GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Focus Groups with Consumers on Oropouche

OMB Control No. 0920-1154

October 3, 2024

Supporting Statement A

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- **Goals of the project:** To understand awareness, perceptions, and information needs related to Oropouche, and to determine the clearest and most effective message themes to motivate consumer preventative behaviors on the subject.
- **Intended use of the resulting data:** The data will be used to inform future communications initiatives including tailored messaging strategies on the topic of Oropouche.
- **Methods to be used to collect data: Online** focus groups.
- **The subpopulation to be studied:** Consumers (general public) who frequently travel to at-risk countries for Oropouche and who are pregnant (self-identify as pregnant) or are pregnancy planners (planning pregnancy within the next 12 months).

- **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 CDC messages, materials, or communications resources on the topic of Oropouche for the public.

In this project, members of the public who are pregnant or planning to be pregnant and frequently traveling to at-risk countries for Oropouche will participate in focus groups. These audiences are potentially more at risk of contracting Oropouche. These audiences will share their knowledge, perceptions, current behavior of preventing bug bites, information needs related to Oropouche, and to assess terminology and draft messages that are intended to motivate preventative behavior.

Oropouche is an emerging serious, potentially life-threatening virus. According to CDC, Oropouche is spread to people by the bite of infected biting midges, and from bites from some mosquitoes. Most people infected with the Oropouche virus will have symptoms that can reoccur, and there are no vaccines or medicines to prevent or treat Oropouche. There remains much to learn about Oropouche such as "the risks of Oropouche virus infection during pregnancy." CDC further says, "Brazil has reported cases of Oropouche virus being passed from a pregnant person to their fetus, possibly resulting in the death of the fetus or congenital abnormalities like microcephaly."[1]

According to CDC, before the year 2000, outbreaks of Oropouche were reported in Brazil, Panama, and Peru. "In the last 25 years, cases of Oropouche have been identified in many countries, including Argentina, Bolivia, Brazil, Colombia, Ecuador, French Guiana, Panama, and Peru. In June 2024, Cuba reported its first confirmed Oropouche case." Additional data collection is needed to understand how many people are affected by this condition.[2]

As a result of the growing number of countries with confirmed Oropouche cases the Division of Vector-Borne Diseases (DVBD) within the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) must ensure that CDC is able to communicate clearly with the public about Oropouche virus and its risk factors. However, limited data collection has been conducted on Oropouche. What little data collection has been conducted points to the potential for Oropouche to spread geographically, and the potential for misdiagnosis. For example, one academic article states that a lack of knowledge on host species and transmission cycles makes "predicting the potential area of endemicity difficult."[3] A separate academic article states "the common symptoms and rare clinical manifestations are similar to numerous other (and more

[1] https://www.cdc.gov/oropouche/about/index.html

[2] https://www.cdc.gov/oropouche/about/index.html

[3] Zhang Y, et al. Oropouche virus: A neglected global arboviral threat. Virus Res. 2024 Mar;341:199318. doi: 10.1016/j.virusres.2024.199318. Epub 2024 Jan 16. PMID: 38224842; PMCID: PMC10827532. https://Ncbi.nlm.nih.gov/pmc/articles/PMC10827532/.

prevalent) arboviral diseases including dengue, yellow fever, Zika, chikungunya, and Mayaro making clinical recognition difficult."[4]

Given the limited number of studies on the subject, little qualitative data has been conducted to explore the extent to which information about Oropouche is clear and understandable; what questions audiences have about Oropouche; and what information audiences have found and need on the subject. The proposed data collection in this package fills an important gap in CDC knowledge about consumer answers to these questions. This data collection also includes an important message testing component to assess clarity and utility of message themes that CDC may use in communications about the subject. The data collected will allow CDC to better tailor communication messaging for priority audiences, potentially increasing uptake in preventative behaviors.

2. Purpose and Use of Information Collection

The goals of this evaluation are to assess: (1) health precautions known and undertaken to prevent bug bites at home and abroad, (2) understand barriers and challenges to taking above precautions, (3) evaluate knowledge (transmission, symptoms, prevention, etc.) and attitudes toward vector-borne diseases including Oropouche, (4) identify sources of information for topics on Oropouche and vector-borne diseases, as well as sources of trust and reasons for trust, (5) identify resource or information needs, preferred communication channels, and if participants prefer information in English or Spanish for above topics, and (6) test language, messages, or concepts about Oropouche for use in future communications. The results will be used to inform future communications initiatives including tailored messaging strategies on the topic of Oropouche.

KRC Research, a contracted research firm, will conduct all data collection related to the proposed formative evaluation project, under the supervision of NCEZID DVBD. KRC's data collection will include recruiting and screening participants into the project, and conducting three 90-minute focus groups among consumers. These are one-time data collections resulting in qualitative data based on conversations.

Description of Instruments

The attachments that accompany this supporting statement are instruments for use in the evaluation among this audience and include a screening questionnaire to identify qualified participants (Attachment 1), a consent form to ensure participants are aware of policies and procedures related to their participation (Attachment 2), a discussion guide for use by moderators to guide the conversation and meet project objectives (Attachment 3), and draft message stimuli which will be displayed and discussed during the focus groups (Attachment 4).

The discussion guide includes questions designed to elicit the following, among other topics:

- Knowledge and experiences with bug bite prevention during travel
- Awareness, knowledge, and experiences with vector-borne diseases and Oropouche

[4] Angel N. Desai, et al. Oropouche virus: a re-emerging arbovirus of clinical significance, IJID Regions, 2024, 100456, ISSN 2772-7076, https://doi.org/10.1016/j.ijregi.2024.100456.

- Awareness and use of preventative behaviors against vector-borne diseases and Oropouche
- Perceptions of Oropouche risk during pregnancy
- Oropouche information sources and needs, trusted messengers, and preferred language of messaging
- Assessments of Oropouche health messages, and preferences or distinctions between terminology options

Use of Information and Consequences of Not Collecting
The insights will be used to inform future communications initiatives including tailored messaging strategies and refinement of draft messages on the topic of Oropouche that are tailored to priority audiences. Insights will further help DVBD ensure it communicates about Oropouche using language and terminology that is clear, descriptive, and informative.

Failure to collect the information in this package will leave DVBD without clear evidence of priority audiences' perceptions and information needs about a recently emergent vector-borne disease. Failure to collect this information may also mean that communications on the subject are suboptimal and leave recipients with questions, confusions, or frustrations, and potentially at great risk in the absence of effective information about preventative behaviors. Communications efforts that have not been evaluated may be ineffective and the CDC resources used may not be used efficiently.

3. Use of Improved Information Technology and Burden Reduction
Data will be collected via online focus groups through web-based platforms, meaning that participants will not have to download anything to their personal devices (participants need only to have an internet connection). All discussions will be moderated by professional moderators and interviewers from KRC Research, a contracted company. All discussions will be audio and video recorded to ensure participant responses are captured accurately and transcribed. Questions included on the discussion guides 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
This topic is a new area of inquiry for NCEZID. To date, there has been little formative qualitative evaluation exploring consumer awareness, perceptions, and information needs related to Oropouche. In particular, little is known of the extent and reasons for Oropouche risk perception or preferences and points of confusion related to Oropouche terminology and key information.

5. Impact on Small Businesses or Other Small Entities
No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently
The screeners and the discussions are both one-time information collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
There are no special circumstances with this information collection package. This request fully complies with the guidelines in 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. This information collection request does not require publication of a 60-day notice in the *Federal Register*.

B. KRC Research, a contracted research firm, has been consulted in the development of the research plan, sampling parameters, and discussion guides. Under the supervision of NCEZID DVBD, KRC will ultimately conduct all data collection related to the proposed evaluation. Data collection will include recruiting and screening participants into the formative project and conducting three 90-minute focus groups with consumers.

9. Explanation of Any Payment or Gift to Respondents

Focus group and interview 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 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 determined that the Privacy Act does not apply to this information collection. KRC Research, a contracted firm, will manage recruitment and moderation for this initiative, and PII will not be transmitted to NCEZID or CDC.

The screening instrument for this evaluation is provided as Attachment 1. This screening instrument will be used to evaluate the qualification of potential 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 scheduling, they will be given a separate consent form that reiterates privacy and confidentiality policies. The consent form is included as Attachment 2. Each participant will be required to sign the form (electronic submission is allowed) and deliver a copy to the recruiting team. No participants' personally identifiable information will be shared or made available to anyone outside of the evaluation staff and NCEZID DVBD staff directly involved in the data collection.

The consent forms will make clear:

- Participation is entirely voluntary.
- The discussion will be audio and video recorded so it can be transcribed and used to help write a report. Recordings and transcripts based on the recordings will be shared with CDC, but these transcripts will not include your name or any identifying information. No comments made will be linked with participants' names in any way in reports about these discussions.
- Project staff will keep all information, notes, and audio recordings stored securely. Only project staff and directly involved CDC staff will be able to access the information.

Project records will be maintained in accordance with the federal record retention requirements.

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

- Only first names will be used during this conversation. Participants may choose to use a nickname or any other name you prefer.
- Participation is voluntary, and participants do not have to answer anything they are uncomfortable with.
- The discussion will be audio and video recorded for transcribing purposes.
- A few colleagues are observing virtually.

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

Institutional Review Board (IRB)
This project was reviewed by NCEZID's human subjects advisor and determined to not meet the definition of research under 45 CFR 46. IRB review is not required (Attachment 5).

Justification for Sensitive Questions
All of the questions asked in the discussion will be non-sensitive in nature and focus on awareness, perceptions, and information needs related to Oropouche. 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
The total estimated burden is 56 hours. Table 1 below describes the burden associated with the information collection.

The burden table assumes that 10 respondents will be screened for every one successfully recruited and scheduled for a focus group. (Sampling is conducted from within a panel of individuals already opted in surveys, focus groups, and interviews, where each individual also has a preexisting demographic profile that makes targeting recruitment fairly efficient.) The burden table assumes screening will take 5 minutes per person. Participation in focus groups takes 90 minutes.

Table 1. Annualized Burden

Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Focus Group Screener	Consumers (at-risk audiences)	240	1	5/60	20

(Attachment 1)					
Focus Group Discussion Guide (Attachment 3)	Consumers (at-risk audiences)	24	1	1.5	36
Total					56

According to the U.S. Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates, the median hourly wage for all occupations is $23.11. This has been used to calculate cost of participation for the general public audience.

The total estimated cost burden is $1,294.16.

Table 2. Cost burden associated with information collection

Form Name	Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Focus Group Screener (Attachment 1)	Consumers (at-risk audiences)	20	$23.11	$462.20
Focus Group Discussion Guide (Attachment 3)	Consumers (at-risk audiences)	36	$23.11	$831.96
Total				$1,294.16

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government
The annualized cost to the Federal Government to collect this information is $32,409.44. Table 3 below describes the cost in more detail.

Recruiting and focus groups 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 NCEZID DVBD on this and other communications initiatives and include 8 hours of labor for a KRC Senior Vice President, 30 combined hours for a Vice President and Field Vice President (recruitment management tasks), 27.5 hours for a Director, and 31.5 hours for an Analyst. 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 co-leading the project, totaling an estimated 20 hours (10 hours each). Estimated federal employee cost is based on these two employees' current hourly wages. Their work will include providing oversight to KRC Research on the purpose and objectives of the project; guidance and feedback on recruitment, screening, and discussion 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 NCEZID staff so they can use the findings to strengthen communication messages.

Estimated federal employee cost is tabulated based on these two employees' current hourly wages:

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	**Estimated Annualized Cost**
Contractor personnel costs: costs to oversee sampling, moderate, etc.	$8,339.00
Contractor personnel costs: costs to report on results	$7,673.00
Contractor expenses: recruitment panel, transcription, incentives	$15,000.00
Federal government personnel costs: oversight, report review	$1,397.44
Total	$32,409.44

15. Explanation for Program Changes or Adjustments
This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule
This initiative is expected to take five weeks from start to finish. Three weeks will be spent recruiting and conducting focus groups, two weeks will be spent in analysis and reporting, and three weeks will be spent in report review and rounds of revision. A timeline is in Table 4.

Table 4. Project Time Schedule

Activity	Time Schedule
Recruit focus group participants	2 weeks, beginning immediately after gen-IC approved
Conduct focus groups	1 week, overlapping with recruitment (3 total)
Transcription, data processing, and analysis	1 week after focus groups end
Report development and delivery	2 weeks after focus groups end
Report review, discussion, and revisions	3 weeks after first draft delivery

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 NCEZID DVBD.) Results will be used to develop a written report with an assessment of findings, recommendations for tailored messaging strategies for CDC communications with these audiences, and considerations for further robust information collections among these audiences in the future.

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 the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.

List of Attachments

1. Focus Group Screener
2. Focus Group Consent Form
3. Focus Group Discussion Guide
4. Draft Message Stimuli
5. Human Subjects Determination