Triazole-resistant *Aspergillus fumigatus* Case Report Form
Request for OMB approval of a New Information Collection

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OMB Control # 0920-New

Supporting Statement A

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- **Goal of the study:** The goal is to monitor for and characterize features (e.g., demographics, underlying conditions, treatments, and clinical outcomes) of persons affected by triazole-resistant *A. fumigatus*.
- **Intended use of the resulting data:** Data on features (e.g., demographics, underlying conditions, treatments, and clinical outcomes) of persons affected by triazole-resistant *A. fumigatus* will be used to inform clinical practice and public health policy.
- **Methods to be used to collect:** Public health officials and clinicians will voluntarily submit data using a case report form that collects de-identified data. The collection will involve a convenience sample of patients receiving testing for triazole-resistant *A. fumigatus*.
- **The subpopulation to be studied:** The subpopulation will involve patients receiving care for triazole-resistant *A. fumigatus* at U.S. healthcare facilities.
- **How data will be analyzed:** Descriptive analyses will be used to analyze the collected data.
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1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR). The request is to approve 3 years of information collection from date of approval.

The environmental mold *Aspergillus fumigatus* is the primary cause of invasive aspergillosis and is associated with ~50% mortality in high-risk patients, including stem cell and organ transplant recipients. The use of triazole antifungals has greatly improved survival; however, triazole-resistant *A. fumigatus* infections are increasingly reported worldwide and are associated with increased mortality and treatment failure. Of particular concern are resistant A. fumigatus isolates carrying the TR34/L98H and TR46/Y121F genetic resistance markers, which are associated with environmental triazole fungicide use rather than previous patient exposure to antifungals. Infections with these triazole-resistant strains have become common among patients with *A. fumigatus* infections in Europe, Asia and South America, and have been characterized epidemiologically. However, US reports of isolates carrying TR34/L98H or TR46/Y121F markers are limited to date and clinical data on affected U.S. patients are lacking. CDC is conducting testing for triazole-resistant *A. fumigatus* through the Antibiotic Resistance Laboratory Network (ARLN) and through direct submission to CDC laboratories.

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

2. Purpose and Use of Information Collection

CDC is already receiving *Aspergillus fumigatus* isolates from laboratories across the nation, primarily through ARLN and sometimes directly from submitters. These isolates undergo testing for triazole resistance (defined using minimum inhibitory concentrations or epidemiologic cutoff values set forth by Clinical and Laboratory Standards Institute). For patients involving triazole-resistant isolates, CDC

would use a standardized case report form (CRF) to characterize demographics (e.g., race/ethnicity, country of residence) underlying medical conditions, treatments, and outcomes (e.g., vital status at 30 days for initial positive specimen). The CRF would be filled out voluntarily by state and local health departments and contains an optional supplement at the end involving a brief interview (including data on occupational and environmental exposures) of a patient or their representative.

Azole-resistant *Aspergillus fumigatus* is an urgent public health threat, and detailed clinical and demographic information about patients affected by this organism are needed to guide public health policies and clinical decision-making. Not having such information might permit the spread and impact of triazole-resistant *A. fumigatus* to go unnoticed and unaddressed. We expect each jurisdiction might be asked to fill out a maximum of 2 forms per year; most jurisdictions would not have any forms to fill out. The form would take approximately 30 minutes to complete.

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

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

Triazole-resistant *A. fumigatus* is an urgent public health threat to the United States. The data collection instruments are as short as possible while still collecting the critical information needed from public health officials. Not collecting this information or collecting it less frequently might permit the spread and impact of triazole-resistant *A. fumigatus* 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 21, 2021, vol. 86, No. 242, pp. 72238-9 (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 the Privacy Act does not apply.

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.

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

The respondents include state and local public health officials. The anticipated yearly number of respondents is approximately 15, with each respondent filling out the form once per year. The estimated average burden of the response is about 0.5 hours. This estimate was derived from the amount of time it took partners to fill out a similar pilot form in the past.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Public health officials, clinicians	Triazole-resistant *Aspergillus fumigatus* Case Report Form	15	1	.5	8
Total					8

B. Estimated Annualized Burden Costs

The estimated cost to respondents for this form was based on the U.S. May 2021 National Occupational Employment and Wage Estimates, found on the Department of Labor website. The average hourly wage was multiplied by the estimate total burden of hours, yielding an estimated total respondent cost of $625.50.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public health officials, clinicians	Triazole-resistant *Aspergillus fumigatus* Case Report Form	15	$41.70 (reference: occupation code 19-1041 from the department of labor website)	$625.50
Total				

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 $97,078/year)	1 GS-13 FTE (5%)	$4853.90

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be entered and analyzed on a monthly 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
4. Non-Research Determination