**GenIC Clearance for CDC/ATSDR**

**Formative Research and Tool Development**

**Healthcare Provider Communication Evaluation: Assessing Foodborne Illness and Waterborne Illness Prevention Messages, Knowledge, and Attitudes**

**OMB Control No. 0920-1154 [genIC(24CU)]**

#### Supporting Statement B

**Contact:** Sara Bresee, MPH

Office of the Director

Division of Foodborne, Waterborne, and Environmental Diseases

Centers for Disease Control and Prevention

1600 Clifton Road, NE

Atlanta, Georgia 30333

Phone: (404) 639.3371

Email: yla4@cdc.gov

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**LIST OF ATTACHMENTS**

1. Eligibility Screener
2. Recruitment Materials
3. Eligible Participant Screener
4. Privacy Agreement
5. Respondent Consent Form
6. Standard Invitation
7. Participant Confirmation Email
8. Interview/Focus Group Moderator Guide
9. Messages/Materials to be Tested
10. Human Subjects Determination

**Supporting Statement B**

The collection of data for this project does not involve statistical methods, and the purpose of the collection is not to make statistical generalizations beyond the respondents included in the study. The objectives of the project are to:

* Identify appropriate and effective messages/materials for healthcare providers to increase awareness on preventing foodborne and waterborne illnesses among their patients.
* Gather data on the preferred tone, format, and placement of those messages/materials on CDC’s communication channels.

# Respondent Universe and Sampling Methods

The project team will enlist a national recruitment agency to recruit and manage participant screening. They will recruit from a national proprietary database of individuals. The primary audience for the interviews/focus groups is healthcare providers. Key audiences will consist of family/internal medicine physicians or primary care physicians, obstetricians/gynecologists (OB/GYNs), pediatricians, oncologists, nurse practitioners (NP) or physician assistants (PAs), and healthcare providers of any type who work at federally qualified health centers (FQHCs) or community health centers. These healthcare provider types were selected because their primary patient populations are at increased risk of foodborne or waterborne illnesses; obstetricians/gynecologists care for pregnant individuals; pediatricians often care for children; oncologists care for individuals diagnosed with cancer; healthcare providers working at federally qualified health centers or community health centers often care for low-income individuals. Primary care physicians or family/internal medicine physicians often care for a variety of populations, including those at increased risk for foodborne and waterborne illnesses (e.g., older adults). Nurse practitioners and physician assistants were included as they may serve as the primary healthcare provider in some settings instead of physicians. We will conduct a series of virtual interviews/focus groups lasting 60 minutes each. Each interview/focus group will consist of 1-2 participants, for a maximum of 33 participants.

Table 1. Interview/Focus group demographic makeup by key audience, type, and number.

| **Population** | **Number of Participants** |
| --- | --- |
| Primary Care Physicians or Family/Internal Medicine Physicians | 5 |
| Obstetricians/Gynecologists (OB/GYNs) | 5 |
| Pediatricians | 5 |
| Oncologists | 5 |
| Nurse practitioners (NP) or physician assistants (PAs) | 5 |
| Healthcare providers (of any type) who work at federally qualified health centers (FQHCs) or community health centers | 8 |
| **Total** | **33** |

Table 2. Demographic characteristics to be captured.

|  |
| --- |
| * Geographic location of healthcare practice * Race * Ethnicity * Gender * Age |

# Procedures for the Collection of Information

*Recruitment*

The team will use screeners **(Attachments 1 &3)** to meet the necessary inclusion criteria and help achieve the project team’s recruitment goals across identified demographic characteristics for interview/focus group participants.

To identify and recruit participants for the interviews/focus group discussions, we will employ a two part screening process to assess eligibility for participation. The first screener (**Attachment 1)** will ensure if they are eligible to participate in the interview/focus groups. The second screener: Eligible Participant Screener (**Attachment 3**) will allow the recruiters to ensure recruitment goals are achieved and (for focus groups) group the participants into specific focus groups (e.g. pediatricians).

Exclusion criteria for participation includes people:

* under 18 years of age;
* who are not comfortable speaking or reading in English;
* who are not one of the specified types of healthcare providers;
* who do not have access to the internet with a computer or mobile device.

These comprehensive screeners were developed in collaboration between CDC and the contractor. During the recruitment phase, the recruitment firm will provide a respondent report, confirmed attendees, and respondents for review. Staff will review these documents to ensure the recruitment mix is being reached. The recruitment firm will complete confirmation calls and provide a recruitment report after each interview/focus group session is completed. Once participants are chosen they will receive a standard invitation **(Attachment 6)** and once they accept the invitatation they will receive the participant confirmation email **(Attachment 7)**.

The contractor and recruitment agency will provide ongoing screening and recruitment updates to CDC and work with the project team to select a diverse sample for the groups during the recruitment phase. Samples of the recruitment materials that may be used by the recruitment agency can be found in **Attachment 2**. These, and similar items, will be used for recruitment.

*Implementation*

The project team will conduct 33 virtual interviews/focus groups lasting about 60 minutes each. The team has developed an approach designed to gather information about and assess healthcare providers’ knowledge, attitudes, beliefs, and behaviors about foodborne and waterborne illness prevention for their patients. The interviews/focus groups will also provide responses to specific questions about the effectiveness, preferred tone, format, and placement of new and existing materials and messages designed to help healthcare providers facilitate conversations with patients or to hand out to patients. Experienced moderators will facilitate the interviews/focus groups following approved semi-structured moderator guides **(Attachment 8**). The guides will contain multiple items and probes, which start more generally and get more specific, for individuals to respond to throughout the session. The contractor will conduct the virtual interview/focus groups using a web conferencing platform. The messages will be tested in rotation that are listed in **F**.

CDC project staff who have signed privacy forms will have access to observe live focus groups. The focus groups will be audio and video recorded and the de-identified transcripts will be provided to CDC upon completion of all focus groups.

To protect the privacy of participants, personally identifiable information (e.g., names, places of employment mentioned) will be redacted from all transcripts and not included in the field notes, final report, or any presentation about the project. Further, to ensure security, the contractor will provide CDC with password-protected files of the transcripts, notes, and analysis files.

*Analysis and Reporting*

The contractor will use iterative thematic analysis to identify key themes and subthemes captured in the data collected during interviews/focus groups. Using ATLAS.ti, the contractor will use both inductive and deductive coding to identify themes and organize the data captured from participants. The contractor will provide CDC with a final report summarizing the results of the focus groups. The report will also include quotes from participants to illustrate themes and topics of interest.

# Methods to Maximize Response Rates and Deal with No Response

Tokens of appreciation will be used in the focus groups to increase the likelihood of participation and offer a token of appreciation to participants for their time and input to the study. Based on industry standards and national vendor’s expertise, and a previously cleared project, the team recommends a participant token of appreciation of $200-250 per interview/focus group participant. In order to optimize and increase the chance of having at least a minimum of eight participants in each focus group, the contractor will over-recruit by 20 percent. This will account for any last-minute cancellations or no-shows and aim to get eight people per focus group.

A project involving interviews of physicians conducted in 2011 proposed and was approved for $100 to $250 per person for 60 minute interviews (OMB: 0920-1154, CDC ID: 0920-22CW). A more recent and more similar communication evaluation project that was conducted in the Spring of 2023 proposed and was approved for $250 and physicians and then NPs/Pas for $200 for 60 minute interviews (OMB: 0920-1182).

This year, the team plans to conduct 60 minute interviews/focus groups with the same populations, therefore $200 to $250 per person, depending on healthcare provider type, is appropriate. This amount was chosen because these participants (healthcare providers) are highly paid and may need to forgo work to participate; their time is in high demand, for a variety of reasons; there is past evidence of difficulty attracting this audience to participate in qualitative studies (see SSA for additional information). In addition, there is a health equity component of this work, where the team is selecting types of healthcare providers because they typically serve patient populations that are at increased risk for foodborne and waterborne illnesses. Therefore it is important from a health equity perspective to ensure that these various types of healthcare providers are included in this study.

In addition, reviewed literature revealed the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality. (See References.)

# Tests of Procedures or Methods to be Undertaken

One technical run-through will be conducted with contractor staff prior to the start of the study.

# Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

No individuals outside of the project team were consulted for statistical aspects of the design. Target numbers for the focus participants and groups were informed by the project scope of work, foodborne illness surveillance data and research, waterborne illness surveillance data and research, and DFWED priorities. The data being collected are qualitative and descriptive and there will be no statistical aspects of analysis. The individuals collecting and/or analyzing data include:

**Lead Investigator:** Sara Bresee, MPH, Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Foodborne, Waterborne, and Environmental Diseases (DFWED), Office of the Director (OD)

**Collaborators**

|  |  |
| --- | --- |
| **Name** | **Organizational Unit** |
| Nora Kuiper, Project Director | Banyan Communications (contractor) |
| Tola Aina, Project Director | Banyan Communications (contractor) |
| Sharanya Thummalapally, Lead Research and Evaluation Specialist | Banyan Communications (contractor) |
| Amanda White, Senior Communications Strategist | Banyan Communications (contractor) |
| Bria Berry, Research and Evaluation Specialist | Banyan Communications (contractor) |

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