	Private Sectors	125	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$5,435.00
Mycetoma case report form (Attachment 3h)	Private Sectors	63	$43.48 (reference: occupation code 19-1041 from the department of labor website	$2,717.50
Sporotrichosis case report form (Attachment 3i)	Private Sectors	125	$43.48 (reference: occupation code 19-1041 from the department of labor website)	$5,435.00
Total				$67,937.50

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 cost for the federal government is calculated to be approximately 5% of the workload of one GS-13 federal government employee salary at the Atlanta, GA locality

Contract and Personnel	Role	Average Cost
Federal employee costs, per information collection, (e.g. 30% FTE of one GS-13 at $109,278/year)	1 GS-13 FTE (5%)	$5,463.90

15. Explanation for Program Changes or Adjustments

This is a revision to a currently approved collection. Proposed changes include the addition of three new CRFs, corresponding to chromoblastomycosis, mycetoma, and sporotrichosis. The proposed changes increased the annualized burden by 426 hours. The proposed changes increased the cost per respondent by $20,970.12.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be entered and analyzed on a quarterly basis and reported in publications (e.g., journal manuscripts) approximately every 1-2 years.

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

No exemption is being requested. 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.

Attachments

1. Authorizing Legislation
2. Published 60-Day FRN
3. Information Collection Instrument
    a. Triazole-resistant Aspergillus fumigatus Case Report Form
    b. Coccidioidomycosis Case Report Form
    c. Histoplasmosis Case Report Form
    d. Blastomycosis Case Report Form
    e. *Candida auris* Case Report Form

    f. Antifungal-resistant dermatophytosis case report form
    g. Chromoblastomycosis case report form
    h. Mycetoma case report form
    i. Sporotrichosis case report form
4. Non-Research Determination
5. Privacy Impact Assessment