

Behavioral determinants of community hand hygiene behavior: A formative qualitative evaluation

Generic Information Collection (0920-1154)

Supporting Statement Part A

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5. Focus Group Moderator Guide
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7. CDC non-research determination

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| <ul style="list-style-type: none">▪ Goals of the project: The purpose of this project is to conduct a theory driven formative evaluation to understand the behavioral determinants of community hand hygiene behavior among U.S. adults, and to gain insights into the preferred health communication strategies among U.S. adults.▪ Intended use of the resulting data: To inform the development of health communication |
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materials to promote community hand hygiene behavior in the U.S.

- **Methods to be used to collect data:** Focus group discussions.
- **The subpopulation to be studied:** Adults in middle-income brackets (>25th and <75th percentile gross income) who do not work in healthcare, food service, or educational settings.
- **How data will be analyzed:** Descriptive analyses and thematic or grounded theory analysis of qualitative data.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new generic information collection (gen-IC), “Behavioral determinants of community hand hygiene behavior: A formative qualitative evaluation”. The goals of this evaluation are to examine the type of information U.S. adults need to engage in hand hygiene behavior by identifying behavioral determinants of hand hygiene behavior, and to gain insights into the preferred health communication strategies among U.S. adults.

Hand hygiene is the single most effective action an individual can take to prevent the spread of respiratory and gastrointestinal infections to others, especially among fecal-oral enteric pathogens. Cleaning hands serves as the last barrier against infection in the transmission of pathogens [1, 2]. When practiced regularly and effectively, it may prevent up to 33% of episodes of diarrhea in children in high-income settings [3, 4]. Specifically, hand hygiene acts as an important barrier against both bacterial and viral foodborne pathogens, such as *Campylobacter* spp. and Norovirus, in places like the United States and the United Kingdom [1]. Hand contact rates with eyes, noses, and mouths are high—almost 16 per hour on average for office workers alone [5]—and are even higher for children [6]. Infectious doses of gastrointestinal pathogen may range from fewer than 10 particles (e.g. for viruses) to more than 10⁶ bacteria, depending on the organism [7], and these amounts can easily be transmitted by fecal contamination on hands. Hand-associated exposure routes remain a significant contributor to both childhood and adult gastroenteritis.

Efforts to understand the barriers to high rates of hand hygiene have been focused in domestic healthcare and industrial (e.g. food-preparation) settings, where consequences for transmission of pathogens beyond a few individuals are of importance and where national attention has been most-focused. Within these settings, “top-down” adherence measures and monitoring (remotely or otherwise) combined with “bottom-up” peer-pressure and other motivators are both necessary to achieve high compliance [8]. Changes at all levels of such hierarchical institutional structures are necessary, especially in healthcare settings where competing demands on workers’ time and effort may inadvertently limit adherence [9, 10]. Notably, research into adherence in healthcare workers found that the belief structures surrounding hand hygiene practices that workers bring into the healthcare setting is driven by their community practices [11]. Thus, understanding and addressing community-level drivers of hand hygiene become even more important from a young age.

Community rates of hand hygiene remain poor both worldwide and in the United States. Only an estimated 19% of the world's population washed their hands with soap after contact with excreta [12]. Proportions in the United States are better, at an estimated 66% of people reporting always washing their hands after using a public restroom [13]. A 2011 survey reported similar findings in children: about 33% reported times when they had used the restroom and not washed their hand [14].

Community and home environments serve as the locale where hand hygiene behaviors are first learned. These behaviors begin as early as toilet training with a young child. However, there is considerable room for improvement in these behaviors, as parents revealed they were not always ideal role models for hand hygiene themselves [11, 14].

Hand hygiene rates within communities in the United States need to increase. To promote community hand hygiene behavior, a health communication and social marketing campaign could be an effective strategy. Health communication and social marketing campaigns have been used to promote a range of health behaviors in areas such as tobacco use, alcohol use, physical activity, HIV prevention, cancer, road safety, and nutrition [15]. Formative components of effective health communication campaigns include segmenting the key audience, conducting formative research, and using theory to guide campaign development [16].

To date, there are few health communication campaigns that have promoted community hand hygiene behavior at mass-scale in the U.S., and even fewer that have utilized recommended components of successful health communication campaigns such as theory driven formative research. The majority of hand hygiene campaigns in community settings have focused on daycare centers and schools, and not the general public [3, 17-23]. Early hand hygiene interventions were often efficacy, rather than effectiveness, evaluations, and thus were absent "real-world" considerations of cost, sustainability, and logistics of delivery of educational materials and/or hand sanitizer products, for example [24-26]. They were also mostly absent any grounding in behavior change constructs or theories. More recent studies have targeted college students or been observational assessments of handwashing in public areas [27-33]. Overall, the literature is absent domestic data on community-level hand hygiene campaigns grounded in behavioral change theory with a more general audience as its target.

2. Purpose and Use of Information Collection

The purpose of this project is to conduct a theory driven formative evaluation to examine the type of information U.S. adults need to engage in hand hygiene behavior by identifying behavioral determinants of hand hygiene behavior, and to gain insights into the preferred health communication strategies among U.S. adults. The evaluation results will be used to develop a health communication campaign to educate adults about community hand hygiene behaviors (these health communication messages will be tested in two additional 60-minute, in-person, focus groups. This second information collection will be submitted to OMB for review separately using CDC's health message testing generic package (0920-0572)).

A contracting company will be used to conduct all data collection related to the proposed formative research project. Data collection will include recruiting and screening participants into the project, and conducting two 90-minute long in-person focus groups with adults in the U.S.

Through these focus groups, the following issues will be examined:

- Hand hygiene and food preparation
- Hand hygiene after using the bathroom
- Hand hygiene after sneezing, coughing, or blowing one's nose
- Preference for health communication materials

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via in-person focus group discussions conducted by a contracting company. A note taker will be present to take notes for each focus group; all focus groups will be audio recorded to ensure participant responses are captured accurately. Questions included on the focus group moderator guide have been limited to only those relevant to the target audience to reduce burden on respondents.

A recruitment flyer will include brief information about the focus groups, and will link to an online screening portal which has more extensive information. Individuals interested in participating in the focus groups will use the web link provided in the recruitment flyer which will take them to an online screening form (Attachment 2). Those who do not meet inclusion criteria will be notified during the screening of their ineligibility. Those that meet inclusion criteria will be notified during the screening of their potential eligibility.

4. Efforts to Identify Duplication and Use of Similar Information

To date, there has been little theory driven formative qualitative evaluations exploring the behavioral determinants of community hand hygiene behavior among U.S. adults, and little formative qualitative evaluations examining preferences for health communication materials to promote community hand hygiene behavior among U.S. adults.

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 screener and the focus group 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. A contracting company will be used to conduct all data collection related to the proposed evaluation. Data collection will include recruiting and screening participants into the formative research, and conducting two 90-minute long in-person focus groups with adults in the U.S.

9. Explanation of Any Payment or Gift to Respondents

Focus group participants will receive a monetary token of appreciation for their participation. It is assumed that many of these participants will be taking time either during work hours or personal time to complete the focus groups, and may have children. Therefore the monetary gift may serve to offset costs related to participating in the evaluation in the amount of \$40 for participation in the 90-minute focus group.

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

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) has determined that the Privacy Act does not apply to this information collection. Focus group participants will be recruited and moderated by a contracting company. PII will not be transmitted to CDC.

The screening instrument for this evaluation is provided in Attachment 2. Before data collection, participants will be given time to read the consent form (Attachment 4) and ask questions. They will be given two copies of the informed consent: one to keep and one to sign to indicate consent and return to the research team. During the introduction to the focus groups, the moderator will review key parts of the informed consent, which will include informing participants of the following:

1. This discussion is completely voluntary. Participants may choose to leave the focus group and/or not answer a question at any time for any reason.
2. The evaluation team will take every precaution to protect participant identity and ensure privacy unless otherwise determined by law. This includes keeping names and answers to questions private and keeping contact information separate from any focus group responses.
3. Results of the focus groups will be presented in aggregate, and names will not be used in any reports.
4. Discussions will be audio-recorded and notes will be taken during the discussion. All information, notes, and audiotapes locked in a file cabinet or a secure computer file. Only evaluation staff will be able to access the information.

The informed consent form includes the phone numbers for a point of contact at the contracting company in case participants have any questions about the focus groups after participating.

The contractor will conduct the formative work in the following ways:

Screening: A contracting company will recruit participants using a recruitment flyer (Attachment 1). The flyer will include brief information about the focus groups, and will link to an online screening portal which has more extensive information. Individuals interested in participating in the focus groups will use the link provided in the recruitment flyer which will take them to an online screening form (Attachment 2). Those who do not meet inclusion criteria will be notified during the screening of their ineligibility. Those that meet inclusion criteria will be notified during the screening of their potential eligibility. To create a pool of potential participants from which to engage in purposive maximum variation sampling, a maximum of 500 individuals will be screened for eligibility.

A total of 20 participants will be purposively selected from this pool of eligible participants. Participants will be selected to maximize variability based on age, race/ethnicity, gender, place of residence, socioeconomic status, relationship status, parental status, source of health information, and perceptions of hand hygiene importance. If a participant is selected to participate, they will be contacted and provided with information on the time and location of the focus group (Attachment 3). If, at the time of invitation, the participant declines to participate, a replacement participant will be selected from the pool of eligible participants. Participants will receive an email reminder from the contracting company prior to the focus groups. PII (e.g., name, address, e-mail address, and telephone number) will be used by the contractor to make contact with, and send reminders, to participants. All personally identifiable information (PII) will be maintained by the contractor in a locked file cabinets or on secure online servers. No PII will be sent to CDC. The contractor will share with CDC the de-identified screening data for recruited participants and CDC using a password protected, encrypted, FTP site supplied by CDC. CDC will keep these screening data on CDC's secure network in a drive accessible only to CDC evaluation staff.

Focus Groups: Two in-person focus groups will be conducted. Each focus group will last no more than 90-minutes. Prior to starting the focus groups, all participants will complete an informed consent form and will be provided with an additional consent form to take home (Attachment 4). During the focus group, participants will be encouraged to use pseudonyms or nicknames rather than their real names. The contracting company will keep all consent forms in locked file cabinets or on secure online servers at their facility, and they will not share these documents with CDC. Audio recordings of the focus groups, and field notes taken during the focus groups will be kept in locked file cabinets or on secure online servers at the contracting company's facility. The contracting company will share with CDC audio files, field notes, and focus group transcripts using a password protected, encrypted, FTP site supplied by CDC. CDC will keep all focus group materials on CDC's secure network in a drive accessible only to CDC evaluation staff.

All findings will be reported in aggregate only. Reports will not include PII and will be stored on a secure share drive and password-protected computers. The contracting company used for this evaluation will be instructed to destroy their project-related records (i.e., screening data, contact logs, informed consent forms, audio files, transcripts, and field notes) upon completion of the evaluation.

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 7).

Justification for Sensitive Questions

All of the questions asked in the focus groups will be non-sensitive in nature and focus on hand washing and hand hygiene behavior, and preferences for hand hygiene health communication materials. 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

Table 1 below describes the burden associated with the information collection.

The burden estimate for the moderator guide includes the burden to review the informed consent, which will be completed by a contracting company. The total estimated burden is 114 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
General public	Screener	500	1	10/60	83
	Moderator Guide	20	1	1.5 hours	30
Total					113

Table 2 below describes the cost burden associated with this information collection. It was calculated based on the hourly wage rate for “all occupations” in the Bureau of Labor Statistics May 2017 National Occupational Employment and Wage Estimates (BLS, 2017) and from the U.S. Department of Labor Federal Minimum Wage Standards. The total estimated cost burden is \$2,774.76.

Table 2. Cost burden associated with information collection

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	Screener	83	\$24.34	\$2,020.22
	Moderator Guide	30	\$24.34	\$730.20
Total				\$2,750.42

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 average annualized cost to the Federal Government to collect this information is \$43,514.14. The federal government personnel estimate is based on cost of the four CDC staff and one CDC Foundation consultant. Federal staff and consultant responsibilities include overall management and oversight of the project, provision of content matter expertise in the development of the research strategy and data collection instruments, oversight of focus group composition, and overseeing all data analyses and dissemination activities.

Contractor costs include direct labor for recruiting and screening participants, conducting focus groups, and transcribing focus group audio recordings. Other direct contractor costs include subcontractors, travel, and facility rental, participant recruitment and incentives; and indirect costs such as fringe, overhead, general and administrative fees (Table 3)

Table 3.

		Percent Time	Total (\$)
Federal Government Personnel Costs	CDC Epidemiologist (GS-12)	20%	\$15,925.20
	CDC Epidemiologist (GS-13)	15%	\$13,744.65
	CDC Health Communication Specialist (GS-13)	5%	\$4,581.55
	CDC Supervisory Health Scientist (GS-15)	5%	\$8,200.00
	ORISE Fellow (GS-9/1)	2%	\$1,062.74
Total Annualized Cost to Government			\$43,514.14

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be tabulated and a report will be developed.

Project Time Schedule

Activity	Time Schedule
Recruit focus group participants (P)	1 month after OMB approval
Conduct focus groups (P)	2 weeks after recruitment ceases
Transcribe audio recordings (P)	2 weeks after completing focus groups
Code data, conduct quality control, and analyze data (C)	1 month after transcription
Prepare summary report(s) (C)	1 month after complete analyses
Disseminate results/reports (C)	1 month after complete analyses

Principal Partner(s) Responsible: (C) CDC; (P) Contracting Company

Analysis

Quantitative data from the screening forms will be imported into and analyzed using SAS. Audio files will be transcribed verbatim in a Word document. MAXQDA qualitative software will be used to manage focus group transcripts and for qualitative data analyses. Data will be analyzed using thematic coding.

Dissemination of results.

These findings will be used to develop and disseminate health communication materials to promote community handwashing and hand hygiene behaviors. Community hand hygiene promotion materials developed during this project will be made freely available through the CDC website and will be shared with a variety of partners. These materials will help inform the general public about community hand hygiene behaviors.

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.

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