

**GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development**

**Focus Groups with Healthcare Providers on
Endemic Mycoses**

OMB Control No. 0920-1154

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Supporting Statement A

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- **Goal of the study:** The purpose of this project is to understand healthcare providers' awareness and experiences with endemic mycoses (in particular, coccidioidomycosis, histoplasmosis, and blastomycosis) and motivators and barriers to testing.
- **Intended use of the resulting data:** Insights will inform the development and refinement of communications materials and strategies to advance awareness of endemic mycoses and the use of diagnostic testing (and associated algorithms) among healthcare providers.
- **Methods to be used to collect:** Online focus groups.
- **The subpopulation to be studied:** Physicians, physician assistants, and nurse practitioners in primary care, urgent care, and emergency care settings.
- **How data will be analyzed:** Descriptive and thematic analyses of qualitative data.

1. Circumstances Making the Collection of Information Necessary

CDC requests approval for a new Gen-IC under OMB Control No. 0920-1154.

Information collection activities are limited to formative work that will result in the development of new or improved messages and tools.

Certain types of fungi found in the environment can release spores that can affect the lungs and cause pneumonia. Three such fungal infections are coccidioidomycosis (also called Valley fever), histoplasmosis, and blastomycosis. Each is endemic to large parts of the United States, meaning each has been identified consistently in distinct areas or regions of the country. These are also referred to as community-acquired pneumonias because people who live in or travel to communities in impacted areas can be exposed and infected. These endemic mycoses are the primary subject of this data collection.

According to CDC, “Early diagnosis of these fungal diseases, mainly in primary and urgent care settings, can prevent severe and disseminated disease.”¹ However, and crucially, these endemic mycoses are often misdiagnosed or much delayed in diagnosis by healthcare providers, because many providers do not consider fungal infections as candidate conditions when evaluating patients with community-acquired pneumonia.

In one recent survey study of 1258 healthcare providers, fewer than four percent of providers said they “frequently” test their patients for either Valley fever or histoplasmosis when caring for patients with community-acquired pneumonia; the study concluded, “These diseases are likely underdiagnosed, and increased awareness is needed.”² Another study estimated that “82.9% of patients with histoplasmosis experienced at least one missed diagnostic opportunity. The average delay was 39.5 days with an average of 4.0 missed opportunities.”³ A third analysis, this time on

¹ https://emergency.cdc.gov/coca/calls/2023/callinfo_092123.asp

² Benedict, K., Li, Y., Molinari, N. A. M., & Jackson, B. R. (2021). Health Care Providers' Testing Practices for Coccidioidomycosis and Histoplasmosis in Patients With Community-Acquired Pneumonia-United States, 2020. *Open forum infectious diseases*, 8(2), ofab020. <https://doi.org/10.1093/ofid/ofab020>

³ Miller, A. C., Arakkal, A. T., Koeneman, S. H., Cavanaugh, J. E., Thompson, G. R., Baddley, J. W., & Polgreen, P. M. (2022). Frequency and Duration of, and Risk Factors for, Diagnostic Delays Associated with Histoplasmosis. *Journal of fungi (Basel, Switzerland)*, 8(5), 438. <https://doi.org/10.3390/jof8050438>

positive blastomycosis cases, found that “most patients received multiple antibiotic courses before being diagnosed, and the sputum KOH smear was rarely used.”⁴ These delays, misdiagnoses, and dearth of testing can have serious negative health effects on infected patients because the patients do not receive the antifungal drugs they need and may be prescribed ineffective antibiotics for other non-fungal infections.

The Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) within CDC’s National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) has determined that this proposed data collection is necessary in order to develop and refine effective communications strategies and materials that increase healthcare providers’ awareness of endemic mycoses, inspire increased consideration of endemic mycoses as candidate conditions when evaluating pneumonia patients, and lead to confident and efficient use of recommended diagnostic algorithms.

2. Purpose and Use of Information Collection

Prior research has shown that endemic mycoses like Valley fever, histoplasmosis, and blastomycosis are often misdiagnosed. As a result, this data collection is designed to determine: (1) provider knowledge, perceptions of, and experiences with endemic mycoses, (2) awareness, knowledge, and experience with diagnostic testing, (3) factors that motivate decisions whether or not to clinically suspect endemic mycoses and order tests, (4) barriers to ordering tests for endemic mycoses and interpreting results, (5) awareness, experience, and feedback on diagnostic algorithms, and (6) information sources and needs on these topics.

Insights generated from the data collection will guide communication efforts to build endemic mycoses awareness and the use of diagnostic testing. Insights will inform communications strategies and materials meant for providers on this topic, including those strategies and materials related to existing diagnostic algorithms.

KRC Research, a contracted research firm, will conduct all data collection related to this initiative, under the supervision of DFWED. KRC’s data collection will include recruiting and screening participants into the project and conducting six 90-minute-long online focus groups with healthcare providers. This data collection will happen once; it is not recurring.

Audience Rationale

This data collection is based on focus groups of healthcare providers. In particular, it is focused on physicians, physician assistants (PAs), and nurse practitioners (NPs) in three types of common settings: primary care, urgent care, and emergency care. These providers within these settings are most likely to encounter patients seeking initial care for pneumonia of any cause, including from a fungal infection; at the same time, these providers are not specialists in fungal diseases, and many may not consider fungal diseases when they encounter patients with pneumonia even after initially failing antibiotic treatment. Many are expected to have important gaps in knowledge or points of confusion about testing and interpreting results. Physicians, PAs, and NPs also play somewhat different roles and have different types of training; part of the

⁴ Alpern, J. D., Bahr, N. C., Vazquez-Benitez, G., Boulware, D. R., Sellman, J. S., & Sarosi, G. A. (2016). Diagnostic Delay and Antibiotic Overuse in Acute Pulmonary Blastomycosis. *Open forum infectious diseases*, 3(2), ofw078. <https://doi.org/10.1093/ofid/ofw078>

rationale for the inclusion of these audiences is to assess what their knowledge, experiences, barriers, and needs share in common and where they differ.

Description of Instruments

This data collection involves online focus groups. The instruments involved include a screening questionnaire (Attachment 1), a consent form (Attachment 2), and a focus group moderator guide (Attachment 3). The screening questionnaire has two primary purposes: (1) to ensure the proper qualifications for those who participate in the focus groups, and (2) to ensure a balance of included participants based on demographic and healthcare-related variables. The consent form is designed to ensure qualified participants are aware of key information about the group, such as privacy and the voluntary nature of the conversations. The moderator guide will be used by a trained KRC Research focus group moderator to direct the conversation and keep it on track.

Consequences of Not Collecting Information

This data collection is necessary to ensure DFWED communications initiatives are based on information gathered directly from the intended audience. If this collection were not to be carried out, DFWED would not have timely, nuanced information about knowledge, barriers, motivators to test, and information needs of its priority audiences. Communications efforts that are not based on research may be ineffective and the CDC resources used may not be used efficiently or may not reach intended populations with uninformed outreach strategies.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via online focus groups through a web-based platform, meaning that participants will not have to download anything to their personal devices (participants need only to have an internet connection) and participants, CDC, and its contractor KRC Research do not need to travel. All focus groups will be conducted by professional moderators from KRC Research, a contracted company. All focus groups will be audio and video recorded to ensure participant responses are captured accurately and transcribed. Questions included on the focus group moderator guide have been limited to only those relevant to the target audience to reduce burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

While some quantitative survey research has been conducted to assess the frequency of endemic mycoses testing, to date there has been little formative qualitative evaluation exploring the perceptions, attitudes, barriers, motivators, and information needs of healthcare providers in these priority settings on this topic. In particular, little is known about providers' impressions and experiences with CDC's newly developed endemic mycoses diagnostic algorithms. This data collection will address these points while focusing in analysis on implications for communications specifically.

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.

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 *Federal Register* notice was published for this generic package on July 22, 2022, Vol. 87, No.140 , pp. 43860. No public comments were received.

B. KRC Research, a contracted research firm, has been consulted in the development of the research plan, sampling parameters, and focus group guide. Under the supervision of DFWED, KRC will ultimately conduct all data collection related to the proposed evaluation. Data collection will include recruiting and screening participants into the formative research, and conducting six 90-minute long online focus groups with providers in primary care, urgent care, and emergency care settings.

9. Explanation of Any Payment or Gift to Respondents

Focus group participants will receive a monetary incentive of \$75 for their participation. Such an incentive is a standard practice in the market research industry and helps to ensure efficient recruitment and ultimate participation among the qualified and scheduled participants. The amount is also standard for a healthcare provider audience participating in a 90-minute interview. The incentive is also intended to offset the cost of personal or professional time taken to participate.

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

NCEZID has reviewed this submission and determined that the Privacy Act does not apply.

KRC Research, a contracted firm, will manage recruitment and execution for this evaluation, and PII will not be transmitted to NCEZID/DFWED or anyone at CDC.

This screening instrument, Attachment 1, will be used to evaluate the qualification of potential focus group participants. The screening instrument includes information about privacy and confidentiality; only those individuals who agree to these terms will qualify for participation in focus groups. After an individual agrees to the terms and has qualified for focus group scheduling, they will be given a separate consent form, Attachment 2, that reiterates privacy and confidentiality policies. The participant will be required to sign the form (electronic submission is allowed) and deliver a copy to the recruiting and moderating team. The participant will be reminded that participation is entirely voluntary.

After the consent form is signed, participants will confirm their focus group slots. During the introduction to each focus group, the trained moderator will review key parts of the privacy and confidentiality agreement, including:

1. The discussion is completely voluntary. Participants do not have to join the focus group and do not have to answer any questions they are not comfortable with.
2. Only first names or preferred names will be used during the conversation, and nothing participants say or do will be reported in association with their names.
3. Discussions will be audio and video recorded and notes will be taken during the discussion. All information, notes, and files will be kept on a secure server. Only KRC Research and the core DFWED team that manages the evaluation will have access to these files.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

A. 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).

B. Justification for Sensitive Questions

All the questions asked in the interviews will be non-sensitive in nature and focus primarily on knowledge, attitudes, and professional experiences with endemic mycoses and testing. All participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The total estimated burden is 112 hours. Table 1 below describes the burden associated with the information collection.

Eight individuals will be recruited for participation in each of six focus groups. The burden table assumes that 10 respondents will be screened for every one successfully recruited and scheduled for a focus group. (This one in ten rate is relatively high because sampling is conducted from within a panel of individuals already opted in surveys, focus groups, and interviews. Each individual also has a preexisting demographic profile that makes targeting recruitment much more efficient.)

The burden table assumes screening will take 5 minutes per person, and the consent form will take an additional 5 minutes for those 48 total individuals who are successfully recruited. Focus groups last 90 minutes, or 1.5 hours.

Table 1. Annualized Burden

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response	Total Burden Hours

				(hours)	
Healthcare providers (physicians, PAs, NPs)	Screeners	480	1	5/60	40
	Focus Group Guide (FG participation)	48	1	1.5	72
Total					112

B. Estimated Annualized Burden Costs

According to the U.S. Bureau of Labor Statistics (BLS) May 2022 National Occupational Employment and Wage Estimates, the median hourly wage for physicians is \$109.22, the median for physician assistants is \$60.58, and the median for nurse practitioners is \$58.47. Of the 48 focus group participants, half will be physicians (24 across three physician groups), and one quarter each will be PAs and NPs (12 each across three PA/NP groups). These wages and counts have been used to calculate the cost of participation for the audiences.

The total estimated cost burden is \$9,449.72.

Table 2. Cost burden associated with information collection

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physicians	Screeners	20	\$109.22	\$2,184.40
	Focus Group Guide (FG participation)	36	\$109.22	\$3,931.92
Physician Assistants	Screeners	10	\$60.58	\$605.80
	Focus Group Guide (FG participation)	18	\$60.58	\$1,090.44
Nurse Practitioners	Screeners	10	\$58.47	\$584.70
	Focus Group Guide (FG participation)	18	\$58.47	\$1,052.46
Total				\$9,449.72

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 annualized cost to the Federal Government to collect this information is \$125,385. Table 3 below describes the cost in more detail.

Recruiting and interviewing will be conducted by KRC Research, a contracted firm. KRC's work includes recruitment, screening, scheduling, management of consent forms, conducting focus

groups, transcription and data cleaning, reporting, and presentation. Contractor costs cover the work of an existing team working with DFWED on this initiative and include 28 hours of labor for a KRC Senior Vice President, 36 hours for a Vice President, 47 hours for an Analyst, and 21 hours for a Field Vice President (recruitment management tasks). Hours are tabulated based on existing contractor hourly rates. Contractor expenses are based on competitively bid prices for panel recruitment / screening and transcription, plus cost of incentives.

Oversight and review of all materials and reports will be conducted by two federal government employees who are jointly leading the project. Their work will include providing oversight to KRC Research on the purpose and objectives of the project; guidance and feedback on recruitment, screening, and focus group guide materials; entering the project materials into CDC's STARS system for project determination; meeting regularly with KRC Research staff to discuss the project's progress and answer any questions; reviewing the transcripts and reports; and sharing topline findings with DFWED staff so they can use the findings to strengthen communication messages. The estimate includes 700 hours for Health communication specialist 1 and 500 hours for Health Communication Specialist 2.

Estimated federal employee cost is tabulated based on these employees' current hourly wages (locality-adjusted GS pay table for Atlanta-area workers):

- Health Communication Specialist 1 (CDC Project Officer): 700 hours @ \$50/hour = \$35,000
- Health Communication Specialist 2 (CDC Co-Principal Investigator): 500 hours @ \$50/hour = \$25,000
- Total = \$60,000

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	Estimated Annualized Cost
Contractor personnel costs: costs to oversee recruit, conduct focus groups	\$17,258
Contractor personnel costs: costs to report on results	\$5,897
Contractor expenses: recruitment panel, transcription, incentives	\$42,230
Federal government personnel costs: oversight, report review	\$60,000
Total	\$125,385

15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This initiative is expected to take nine weeks from start to finish. Three weeks will be spent recruiting participants, three weeks will be spent and conducting focus groups, and three weeks will be spent in analysis and reporting. A timeline is available in Table 4.

Table 4. Project Time Schedule

Activity	Time Schedule
Recruit participants	3 weeks, beginning immediately after gen-IC approved
Conduct focus groups	3 weeks after recruitment
Transcription, analysis, report development	3 weeks after focus groups end
Disseminate results/reports	As soon as summary report is complete

Focus groups will be audio and video recorded for aid in reporting and analysis. Audio files will be transcribed verbatim in Microsoft Word and used for reporting. (Deidentified transcripts will be delivered to DFWED.) Results will be used to develop a written report with an assessment of findings and recommendations for targeted messaging strategies for CDC communications with this audience.

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

The expiration date of OMB approval will be displayed on all information collection instruments.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Screener
2. Consent Form
3. Focus Group Guide
4. Human Subjects Determination