GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Public Health Communications Messages and Materials Testing Focused on Antimicrobial Resistance Among the U.S. General Population Pilot Data Collection Project

OMB Control No. 0920-1154

August 3, 2023

Supporting Statement A

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- **Goal of the study:** To inform the development of educational public health messages that motivate adult members of the U.S. general population to engage in actions that have the potential to slow the spread and development of antimicrobial resistance.
- **Intended use of the resulting data:** The data will determine which concepts and/or messages are the most effective in combating antimicrobial resistance among adults in the U.S. general population.
- **Methods to be used to collect:** We plan to conduct virtual staggered focus groups and/or virtual in-depth-interviews.
- **The subpopulation to be studied:** The five target audiences are adult members of the U.S. population, by age: 1) Ages 21-30, 2) Ages 31-40, 3), Ages 41-50, 4) Ages 51-60, and 5), Ages 61-70. All participants must be conversant in English.
- **How data will be analyzed:** Focus group discussions and in-depth-interviews will be examined using qualitative content coding.
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1. Circumstances Making the Collection of Information Necessary

CDC's Antimicrobial Resistance Coordination and Strategy Unit (ARX) requests approval for a new information collection titled, Public Health Communications Messages and Materials Testing Focused on Antimicrobial Resistance Among the U.S. General Population" under GenIC OMB Control No. 0920-1154 (Expiration Date: 03/31/2026). Information collection activities are limited to formative work that will result in the development of public health communication messages and materials that encourage and motivate adults from the U.S. general population to change their behavior to help reduce antimicrobial resistant infections.

Antimicrobial resistance, the ability of germs to resist the drugs designed to kill them, is one of the greatest global public health challenges of our time (Aslam et al., 2018; Centers for Disease Control and Prevention [CDC], 2019a; Ventola, 2015). We now live in an era when people around the world are dying from untreatable infections because of antimicrobial resistance (CDC, 2019a).

- Survey data show that people do not fully understand antimicrobial resistance.
- Because everyone has a role to play in public health, we need everyone to take action to help slow and/or reduce the spread of antimicrobial resistance.
- Existing CDC public health campaigns have focused on increasing awareness of antibiotic/antifungal drug use and its role in antimicrobial resistance.

Effective public health campaigns are needed to increase awareness of antimicrobial resistance among adults in the U.S. general population and motivate them to engage in actions that have the potential to slow the spread and development of antimicrobial resistance (e.g., hand washing, improved use of antibiotics/antifungals, getting vaccinated, etc.). This project will test antimicrobial concepts and

materials to inform the development of educational public health messages. Without this data collection CDC ARX will not know if antimicrobial resistance campaign messages are effectively reaching and educating the general population nor how to refine or refresh the messaging to improve clarity, receptivity, relevance, and effectiveness.

2. Purpose and Use of Information Collection

The goals and objectives of this project are:

- Identify existing knowledge, attitudes, beliefs, and overall understanding of antimicrobial resistance among adults in the U.S. general population.
- Capture feedback on the content/messages, tone, style, and format of potential future public health communication materials to understand what resonates with the adult general population.
- Capture feedback to assess different public health communication materials and messages to understand which would motivate people to change their behavior to help reduce the spread of antimicrobial-resistant infections.

CDC contracted with CATMEDIA, a Program Management and Creative Services firm in Tucker, Georgia, to develop and execute this data collection on behalf of the CDC. CATMEDIA has partnered with C.E.K. & Partners, a marketing and research firm located in Atlanta, Georgia to lead the projects recruitment and data collection activities (note that hereafter CATMEDIA and C.E.K are collectively referred to as the ‘contractor”).

The intended audiences for this data collection are adults from the U.S. general population, segmented by age: 1) Ages 21-30, 2) Ages 31-40, 3), Ages 41-50 4), Ages 51-60, and 5), Ages 61-70. Data will be collected by the contractor through staggered virtual focus groups. Respondents for this project will be a maximum of 45 individuals (n=9 per audience segment). To compensate for potential focus group dropouts or no shows and ensure an n=9 per audience segment, the contractor will conduct virtual individual in-depth interviews (IDIs) if needed to ensure reaching n=9.

The contractor will enlist a market research vendor to recruit and manage participant screening. The vendor will recruit from their national proprietary database of individuals. Participants must meet a set of criteria to ensure all focus groups/IDIs will include a maximally diverse group of participants considering age, educational level, gender, and ethnicity and will include a mix of geographical areas (Attachment A. Recruitment Screener). Individuals who are deemed eligible will be asked to consent electronically prior to participating in a focus group/IDI (Attachments B & F. Participant Sheet & Informed Consent). Participants will receive a PDF copy of the consent form. If a participant is visually impaired or has limited reading skills, they will be permitted to have an assistant join them during the focus group/IDI to help read the content of the materials presented. The assistant will not be considered a project participant.

Due to geographic dispersion of participants, all focus groups/IDIs will be conducted virtually via Zoom Video Communications, Inc. and will be audio and video recorded for the purpose of completing the analysis and reporting. Participants will be required to use a personal computer, tablet, or mobile device to join the focus group via Zoom. The focus group/IDI will be conducted in English only. A participant will only be allowed to participate in one focus group/IDI.

An experienced moderator will lead the focus groups/IDIs using a semi-structured discussion guide. The discussion questions will touch on knowledge and awareness of antimicrobial resistance and getting feedback on pre-developed messages, concepts, and materials developed by CDC (Attachment C. Discussion Guide). Each focus group discussion will last a total of 60 minutes and each IDI will last a total of 30 minutes. The contractor will conduct a 15-minute technical pre-check with participants at least one day prior to the focus group/IDI (Attachment D. Technology Check). During the pre-check, participants will be provided with instructions on when and how to access the virtual Zoom focus group/IDI. Participants will be asked to use a pseudonym and provided instructions on how to change their screen name in the Zoom platform.

3. Use of Improved Information Technology and Burden Reduction

All project activities will use virtual methods to engage with potential respondents including phone, email, and Zoom Video Communications, Inc. (Zoom), therefore eliminating participants burden of responding using paper forms and/or traveling to a focus group site. Focus group/IDI 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

The information that the CDC collects is not available from any other source. No other governmental or institutional agencies are attempting to collect this data as this work is specific to evaluating messages and materials developed by CDC ARX.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection. Without insights and feedback from this data collection, health education materials cannot be developed effectively. Careful consideration has been given to the project design to effectively balance the information collection objectives with participant burden.

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

A. A *Federal Register* notice was published for this generic information collection request on July 22, 2022, Vol. 87, No. 140, pp. 43860-3861. No public comments were received. No additional comment periods are required for project-specific requests submitted under this generic.

B. No consultations outside of CDC occurred other than with the previously mentioned contractors on this project.

9. Explanation of Any Payment or Gift to Respondents

Participants who complete either a focus group interview or a one-on-one interview will receive a token of appreciation for their time/participation based on OMB's guidance (OMB,2016) on factors that may justify provision of a token of appreciation. Focus group participants will receive $125.00 and one-on-one interview participants will receive $75.00, an amount commensurate with other market surveys (Halpern et al., 2004). Assistants who join a session to support a participant who is "visually impaired" or has "limited reading skills" will not receive a token of appreciation. However, participants who decline to be recorded upon joining the virtual meeting will be politely thanked for their time and provided exit instructions. By exiting the study, the participant will forfeit their token of appreciation. Participants will receive their token of appreciation following completion of their focus group/IDI in the form of prepaid gift cards. Virtual focus groups have been found to have a higher dropout rate, thus presenting the need for a higher incentive (Rupert et al., 2017). The average incentive range for a non-expert accessible member of the public falls between USD $75-$150 (Gell, 2021). 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.

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

The privacy act does not apply.

Personally identifiable information (PII), including individual names, will be collected from the market research vendor for recruitment purposes and to provide incentives only. The vendor's database is maintained according to privacy regulations. Demographic information (e.g., age, gender, race/ethnicity, etc.) will be collected as part of the screening to determine participant eligibility, however no direct personal identifiers (e.g., date of birth, social security number, etc.) will be collected or maintained. Participants will be advised not to share PII during the focus groups/IDIs and will be issued a pseudonym and provided instructions on how to change their screen name in the Zoom web-hosting platform. No PII, such as names, addresses, or phone numbers, will be collected during the data collection. All PII will be kept separate from participants responses to the focus group/IDI questions. None of the files or documents received by the CDC project team will include PII.

Participants will be informed about the security measures for privacy protection during the consent process (Attachments B). The recordings/videos will be edited shortly after completion of the interviews to fully de-identify them. Fully de-identified recordings and transcripts will be maintained on the contractor's password-protected/encrypted servers. Any transcripts or recordings with PII will be deleted after being fully de-identified. All analyses will be conducted on aggregated data, and participants'

information will not be appended to the data file used. Aggregated, de-identified data from this project may be used in future analysis and/or shared with other social marketing and communication specialists. Quotes that may be used in the final report to illustrate a key point will not be attributable to a specific participant.

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

CDC's contractor submitted the project to Advarra (https://www.advarra.com/), a commercial IRB, for human subjects' research determination. Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(2), the IRB determined that this research project is **exempt** from IRB oversight. The IRB also completed the necessary additional limited review considerations as set forth under the Revised Common Rule, 45 CFR 46.104(d). The IRB granted this exemption on February 24, 2023 (see Attachment E: IRB Exempt Determination).

Justification for Sensitive Questions

It is important to understand the experiences and perceptions of people who might be, whether intentionally or not, engaging in behaviors that may contribute to antimicrobial-resistant infection. While these questions are similar in sensitivity to other topics discussed in everyday life, it is possible that a participant may be sensitive to these questions. All questions are voluntary, and participants may skip any question they are not comfortable answering.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The total estimated annualized response burden hours are 306. Time estimates are based on the contractor's previous experience conducting qualitative data collections with adults. We anticipate screening 1,500 individuals to obtain the 45 respondents annually (Attachment A. Recruitment Screener); screening will take approximately 10 minutes per individual to complete (250 annual burden hours). Those who screen in and consent to participate in the project will be asked to participate in a 15-minute Technology Pre-check (11 annual burden hours). Following the technology pre-check (Attachment D. Technology Pre-Check), participants will participate in a 60-minute virtual focus group (45 annual burden hours) or a 30-minute virtual IDI if needed to compensate for potential focus group dropouts or no shows. Because focus group participation lasts longer than an IDI, we calculated the estimated annualized burden based on the longer activity (e.g., 60-minute focus group).

Estimated Annualized Burden Hours					
Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)*	Total Burden (in hrs.)
Individual	Recruitment Screener	1500	1	10/60	250
Individual	Technology Pre-Check	45	1	15/60	11
Individuals Ages	Antimicrobial-	45	1	1	45

21-70	Resistant Infection Formative Evaluation Interview Guide				
Total					**306**

B. Estimated Annualized Burden Costs

The annualized costs for respondents are based on data from the U.S. Department of Labor (DOL), Bureau of Labor Statistics (2022). To calculate annualized costs to consumers, we used the mean hourly wage rate of $29.76 which represents the DOL estimated mean for state, local, and private industry earnings and assumes an average hourly wage rate for respondents who work an estimated 40-hour work week. The total annualized burden cost is estimated at $9114.00.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individuals	Screener	250	$29.76	$7,440.
Individuals	Technology Pre-check	11.25	$29.76	$327.36
Individuals Ages 21-70	Antimicrobial-Resistant Infection Formative Evaluation Interview Guide	45	$29.76	$1339.20
Total				$9106.56

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

Total estimated annualized cost to the government is [$5,450,316.50] based on expenses incurred in the following categories: salary of CDC staff who are responsible for the overall project design and project oversight, and contractor costs associated with data collection and analysis activities.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost

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

Project Time Schedule	
Activity	Time Schedule
Recruitment for virtual focus groups	Within 3 weeks following OMB approval
Rolling recruitment for virtual IDIs	Within 3 weeks following OMB approval
Conducting virtual focus groups & IDIs	Within 5-6 weeks following OMB approval
Data collection conclusion document	1 week
Transcripts produced	2-3 weeks
Recordings sanitized	2-3 weeks
Data compilation/analysis writing findings presentation (PPT & Word)	5-6 weeks
Reviews and revisions to finalize presentations	7 weeks

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment A: Recruitment Screener

Attachment B: Focus Group Participant Information Sheet and Informed Consent Form

Attachment C: Discussion Guide

Attachment D: Technology Pre-Check

Attachment E: IRB Exempt Determination

Attachment F: IDI Participant Information Sheet and Informed Consent Form (Contingency for Focus Group Dropouts)

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