GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Focus Groups and Interviews with Consumers and HCPs on Alpha-Gal Syndrome

OMB Control No. 0920-1154

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Supporting Statement A

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- **Goals of the project:** To understand awareness, perceptions, and information needs related to alpha-gal syndrome (AGS), and to determine the clearest and most effective message themes to motivate both consumer preventative behaviors and healthcare provider recommendations 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 AGS.

- **Methods to be used to collect data:** Focus groups and in-depth interviews.

- **The subpopulation to be studied:** Among consumers, outdoor enthusiasts: hunters, hikers and backpackers, dog owners, and others active outdoors. Among healthcare providers, physicians most likely to see patients with AGS: primary care, emergency care, gastroenterologists, and allergists.

- **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 alpha-gal syndrome (AGS) for both the public and healthcare providers.

In this project, both members of the public who are active outdoors (and therefore potentially more at risk of tick bites, which are associated with AGS) and physicians will participate in focus groups and interviews. These audiences will share their knowledge, perceptions, and information needs related to AGS and to assess terminology and draft messages that are intended to motivate preventative behavior (consumers) and patient recommendations (physicians).

Alpha-gal syndrome (AGS) is an emerging serious, potentially life-threatening allergic condition. AGS is also called alpha-gal allergy, red meat allergy, or tick bite meat allergy. According to CDC, AGS is associated with tick bites. There remains much to learn about AGS, including on the exact nature of "the role that ticks play in starting the condition, and why certain people develop AGS."

Alpha-gal itself is a sugar molecule found in most mammals and can therefore be found in meat. As mentioned, AGS is an allergic condition to this molecule, and a wide range of symptoms may occur after people with AGS eat red meat or are exposed to products that contain it. Symptoms can be severe or life-threatening and may include hives, nausea, indigestion, diarrhea, swelling, dizziness, or stomach pain, among others.

According to CDC, between 2010 and 2022, "more than 110,000 suspected cases of AGS were identified. However, cases of AGS are not nationally notifiable to CDC, so it is not known how many cases of AGS exist in the United States. Additional data and research are needed to understand how many people are affected by this condition."[2]

[1] https://www.cdc.gov/ticks/alpha-gal/index.html

[2] https://www.cdc.gov/ticks/alpha-gal/index.html

As a result of the large number of suspected cases and the association with tick bites, 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 and with healthcare providers about AGS and risk factors. However, limited research has been conducted on AGS. What little research has been conducted points to significant gaps in knowledge among important stakeholder groups. For example, one small-scale study of patients diagnoses with AGS found that "three-quarters of patients rated their primary care provider as having little to no knowledge" about AGS.[3] A separate survey study of healthcare providers found that 42% had not heard of AGS before, and among those who *were* aware of it, nearly half (48%) did not know the correct tests to order to diagnose it, and only 22% of those aware had made a diagnosis in the past year.[4]

Besides these few quantitative studies on the subject, little qualitative research has been conducted to explore the extent to which information about AGS is clear and understandable; what questions audiences have about AGS; which of the several possible names for AGS are most memorable, clear, and descriptive; 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 both consumer and healthcare provider 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 and associated provider recommendations.

2. Purpose and Use of Information Collection

The goals of this evaluation are to assess: (1) knowledge, attitudes, and beliefs about AGS, (2) perceptions of risk about AGS, (3) the extent to which different information about AGS might influence a person to take preventative action against tick bites, (4) AGS questions and resource or information needs, including trusted messengers, and (5) reactions to and assessments of messages, language, and terminology about AGS. The results will be used to inform future communications initiatives including tailored messaging strategies on the topic of AGS.

KRC Research, a contracted research firm, will conduct all data collection related to the proposed formative research project, under the supervision of NCEZID DVBD. KRC's data collection will include recruiting and screening participants into the project, and conducting four 90-minute focus groups among consumers and nine 60-minute long in-depth interviews with physicians. These are one-time data collections resulting in qualitative data based on conversations.

Audience Rationale

DVBD has prioritized two audience types for this evaluation.

[3] Flaherty, M. G., etc. al. Patients' Health Information Practices and Perceptions of Provider Knowledge in the Case of the Newly Discovered Alpha-gal Food Allergy. Journal of Patient Experience, 2020;7(1):132-139.

[4] Carpenter A, Drexler NA, McCormick DW, et al. Health Care Provider Knowledge Regarding Alpha-gal Syndrome — United States, March–May 2022. MMWR Morb Mortal Wkly Rep 2023;72:809–814.

The first is consumers, and in particular a subset who are "outdoor enthusiasts." This audience is engaged in a variety of outdoor activities that put them at increased risk of tick bites. Activities for in this audience definition can be found in the screening questionnaire (Attachment 1) and include hunting, hiking, camping, activities with dogs, biking, and others. Furthermore, this audience has been limited to Northeast, South, and Midwest states where diagnoses of AGS are most prevalent. DVBD has prioritized this outdoor enthusiast consumer audience in order to learn from those who may benefit most from information and prevention recommendations from healthcare providers and others.

The second audience is healthcare providers, particularly those with specialties or focuses are most likely to overlap with AGS through patients who show symptoms or are referred for evaluation or treatment. This evaluation therefore prioritizes physicians in primary care, emergency care, gastroenterology, and allergy or immunology. Providers in these areas are most in need of education about AGS, its risks, its diagnosis, and prevention measures to recommend to patients.

Description of Instruments

The attachments that accompany this supporting statement are instruments for use in the evaluation among these audiences and include screening questionnaires to identify qualified participants in the correct numbers (Attachments 1 and 2), consent forms to ensure participants are aware of policies and procedures related to their participation (Attachments 3 and 4), discussion guides for use by moderators to guide the conversation and meet project objectives (Attachments 5 and 6), and draft message stimuli which will be displayed and discussed during the focus groups and interviews (Attachment 7).

The discussion guides include questions designed to elicit, among other topics:

- Awareness, knowledge, and experiences with AGS
- Attitudes, beliefs, and perceptions of risk related to AGS
- Awareness and use of preventative behaviors (consumers) or recommendation of such behaviors (physicians)
- Extent to which certain information motivates desired behaviors
- Questions, confusions, and information needs
- Information sources and trusted messengers
- Assessments of 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 AGS that are tailored to priority audiences. Insights will further help DVBD ensure it communicates about AGS using language and terminology that is clear, descriptive, and non-stigmatizing.

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 and unconventional allergic condition. Failure to collect this information may also mean that communications on the subject are suboptimal and leave recipients with questions, confusions, or

frustrations. Communications efforts that are not based on research 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 and interviews 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 and healthcare provider awareness, perceptions, and information needs related to AGS. In particular, little is known of the extent and reasons for AGS risk perception or preferences and points of confusion related to AGS 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 research and conducting four 90-minute focus groups with consumers and nine 60-minute in-depth interviews with physicians.

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 instruments for this evaluation are provided as Attachments 1 and 2. These screening instruments will be used to evaluate the qualification of potential participants. The screening instruments includes information about privacy and confidentiality; only those individuals who agree to these terms will qualify for participation in focus groups and interviews. 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. Consent forms are included as Attachments 3 and 4. 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 or interviews. 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.
- For focus groups only: a few colleagues are observing virtually.

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

<u>Institutional Review Board (IRB)</u>

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 8).

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 AGS. 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 93 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 or interview. (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 and interviews take 60 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	Outdoor enthusiasts (general public)	320	1	5/60	27
Focus Group Discussion Guide	Outdoor enthusiasts (general public)	32	1	1.5	48
Interview Screener	Primary care physicians	30	1	5/60	3
	Emergency care physicians	20	1	5/60	2
	Gastro-enterology physicians	20	1	5/60	2
	Allergy physicians	20	1	5/60	2

Interview Discussion Guide	Primary care physicians	3	1	1	3
	Emergency care physicians	2	1	1	2
	Gastro-enterology physicians	2	1	1	2
	Allergy physicians	2	1	1	2
Total					93

According to the U.S. Bureau of Labor Statistics (BLS) May 2022 National Occupational Employment and Wage Estimates, the median hourly wage for all occupations is $29.76. This has been used to calculate cost of participation for the general public audience.

To calculate cost for physician audiences, the following BLS hourly wages from have been used: $103.11 for primary care ("general internal medicine physicians" median), $152.21 for emergency care ("emergency medicine physicians" mean; no median is provided), and $107.41 for gastroenterologists and allergists ("all other physicians" median).

The total estimated cost burden is $4,318.78.

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	Outdoor enthusiasts (general public)	27	$29.76	$803.52
Focus Group Discussio n Guide	Outdoor enthusiasts (general public)	48	$29.76	$1,428.48
Interview Screener	Primary care physicians	3	$103.11	$309.33
	Emergency care	2	$152.21	$304.42

	physicians			
	Gastro-enterology physicians	2	$107.41	$214.82
	Allergy physicians	2	$107.41	$214.82
Interview Discussion Guide	Primary care physicians	3	$103.11	$309.33
	Emergency care physicians	2	$152.21	$304.42
	Gastro-enterology physicians	2	$107.41	$214.82
	Allergy physicians	2	$107.41	$214.82
Total				$4,318.78

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 $66,494.00. 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 and interviews, 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 40 hours of labor for a KRC Senior Vice President, 80 hours for a Vice President, 120 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 co-leading the project, totaling an estimated 60 hours (30 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.	$25,858.00
Contractor personnel costs: costs to report on results	$12,402.00
Contractor expenses: recruitment panel, transcription, incentives	$25,000.00
Federal government personnel costs: oversight, report review	$3,234.00
Total	$66,494.00

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 six weeks from start to finish. Four weeks will be spent recruiting and interviewing, two weeks will be spent in analysis and reporting, and four 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 interview participants	2 weeks, beginning immediately after gen-IC approved
Conduct interviews	2 weeks, overlapping with recruitment (3 total)
Transcription, data processing, and analysis	1 week after interviews end
Report development and delivery	1 weeks after completed analyses
Report review, discussion, and revisions	4 weeks after first draft delivery

Focus groups and interviews 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. Interview Screener
3. Focus Group Consent Form
4. Interview Consent Form
5. Focus Group Discussion Guide
6. Interview Discussion Guide
7. Draft Message Stimuli
8. Human Subjects Determination