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 A

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- **Goal of the study:** CDC would also like to know if and how healthcare providers are having discussions with populations at higher risk of foodborne and waterborne illness about prevention.
- **Intended use of the resulting data:** Data will be used to create communication materials, update existing content and create dissmeination strategies.
- **Methods to be used to collect:** Qualitative data collection (IDIs or small FGDs)
- **The subpopulation to be studied:** Healthcare providers

Exhibits

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

A . JUSTIFICATION

1 Circumstances Making the Collection of Information Necessary

Healthcare providers are a key public health dissemination channel and trusted source of information for the public. Research has shown populations at higher risk for foodborne illnesses prefer to receive information about foodborne illness prevention from their healthcare providers. However, consumers are

reporting that healthcare providers are rarely having discussions with populations at higher risk for foodborne illness about foodborne illness prevention. In July of 2023 DFWED conducted qualitative message testing (focus groups) with audiences at increased risk of foodborne illnesses (e.g., older adults, pregnant individuals, immunocompromised individuals, African American individuals, Hispanic individuals, etc.). The findings from this message testing indicate that these priority audiences rarely, if ever, talk to their healthcare providers about foodborne illness or food safety.

The main goal of this qualitative research project is to explore why healthcare providers are not having these conversations with their patients. CDC would also like to know if and how healthcare providers are having discussions with populations at higher risk of waterborne illness about waterborne illness prevention. To achieve these goals we aim to understand knowledge, attitudes and beliefs in terms of talking to their patients about prevention of foodborne and waterborne illnesses; a secondary objective will be to test the clarity and applicability of the messages and materials related to food and water safety knowledge for healthcare providers; and learn how best to disseminate information that is accessible to healthcare providers and promotes patient education.

Objectives of this research are to:

- To understand if and how healthcare providers are speaking to their patients about foodborne and waterborne illnesses and prevention steps.
    - To understand if they discuss food recalls and/or foodborne outbreaks with their higher risk patients or if they have a system in place to alert their patients on outbreaks.
- To understand if healthcare providers know how to categorize people at high risk for severe foodborne and waterborne illnesses.
    - To learn how we can impact their perceptions of risk.
    - To learn how we can convince them that foodborne and waterborne illnesses are within their purview.
    - To learn how they assume that patients get information about foodborne and waterborne illness risk, if not from their doctors.
    - To understand if different healthcare provider specialities understand these risks differently.
- To understand barriers/facilitators communicating with their patients about foodborne and waterborne illness prevention.
    - To understand what resources healthcare providers need to be able to speak to their patients about foodborne and waterborne illness prevention.
    - To understand if they feel confident/ knowledgeable enough about the topics to speak to their patients.
    - To understand what materials might help healthcare providers have conversations with their patients (e.g., tables for high-risk groups, new listeria factsheets).
- To understand if healthcare providers are aware of common foodborne and waterborne illness risks, for their patients, related to:
    - Not maintaining or using water safely to prevent water-related illness or contamination
    - Recreating at water venues such as pools and splash pads
    - Drinking water from water systems that contain biofilms

    - Eating foods that can cause Listeria/Salmonella/Cronobacter/E.coli poisoning among patients at high risk for these foodborne illnesses
    - Not practicing the four steps to food safety
    - Not being aware of foodborne illness outbreaks/food recalls

- To understand healthcare providers' impressions of and preferences regarding messages and materials related to foodborne and waterborne illness prevention.

Data collection will be used to:

- Develop/update messages and materials for healthcare providers related to foodborne or waterborne illness prevention.
- Tailor content to address current healthcare provider perceptions and concerns; make content easier to access, understand, and implement; and ensure content is presented in an attractive and engaging way.
- Create a dissemination/implementation strategy

CDC's contractor, Banyan Communications, will implement qualitative interviews or small focus groups. The interview/focus group respondents for this project will be a maximum of 33 individuals recruited by Banyan Communications. The project will work with volunteer respondents. Participants must meet a set of criteria to ensure all interviews/focus groups include a maximally diverse group of participants considering gender, race, ethnicity, healthcare provider type, healthcare specialty, location of healthcare practice, and rural/urban setting of healthcare practice. The interviews/focus groups will be conducted between adults (18+) and at least one research staff member. The goal is to obtain feedback to support foodborne and waterborne illness prevention communication initiatives.

The data collection will use

(1) a 5-minute eligibility screener (Attachment 1)
(2) a 5-minute eligible participant screener (Attachment 3)
(3) a virtual 60-minute interview/focus group (Attachment 8).

This information collection does not involve websites or website content directed at children less than 13 years of age.

2 Purpose and Use of the Information Collection

The purpose of this study is to conduct one-time, semi-structured, in person in-depth interviews with health care providers (e.g., primary care physicians/family medicine physicians, obstetricians/gynecologists, pediatricians, oncologists, nurse practitioners, physician assistants, registered nurses) to develop and improve communication materials related to foodborne and waterborne illness prevention. Banyan Communications will conduct the interviews/focus groups.

Objectives of this research are to:

- To understand if and how healthcare providers are speaking to their patients about foodborne and waterborne illnesses and prevention steps.
- To understand if healthcare providers know how to categorize people at high risk for severe foodborne and waterborne illnesses.
- To understand barriers/facilitators communicating with their patients about foodborne and waterborne illness prevention.
- To understand if healthcare providers are aware of common foodborne and waterborne illness risks, for their patients.

Data collection will be used to:

- Develop/update messages and materials for healthcare providers related to foodborne or waterborne illness prevention.
- Tailor content to address current healthcare provider perceptions and concerns; make content easier to access, understand, and implement; and ensure content is presented in an attractive and engaging way.
- Create a dissemination/implementation strategy

3 Use of Improved Information Technology and Burden Reduction

We will record each interview/focus group to use for preparing reports. Our data collection requires that we employ qualitative research methods using one-time virtual interviews/focus group discussions. We will receive recorded verbal confirmation from participants to record the interview/discussion. Questions will be kept to a minimum required for the intended use of the data.

4 Efforts to Identify Duplication and Use of Similar Information

There are no other federal generic collections that duplicate the project types included in this request. Health messages developed by CDC are unique in their mix of intended audience, health behavior, concept, and execution. Therefore, in most cases, there are no similar data available. We have reviewed existing published data and consulted with outside experts to identify information that could facilitate message development prior to conducting any data collection.

DFWED leads an interagency working group with other U.S. government agencies. In this working group we discuss research and communication projects to ensure there is a lack of redundancy.

5 Impact on Small Businesses or Other Small Entities

This project does not have an impact on small businesses or other small entities.

6 Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data over a 12-month period.

7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

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

For subcollection requests under an approved generic ICR, Federal Register notices are not required, and none were published.

Exhibit A.8.1. Outside Consultation

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To ensure there is no duplication or redundancy of effort across projects and programs, program staff will consult with a variety of sources on the availability of data, frequency of collection, clarity of instructions, and record keeping, disclosure, and reporting format (if any), and on the data elements to be recorded, disclosed, or reported. CDC staff has consulted with relevant Federal agencies and national associations that conduct food safety messaging (e.g., USDA, FDA).

9 Explanation of Any Payment or Gift to Respondents

We will provide a token of appreciation for each individual who participates in an interview/focus group; $250 for each medical doctor (MD) and $200 for each health care provider that is not a MD. Tokens of appreciation were determined based on previous projects and experience with conducting interviews with healthcare providers, recognizing that healthcare providers are a difficult population to reach. The range of monetary reward is consistent with current rates for participation in formative projects. Tokens of appreciation will take the form of gift cards.

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). It also should be

noted that message testing is a marketing technique, and it is standard practice among commercial market researchers to offer incentives as part of respondent recruitment.

We determined the honorarium amounts based upon the respondent population. Healthcare providers may have to take time away from their work to participate in these interviews/focus groups. The honoraria will encourage the healthcare providers' cooperation and participation, and conveys appreciation for contributing to this important study. Numerous empirical studies (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999) have shown that honoraria can significantly increase response rates. Physicians are a difficult population to reach because they are highly paid, and their time is at a premium. Moreover, healthcare providers are in increasing demand due a growing healthcare worker shortage in the U.S. over the last few years. One in five health care workers quit their job during the COVID-19 public health emergency, according to a 2021 Morning Consult report drawing from a survey of 1,000 health care workers (Glavin, 2021). A 2022 study found that nearly 63% of physicians experienced symptoms of burnout by the end of 2021 (Shanafelt et al., 2022), representing a 19% increase from 2017. Another 2022 study determined that 1 in 5 doctors said they were likely to leave their current practice within two years, citing burnout and workload as two major reasons (Sinsky et al., 2021). Physicians are burning out in part because of their demanding workloads. A 2022 Medscape report found that while they experienced burnout for a variety of reasons, one of the top three was "too many hours at work" (Kane, 2023). In addition to healthcare providers having high workloads and experiencing burnout, they are frequently bombarded by numerous entities all requesting their time for interviews, surveys, and pharmaceutical sales presentations. As a result, they often decline to participate.

OMB offers a justification which supports the use of honoraria, in this case "to improve coverage of specialized respondents, rare groups, or minority populations"(Office of Management and Budget, 2006). Healthcare providers are specialized respondents and require unique incentives to ensure participation. There have been numerous studies that show difficulties in recruiting physicians to participate in research (Asch et al., 2000; Berk & Jen, 1985; Cull et al., 2010; Cull et al., 2005; VanGeest et al., 2007). In one systematic review assessing ways to improve physician participation, researchers reviewed 21 different papers from 1981 to 2006 and assessed various ways to improve physician participation ranging from monetary incentives to other types of non-monetary incentives (VanGeest et al., 2007). They found that researchers who provided higher incentives yielded higher odds of physician participation (weighted OR 2.13; 95% confidence interval [CI] 1.7–2.6) (VanGeest et al., 2007). Similarly, studies that provided monetary incentives had much higher odds for participation than those that provided non-monetary incentives (VanGeest et al., 2007).

Over ten years ago, an honorarium of $100 to $250 was utilized with success during a 2011 Prevention is Care (PIC) study titled "Formative Research to Develop Social Marketing Campaigns: Routine HIV Testing for Emergency Medicine Physicians, Prevention Is Care (PIC), and Partner Services" (OMB Control #0920-0775. 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). During this project, the team was very successful and were able to recruit their goal.

Past studies showed that a smaller honorarium does not appear sufficiently attractive to healthcare providers, especially given that a higher number of healthcare providers are now paid on a fee-for-service basis and may be reluctant to take time away from work for an interview/focus group. For example, if a physician sees a minimum of four patients an hour, each with an average billing rate of $75, this equates to a physician hourly rate of $300. Suggested standard honoraria rates range from $250 to $350 for healthcare providers, depending on clinical credentials. This amount is consistent with quotes Banyan received in 2023 from professional recruitment firms for recruiting healthcare providers. We also believe that the honoraria will result in higher data validity as healthcare providers become more engaged in the interview process. Participants will receive their honorarium immediately after completing their participation in the interview/focus group.

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

Contractors and anyone listening to the project will be required to sign a privacy agreement prior to the start of the project (**Attachment 4)**. CDC's contractor, Banyan Communications, will retain notes, audio/video files, and any other project-related documents on secure servers or in locked file cabinets; only project staff members will be able to access the servers via password-protected computers. Findings will be reported in summary form, and participants' names and identifying information will not be included in the findings. Identifiable information will be kept separate from interview/focus group data so that participants' responses cannot be linked with their names. "CDC will treat data/information in a secure manner and will not disclose, unless otherwise compelled by law." All audio and video files will be destroyed three years after completion of the project. No identifiable information describing individual respondents will be included in the analyzed data and aggregate reports provided to CDC.

In review of this application, it has been determined that the Privacy Act is not applicable.
Banyan Communications will identify, screen, and recruit potential participants through a recruitment firm, using a proprietary recruitment list/database. Banyan Communications will use additional recruitment methods, such as including social media notices and snowball sampling as needed.

Individuals will first be screened to assess if they are eligible to be a part of the interviews/focus groups **(Attachment 1**). Those who meet the screening criteria for the interviews/focus groups will then receive a second demographic screener to ensure recruitment goals are met, and [for focus groups] assess which focus groups they will be put into **(Attachment 3)**. Finally, they will be invited to attend a virtual 60-minute interview/focus group. Participants will be asked to give verbal consent on a recording prior to the start of the interview/focus group and will also fill out a consent form (**Attachment 5)** before starting. They will receive a copy for their records.

The screeners will be stored in an encrypted online file hosted by Banyan Communications throughout the project's duration. Once the project ends, the screeners will be destroyed. Banyan Communications will retain notes, video files, and any other project-related documents on secure servers; only project staff members will have access to the servers via password-protected computers. Findings will be reported in summary form and participants' names and identifying information will not be included in the findings.

Identifiable information is kept separate from interview/focus group data so that participants' responses cannot be linked with their names. All video files will be destroyed at the completion of the project.

During each interview/focus group, the moderator will go over key parts of the informed consent during the introduction portion. The moderator will inform participants that the interview/focus group is voluntary, and that they may choose not to answer any question and end participation at any time. The moderator also will inform participants that Banyan Communications will report findings in summary form so that participants cannot be identified and that their identifiable information will be kept secure and separate from the interview/focus group notes and video recordings. The moderator will inform the participant that there is a note taker listening and watching. The informed consent includes the phone numbers for both Banyan Communications, in case participants have questions about their rights as a participant, and the principal investigator, in case participants have questions about the project itself.

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

This data collection was reviewed by CDC's Human Research Protection Office, and it was not deemed as human subjects' research and given a non-research determination (**Attachment 10**).

There is a minimal risk that some questions may make respondents feel uncomfortable. There will be potentially sensitive information collected such as race and ethnicity. These questions are critical to the project because messages are being tested from a health equity perspective and these questions will allow us to ensure a diversity of participant perspectives. Therefore, the team needs to gather data surrounding race, ethnicity, etc.

The respondent consent form includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the session at any time without penalty.

12 Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 69 hours (**Exhibit A.12.1)**. For the interviews/focus group discussions, every individual will be pre-screened using a 5-minute eligibility screener. Those determined to be eligible, will then be subsequently screened using a 5-minute eligible participant screener, to ensure recruitment goals are achieved. This process will be used to get the final interview/focus group participants not to exceed 33 participants. Those who screen in and agree to participate in the project will participate in a 60-minute interview/focus group; consent activities will be included in the 60 minutes.

Exhibit A.12.1. Estimated Annualized Burden Hours

Form Name	Respondent Type	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hours

HCP Eligibility Screener *Attachment 1*	Primary Care Physicians or Family/Internal Medicine Physicians	60	5/60	5
	Obstetricians/ Gynecologists (OB/GYNs)	60	5/60	5
	Pediatricians	60	5/60	5
	Oncologists	60	5/60	5
	Nurse practitioners (NP) or physician assistants (PAs)	60	5/60	5
	Healthcare providers (of any type) who work at federally qualified health centers (FQHCs) or community health centers	60	5/60	5
HCP Eligible Participant Screener *Attachment 3*	Primary Care Physicians or Family/Internal Medicine Physicians	15	5/60	1
	Obstetricians/ Gynecologists (OB/GYNs)	15	5/60	1
	Pediatricians	15	5/60	1
	Oncologists	15	5/60	1
	Nurse practitioners (NP) or physician assistants (PAs)	15	5/60	1
	Healthcare providers (of any type) who work at federally qualified health centers (FQHCs) or community health centers	15	5/60	1
HCP Interview Guide *Attachment 8*	Primary Care Physicians or Family/Internal Medicine	5	1	5

	Physicians			
	Obstetricians/ Gynecologists (OB/GYNs)	5	1	5
	Pediatricians	5	1	5
	Oncologists	5	1	5
	Nurse practitioners (NP) or physician assistants (PAs)	5	1	5
	Healthcare providers (of any type) who work at federally qualified health centers (FQHCs) or community health centers	8	1	8
Total				69

In calculating annualized costs to healthcare providers, we used the estimated hourly wage rate of $107.91 per hour for family medicine physicians; $133.33 per hour for obstetricians/gynecologists; $97.71 per hour for pediatricians; $114.76 for oncologists; and $59.94 for nurse practitioners or physician assistants; and $114.76 for healthcare providers of any type who work who work at federally qualified health centers (FQHCs) or community health centers. We used the mean hourly wage data released from the United States Department of Labor, Bureau of Labor Statistics (May 2022; available online at https://www.bls.gov/oes/current/oes_stru.htm). The estimated annual cost to healthcare provider participants for the hour burden for the collection of information will be $ $7,256.79 .

Exhibit A.12.2 Estimated Annualized Burden Costs

Form Name	**Respondent Type**	**Total Burden Hours**	**Hourly Wage**	**Total Respondent Cost**
HCP Eligibility Screener *Attachment 1*	Primary Care Physicians or Family/Internal Medicine Physicians	5	$107.91	$539.55
	Obstetricians/ Gynecologists (OB/GYNs)	5	$133.33	$666.65
	Pediatricians	5	$ 97.71	$488.55
	Oncologists	5	$ 114.76	$573.80
	Nurse practitioners (NP)	5	$ 59.94	$299.70

	or physician assistants (PAs)			
	Healthcare providers (of any type) who work at federally qualified health centers (FQHCs) or community health centers	5	$114.76	$573.80
HCP Eligible Participant Screener *Attachment 3*	Primary Care Physicians or Family/Internal Medicine Physicians	1	$107.91	$107.91
	Obstetricians/ Gynecologists (OB/GYNs)	1	$133.33	133.33
	Pediatricians	1	$ 97.71	$ 97.71
	Oncologists	1	$114.76	$114.76
	Nurse practitioners (NP) or physician assistants (PAs)	1	$ 59.94	$ 59.94
	Healthcare providers (of any type) who work at federally qualified health centers (FQHCs) or community health centers	1	$114.76	$114.76
HCP Interview Guide *Attachment 8*	Primary Care Physicians or Family/Internal Medicine Physicians	5	$107.91	$539.55
	Obstetricians/ Gynecologists (OB/GYNs)	5	$133.33	$666.65
	Pediatricians	5	$ 97.71	$488.55
	Oncologists	5	$114.76	$573.80
	Nurse practitioners (NP) or physician assistants (PAs)	5	$ 59.94	$299.70
	Healthcare providers (of any	8	$114.76	$918.08

	type) who work at federally qualified health centers (FQHCs) or community health centers			
Total		69		$7,256.79

13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no costs to respondents other than their time for participation.

14 Annualized Cost to the Federal Government

The contractor's costs are based on estimates provided by the contractor, who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be $124,784.75(**Exhibit A.14.1**). This is the cost estimated by the contractor, Banyan Communications, and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Exhibit A.14.1. Estimated Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct cost to the federal government		
CDC oversight of contractor and project	CDC Project Officer and PI	$33,694.75
Subtotal, Direct Costs to the Government		
Contractor and Other Expenses		
Recruitment, data collection, analysis and reporting (contractor)	Labor hours and other direct costs	$91,090.00
Subtotal, contracted services		
Total cost to the government		$124,784.75

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

During qualitative data collection, the Banyan Communications note taker will enter data from the interview/focus group discussion into a qualitative software analysis program (such as ATLAS.ti), which will be stored on a password-protected computer. Analysis of the interview/focus group data will start immediately after completion of data collection and will be conducted under the supervision of a senior

staff member with extensive experience in qualitative research. Banyan Communications will conduct thematic or grounded theory analysis of the data to understand participants' reactions to the messages in as rigorous and detailed manner as possible. Banyan Communications will summarize results in a final report. The final report will include key data from the online eligibility and demographic screener and report it in descriptive data tables with accompanying narrative in the summary and final reports. **Exhibit 16.1** lists the key events and reports**.**

Exhibit A.16.1. Project Time Schedule

Activity	Time Schedule
Begin recruitment	April 30, 2024
Conduct focus groups	Weeks of 5/13, 5/20, 5/27, 6/3, 6/10 of 2024
Report due	September 18, 2024

17 Reason(s) Display of OMB Expiration Date Is Inappropriate

OMB Expiration Date will be displayed on necessary materials and documents.

18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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