GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Focus Groups with Infectious Disease Physicians and Pharmacists on Antifungal Therapeutic Drug Monitoring

OMB Control No. 0920-1154

January 10, 2024

Supporting Statement A

Contact:
Rudith Vice
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404)718-7292
Email: nhr9@cdc.gov

Table of Contents

- **Goal of the study:** The purpose of this project is to assess knowledge, perceptions, experiences, and barriers to antifungal therapeutic drug monitoring among infectious disease physicians and hospital or infectious disease pharmacists.
- **Intended use of the resulting data:** Insights will inform future communications efforts to increase awareness of antifungal therapeutic drug monitoring, address knowledge gaps and barriers to the practice, and improve antifungal therapeutic drug monitoring adherence.
- **Methods to be used to collect:** Online focus groups.
- **The subpopulation to be studied:** Infectious disease physicians and hospital or infectious disease pharmacists.
- **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.

Antifungal therapeutic drug monitoring (TDM) is an important step in ensuring certain patients receive the appropriate level of medication to effectively treat fungal diseases and reduce side effects and overuse of antifungals. This practice tests the amount of an antifungal drug present in a patient's blood to ensure the drug is administered in the right dose while minimizing side effects. This practice of antifungal TDM is important because antifungal drugs have a narrow therapeutic window, meaning that the difference between an effective and toxic dose can be small. Close monitoring is often very important for patients' health.

Despite the importance of antifungal TDM, previous research has highlighted low rates of its performance in the United States and suggested potential barriers to doing so effectively.

For instance, a study found: "In this hospital-based administrative and laboratory dataset, TDM was uncommonly performed (∼16%) among a large cohort of patients for whom TDM is recommended, signifying missed opportunities to monitor antifungal drug levels and potentially improve clinical outcomes."[1] On the topic of barriers to antifungal TDM, another survey study found: "Reported barriers to performing TDM included long turn around times for send-out tests (74%), difficulty coordinating testing logistics (48%), uncertainty around TDM recommendations (39%), difficulty interpreting results (28%), uncertainty about TDM benefits (18%), cost (14%), and challenges with insurance coverage (11%)."[2]

[1] Benedict, K., Gold, J. A. W., Toda, M., Thompson, G. R., 3rd, Wiederhold, N. P., & Smith, D. J. (2023). Low Rates of Antifungal Therapeutic Drug Monitoring Among Inpatients Who Received Itraconazole, Posaconazole, or Voriconazole, United States, 2019-2021. Open forum infectious diseases, 10(8), ofad389. https://doi.org/10.1093/ofid/ofad389

[2] Benedict, K., Gold, J. A. W., Beekmann, S. E., Polgreen, P. M., Toda, M., & Smith, D. J. (2023). Antifungal Therapeutic Drug Monitoring Practices: Results of an Emerging Infections Network Survey. Open forum infectious diseases, 10(9), ofad468. https://doi.org/10.1093/ofid/ofad468

Thus, research has demonstrated a gap in the practice of antifungal TDM as well as several barriers preventing more effective or widespread use of the practice. This proposed data collection is necessary to understand the extent to which healthcare providers' knowledge, perceptions, and role designations are influencing their decisions or ability to perform antifungal TDM, the details of the challenges and barriers they face and how they can be overcome, and the information, data, and resource needs providers have about this subject that may contribute to their ability to make confident decisions.

This data collection will be used by CDC NCEZID, and in particular the Division of Foodborne, Waterborne, and Environmental Diseases (DFWED), to develop and improve providers-focused communications strategies, messages, and materials on the topic of antifungal TDM, with a goal of raising awareness of the importance of the practice and better equipping providers to take appropriate action.

2. Purpose and Use of Information Collection

Previous research has shown that antifungal TDM is often limited in practice in situations where it may be recommended. The goals of this evaluation are to assess: (1) physicians' and pharmacists' perceptions of the benefits of antifungal therapeutic drug monitoring, (2) barriers to antifungal therapeutic drug monitoring and how to address them, (3) role(s) that physicians and pharmacists play in antifungal TDM, and how the two roles interact with each other, and (4) information and data needs, plus feedback on existing antifungal TDM data, educational materials, and tools providers use.

Insights generated from the data collection will guide efforts to increase awareness of antifungal TDM, address knowledge gaps and barriers, and improve antifungal TDM use and adherence. The results will be used to develop and improve communications strategies, messages, and materials on the topic of antifungal TDM.

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 three 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 focuses on infectious disease (ID) physicians and hospital or ID pharmacists. These audiences have been selected because fungal disease treatment and drug administration fall within their purview, and they are expert audiences that are most involved in TDM for their patients. Physicians and pharmacists play somewhat different roles, and part of the rationale for the inclusion of both audiences is the intent to learn about how their roles overlap and complement each other during the practice of TDM.

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 TDM barriers 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, may not reach intended populations, or may reach populations with uninformed outreach strategies. By conducting this data collection, DFWED will have a much clearer understanding of TDM barriers, questions, and provider needs to overcome and answer them.

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

To date, there has been little formative qualitative evaluation exploring the perceptions, attitudes, and information needs of infectious disease physicians and pharmacists as it relates to antifungal therapeutic drug monitoring. This data collection builds upon several quantitative assessments of TDM; these assessments have limited their scope to evaluating extent to which TDM is practiced and enumeration of barriers that exist. However, no information has been collected that focuses on perceptions, steps to overcome barriers or challenges, information or resource needs, and other topics covered by this proposed collection—particularly as those topics relate to the development and improvement of CDC communications.

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 three 90-minute long online focus groups with ID physicians and hospital and ID pharmacists.

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 specialized healthcare provider audience participating in a 90-minute online 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. Files will be deleted within 30 days of CDC approval of the final report of findings.

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 the practice of TDM. 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 56 hours. Table 1 below describes the burden associated with the information collection.

Eight individuals will be recruited for participation in each of three 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 twenty-four 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 (hours)**	**Total Burden Hours**
ID Physicians	Screener	160	1	5/60	13
	Focus Group Guide *(FG participation)*	16	1	1.5	24

ID and Hospital Pharmacists	Screener	80	1	5/60	7
	Focus Group Guide *(FG participation)*	8	1	1.5	12
Total					56

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 and for pharmacists is $63.82. This amount has been used to calculate the cost of participation for the physician and pharmacist audiences. The total estimated cost burden is $5,253.72

Table 2. Cost burden associated with information collection

Type of Respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
ID Physicians	Screener	13	$109.22	$1,419.86
	Focus Group Guide *(FG participation)*	24	$109.22	$2,621.28
ID and Hospital Pharmacists	Screener	7	$63.82	$446.74
	Focus Group Guide *(FG participation)*	12	$63.82	$765.84
Total				$5253.72

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 $94,641. 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 16 hours of labor for a KRC Senior Vice President, 24 hours for a Vice President, 33.5 hours for an Analyst, and 12 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	$8,629
Contractor personnel costs: costs to report on results	$5,897
Contractor expenses: recruitment panel, transcription, incentives	$20,115
Federal government personnel costs: oversight, report review	$60,000
Total	$94,641

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