GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Formative Communications Assessment on Antimicrobial Resistance

OMB Control No. 0920-1154

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Supporting Statement A

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- **Goal of the study:** The purpose of this assessment is to explore the knowledge, attitudes, and behaviors of priority CDC audiences about antimicrobial resistance (AR) and associated actions to combat it.
- **Intended use of the resulting data:** Findings will be used to inform both CDC's current AR communications as well as potential future communications efforts to increase awareness of AR and drive action to combat AR.
- **Methods to be used to collect:** Virtual focus groups, in-depth interviews, and a survey.
- **The subpopulation to be studied:** Human health providers and experts (physicians, physician assistants/associates, nurse practitioners, and medical association experts), consumers (adults, parents, and caregivers, and adults with past antimicrobial-resistant infection) and health policy audiences.
- **How data will be analyzed:** Descriptive and thematic analyses of qualitative data and cross-tabulation of quantitative 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 new or improved messages and tools.

Antimicrobial resistance (AR) occurs when germs like bacteria and fungi develop the ability to defeat the drugs designed to kill them. AR is an urgent, global public health threat, impacting the health of people, animals, and our shared environment. In 2019 alone, AR contributed to more than 4.95 million deaths worldwide. CDC reports that there are more than 2.8 million antimicrobial-resistant infections in the United States (U.S.) each year.[1] AR affects everyone, and its impact extends beyond the healthcare system to the food supply, animals, and the environment. It is a complex problem that requires strong public health infrastructure, innovation, and collaborative global action across the One Health spectrum, including among healthcare providers, policymakers, public health professionals, the public, and others.

AR communications are complex and require a strategic approach based on up-to-date information. First, AR can be difficult to understand, and misperceptions abound (e.g., many wrongly believe it is people who develop resistance to antimicrobial drugs). Second, AR requires a "One Health" approach (i.e., it impacts humans, animals, and the environment and AR outcomes are influenced by many key players) and requires CDC and other organizations to communicate to a vast audience set, but there are disparities of knowledge, attitudes, and beliefs across audiences. Third, many consumers and other audiences may believe the AR threat is not imminent; and still others may lack a sense of personal responsibility for a problem that is "too large."[2]

[1] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019

[2] Capers, K. (n.d.). Communicating Antimicrobial Resistance with the Public: Effective Strategies and Considerations during a Pandemic [Slide show; PowerPoint Presentation]. HHS.gov. https://www.hhs.gov/sites/default/files/communicating-antimicrobial-resistance-public-strategies-considerations-pandemic.pdf

Before designing this data collection, a secondary data analysis was conducted to evaluate existing opinion and communications research on AR and assess collective gaps in knowledge. Insights confirm that AR is a difficult and often-misunderstood topic, and more effective communications are needed to catalyze momentum and spur urgency within the populations who are most capable of combatting the emergence and spread of AR. Knowledge alone is not sufficient to address the AR problem: the secondary analysis found evidence that most healthcare providers have received formal education on the topic but this knowledge is not sufficient for driving recommended actions to combat AR.[3, 4] Additionally, there are gaps in collective understanding of AR's perceived relevance across audiences, individuals' perceived impact on AR, and best communications approaches to overcome barriers to behaviors that combat AR. The secondary analysis has identified a need for additional data collection to ensure CDC can effectively communicate about AR with key audiences.

The proposed data collection will explore the knowledge, attitudes, and behaviors related to AR across priority audiences, with the goal of both informing CDC's existing AR communications and unearthing insights to guide a potential future AR communications campaign.

2. Purpose and Use of Information Collection

The primary overarching objective of this data collection is to explore the knowledge, attitudes, and behaviors of select priority CDC audiences about antimicrobial resistance and associated actions to combat it. This data collection is intended to fill gaps in knowledge identified through a previous secondary communication and opinion research assessment. The results from the data collection will be used by CDC to inform both CDC's current AR communications as well as potential future communications efforts to increase awareness of AR and drive action to combat AR.

KRC Research, a contracted research firm, will conduct all data collection related to this initiative, under the supervision of CDC. KRC's data collection will include recruiting and screening participants into the project and conducting 8 focus groups (4 with human health providers and 4 with consumers), 6 in-depth interviews, or IDIs (3 with medical association experts and 3 with adults with a past bacterial or fungal antimicrobial-resistant infection), and a survey of 100 individuals working with and around those who shape federal health policy. This data collection will happen once; it is not recurring.

Audience Rationale

This data collection involves three core audiences:

- Human health providers: primary care and hospitalist physicians, physician assistants/associates, and nurse practitioners plus medical association experts
- Consumers: younger and older adults, parents of young children and caregivers of older adults, adults with past antimicrobial-resistant infection
- Health policy audiences

[3] Ashiru-Oredope D., et al., "Healthcare workers' knowledge, attitudes and behaviours with respect to antibiotics, antibiotic use and antibiotic resistance across 30 EU/EEA countries in 2019," 2021

[4] Zetts, R. M., et al., "Primary Care Physicians' Attitudes and Perceptions Towards Antibiotic Resistance and Antibiotic Stewardship: A National Survey," 2020

These audiences have been identified because each has the power to play an important role in slowing the spread of AR.

Human health providers play a critical role in combatting AR as they are responsible for prescribing antimicrobials, educating patients on the correct usage of these medications, and implementing infection prevention and control (IPC) measures within healthcare settings. Providers will be recruited from a mix of settings (primary care and hospitals) where patients most often encounter health professionals. Both physicians and PAs/NPs are included to account for their differing training, responsibilities, and patient interactions. Finally, medical association experts and leaders are included because of their insight into provider trends and challenges and their important role in establishing practice guidelines. Together, these sub-audiences will provide a relatively holistic picture of the state of AR knowledge, attitudes, and beliefs in healthcare and will help to inform a potential AR campaign as well as CDC's existing AR efforts.

Consumers primarily contribute to the fight against AR through a host of activities like cleaning hands, getting vaccinated, preparing food safely, practicing healthy habits around animals, using antimicrobials appropriately, and more. A mix of consumers will be recruited (younger and older adults, parents and caregivers) to both learn from a diverse group and uncover additional nuances related to health decisions and concerns for individuals in their care. Finally, adults with past antimicrobial-resistant infections will be interviewed to explore their firsthand experiences with the challenges of AR. Their perspectives on lessons learned, key messages and information, and provider interactions will be uniquely useful in informing CDC's communications efforts.

Finally, health policy audiences play a major role in shaping the rules and regulations that impact how AR is addressed on a widespread level. CDC has conducted surveys of this policy audience as recently as 2022; however, these were limited to only a few questions each for the past several years. An expanded, original survey will allow for a larger and nuanced set of questions that afford more opportunity to explore a variety of topics in greater depth.

Description of Instruments

This data collection involves online focus groups, interviews, and a survey. The instruments involved include screening questionnaires (Attachments 1, 2, 3), consent forms (Attachments 4 & 5), focus group moderator guides (Attachments 6, 7, 8), interview guides (Attachments 9 & 10), and a survey (Attachment 11). The screening questionnaires have two primary purposes: to ensure the proper qualifications for those who participate in the focus groups and interviews, and to ensure a balance of included participants based on demographic and audience-specific variables. The consent form is designed to ensure qualified participants are aware of key information about the data collection, such as privacy and the voluntary nature of their engagement. The focus group and interview guides will be used by a trained KRC Research moderator to direct the conversation and keep it on track.

Consequences of Not Collecting Information

This data collection is necessary to ensure CDC communications initiatives are based on up-to-date information gathered directly from the intended audiences. If this collection were not to be carried out,

CDC would not have timely, nuanced, and center-relevant information about the knowledge, attitudes, beliefs, and needs of its priority audiences regarding AR. Communications efforts that are not based on research may be ineffective and the CDC resources used may not be used efficiently, may not reach intended populations, or may reach populations with uninformed outreach strategies. By conducting this data collection, CDC will have a much clearer understanding of what these audiences know about AR, how they relate to the issue, and how CDC can best empower them to fight AR.

3. Use of Improved Information Technology and Burden Reduction

All data will be collected online 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) and participants, CDC, and its contractor KRC Research do not need to travel. All focus groups and interviews will be conducted by professional moderators and interviewers from KRC Research, a contracted company. All focus groups and interviews will be audio and video recorded to ensure participant responses are captured accurately and transcribed. Questions included in the discussion guides have been limited to only those relevant to the target audience to reduce burden on respondents.

The recruitment, screening, and data collection for the survey will all be self-administered and conducted online, allowing respondents to complete the screening and survey at their convenience, in the comfort and privacy of their homes.

4. Efforts to Identify Duplication and Use of Similar Information

This data collection is preceded and strategically informed by a comprehensive secondary research analysis by KRC Research, a contracted research firm, in collaboration with NCEZID. The purpose of the analysis was to learn from evaluate existing communications and opinion research on the topic of AR but also to assess gaps in collective knowledge about audiences' own knowledge, attitudes, beliefs, and behaviors related to AR. The currently proposed data collection is informed by the findings of that earlier assessment and is focused specifically on areas of inquiry that have <u>not</u> been addressed or need clarification or updating prior to developing new communications or a potential communications campaign.

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.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the 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 package on July 22, 2022, Vol. 87, No. 140, pp. 438360. No public comments were received.

B. KRC Research, a contracted research firm, has been consulted in the development of the research plan, sampling parameters, and data collection instruments. Under the supervision of CDC, 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 8 focus groups (4 with human health providers and 4 with consumers), up to 6 IDIs (3 with medical association experts and 3 with adults with a past bacterial or fungal antimicrobial-resistant infection), and a survey of 100 individuals working with and around those who shape federal health policy.

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 for these audiences 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.

Survey respondents will be compensated for their willingness to participate in the data collection. All such incentives are managed by the vendor that maintains the panel itself. Incentive amounts are variable and determined based on a variety of factors including the time that a respondent will dedicate to the response, the difficulty of reaching a given profile of respondent, and the urgency of the response. These panel incentives and their fulfillment by panel providers is a standard procedure for panels of this type. -

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

CDC has reviewed this submission and determined that the Privacy Act does not apply.

KRC Research, a contracted firm, will manage recruitment and execution for this evaluation, and PII will not be transmitted to anyone at CDC.

For focus groups and interviews, the screening instruments (Attachment 1, 2, 3) will be used to evaluate the qualification of potential participants. The screening instruments include information about privacy and confidentiality; only those individuals who agree to these terms will qualify for participation.

After an individual agrees to the terms and has qualified, they will be given a separate consent form (Attachment 4, 5) that reiterates privacy and confidentiality policies. The participant will be required to sign the form (electronic submission is allowed) and deliver a copy to the recruiting and data collection team. The participant will be reminded that participation is entirely voluntary.

Once participants have signed the consent form, the recruiting team will collaborate with them to confirm their focus group or interview slot. During the introduction to each focus group or interview, the

trained moderator or interviewer will review key parts of the privacy and confidentiality agreement, including:

1. The discussion is completely voluntary. Participants do not have to answer any questions they are not comfortable with.
2. Only first names or preferred names will be used during the conversation, and nothing participants say or do will be reported in association with their names.
3. Discussions will be audio and video recorded and notes will be taken during the discussion. All information, notes, and files will be kept on a secure server. Only KRC Research and the core CDC team that manages the evaluation will have access to these files. Files will be deleted within 30 days of CDC approval of the final report of findings.

For the survey, members of a policy audience panel will be screened in the course of taking the survey itself (Attachment 11). Screening questions have been limited to those only absolutely necessary and worded to avoid collecting sufficient information from respondents that it would be possible to identify them through their answers. Data collection will also be conducted completely independently of any PII (e.g., a participant's name and contact information will not be tied to their responses to the survey). The recruitment panel provider will exclusively manage participant's PII which they use to verify the identities of their panel members and distribute incentives; CDC will never receive or have access to any PII from participants. Each respondent opts in to participate in surveys and can opt out of either the study or panel participation and communication at any time.

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

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required (Attachment 12).

Justification for Sensitive Questions

All the questions asked in the interviews will be non-sensitive in nature and focus primarily on knowledge, attitudes, and experiences with AR. 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

A. Estimated Annualized Burden Hours

The total estimated burden is 201 hours. Table 1 describes the burden associated with the information collection. The paragraphs below describe the assumptions built into the burden table.

Health Care

Four (4) focus groups will be conducted: two (2) among physicians, and two (2) among a mix of physician assistants/associates and nurse practitioners. Eight (8) participants will be approved for

participation per focus group (32 total participants). Based on experience, approximately 10 individuals will be screened for every one scheduled (320 screened). Focus groups last 90 minutes; screening takes 5 minutes.

Up to three (3) in-depth interviews will be conducted among medical association experts. Interviews will be scheduled via direct outreach to individuals with existing relationships with CDC. As such, there is no screening burden involved for this activity. Interviews last 60 minutes.

Consumers

Four (4) focus groups will be conducted: two (2) among general consumers of different ages, one (1) among parents of children, and one (1) among caregivers of adults. Eight (8) participants will be approved for participation per focus group (32 total participants). Based on experience, approximately 10 individuals will be screened for every one scheduled (320 screened). Focus groups last 90 minutes; screening takes five (5) minutes.

Up to three (3) in-depth interviews will be conducted among consumers with previous antimicrobial-resistant infections. Based on experience, approximately 10 individuals will be screened for every one scheduled (30 screened). Interviews last 60 minutes; screening takes five (5) minutes.

Policy Audiences

One (1) online survey of 100 individuals working with and around those who shape federal health policy will be conducted. Based on experience and an understanding of the targeted nature of recruitment within the specialized survey panel, an estimated additional 200 individuals will be screened out early in the survey due to ineligible screening responses. For those who successfully screen in and complete the survey, the survey will take 10 minutes. For those who begin the survey and screen out, the survey will take three (3) minutes.

Table 1. Annualized Burden

Form Name	Type of Respondent	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Focus Group Screener for Healthcare Providers *Attachment 1*	Physicians	160	1	5/60	13
	PAs and NPs	160	1	5/60	13
Focus Group Guide for HCPs about Antimicrobial Resistance	Physicians	16	1	1.5	24
	PAs and NPs	16	1	1.5	24

Attachment 6					
Interview Guide for Medical Association about Antimicrobial Resistance *Attachment 9*	Medical Association Experts	3	1	1	3
Focus Group Screener for Consumers, Including Parents, and Caregivers *Attachment 2*	Consumers	320	1	5/60	27
Focus Group Guide for General Consumers about Antimicrobial Resistance *Attachment 7*	Consumers	24	1	1.5	36
Focus Group Guide for Caregivers about Antimicrobial Resistance *Attachment 8*	Consumers	8	1	1.5	12
In-Depth Interview Screener for Consumers with Previous Antimicrobial-Resistant Infections *Attachment 3*	Consumers	30	1	5/60	3
Interview Guide for Consumers with Past Antimicrobial Resistant Infections on Antimicrobial Resistance *Attachment 10*	Consumers	3	1	1	3
Survey on Antimicrobial Resistance Among	Policy Audiences	300	1	13/60	43

National Policy Audiences *Attachment 11*					
Total					**201**

B. Estimated Annualized Burden Costs

The total estimated cost burden is $10,593.76.

Cost estimates have been calculated for each audience using the U.S. Bureau of Labor Statistics (BLS) May 2022 National Occupational Employment and Wage Estimates. The median hourly wages are as follows: physicians $109.22 (this wage also used as an estimate for medical association experts); combined physician assistants/associates and nurse practitioners $59.52 (average of PA $60.58 and NP $58.47 medians); and all adults $22.26. Because the policy audience is broadly defined and can include a diversity of individuals in government, non-profit, and for-profit sectors, the $51.62 median BLS wage for "management occupations" has been used.

Table 2. Cost Burden Associated with Information Collection

Form Name	Type of Respondent	Total Burden Hours	Hourly Wage Rage	Total Respondent Costs
Focus Group Screener for Healthcare Providers *Attachment 1*	Physicians	13	$109.22	$1,419.86
	PAs and NPs	13	$59.52	$773.76
Focus Group Guide for HCPs about Antimicrobial Resistance *Attachment 6*	Physicians	24	$109.22	$2,621.28
	PAs and NPs	24	$59.52	$1,428.48
Interview Guide for Medical Association about Antimicrobial	Medical Association Experts	3	$109.22	$327.66

Resistance *Attachment 9*				
Focus Group Screener for Consumers, Including Parents, and Caregivers *Attachment 2*	Consumers	27	$22.26	$601.02
Focus Group Guide for General Consumers about Antimicrobial Resistance *Attachment 7*	Consumers	36	$22.26	$801.36
Focus Group Guide for Caregivers about Antimicrobial Resistance *Attachment 8*	Consumers	12	$22.26	$267.12
In-Depth Interview Screener for Consumers with Previous Antimicrobial-Resistant Infections *Attachment 3*	Consumers	3	$22.26	$66.78
Interview Guide for Consumers with Past Antimicrobial Resistant Infections on Antimicrobial Resistance *Attachment 10*	Consumers	3	$22.26	$66.78
Survey on Antimicrobial Resistance Among National Policy	Policy Audiences	43	$51.62	$2219.66

Audiences *Attachment 11*				
Total				$10,593.76

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

The annualized cost to the Federal Government to collect this information is $257,232.74. Table 3 describes the cost in more detail.

All data collection activities will be conducted by KRC Research, a contracted firm. KRC's work includes recruitment, screening, scheduling, management of consent forms, conducting data collection, transcription and data cleaning, and reporting. Contractor costs cover the work of an existing team working with CDC on this initiative and include 390 hours of labor total. 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. A breakdown is as follows: 92 hours at for vice present-level staff, 265 hours for analyst-level staff, and 33 hours for recruitment and fieldwork director staff.

Oversight and review of all materials and reports will be conducted by 3 federal government employees who are overseeing the project. Their work will include providing oversight to KRC Research on the purpose and objectives of the project; guidance and feedback on recruitment, screening, and data collection 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 transcripts, data, and reports; and sharing topline findings with CDC staff so they can use the findings to strengthen communication messages.

The estimate includes 104 hours for Associate Director for Communications, 287 hours for Health Communication Specialist, and 478 hours for Health Communication Specialist. Estimated federal employee and contractor task cost is tabulated based on these employees' current hourly wages (locality-adjusted GS pay table for Atlanta-area workers):

- Associate Director for Communications (CDC Project Officer): 104 hours @ $61/hour=$6,344
- Health Communication Specialist Communication Support 287 hours @ $85.79/hour = $24,621.73
- Health Communication Specialist (CDC Co-Principal Investigator): 478 hours @ $72.38/hour = $34,597.64
- Total = $65,563.37

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	Estimated Annualized Cost
Contractor personnel costs: costs to recruit, conduct focus groups, interviews, and survey	$25,909
Contractor personnel costs: costs to tabulate, analyze, and report	$32,871
Contractor expenses: recruitment panel, transcription, incentives	$73,670
Contractor personnel costs: instrument review, design feedback, report review	$59,219.37
Federal government personnel costs: oversight, report review	$65,563.37
Total	$257,232.74

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

This initiative is expected to take eight weeks from start to finish. One week will be spent recruiting participants, four weeks will be spent conducting data collection, and two weeks will be spent in analysis and reporting. A timeline is available in Table 4.

Table 4. Project Time Schedule for Focus Groups and Interviews

Activity	Time Schedule
Recruit participants	2 weeks, beginning immediately after gen-IC is approved
Conduct qualitative data collection and field survey	4 weeks, following recruitment
Transcription, analysis, report development	2 weeks, after data collection ends
Disseminate results/reports	As soon as summary reports are complete

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.) Results will be used to develop a report with an assessment of findings and recommendations for targeted messaging strategies for CDC communications with this audience.

Survey data will be tabulated into crosstab data files for easy interpretation of results.

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

1. Screener (Provider Focus Groups)
2. Screener (Consumer Focus Groups)
3. Screener (Consumers with Past Infection In-Depth Interviews)
4. Consent Form (Focus Groups)
5. Consent Form (In-Depth Interviews)
6. Focus Group Guide (Providers)
7. Focus Group Guide (General Consumers)
8. Focus Group Guide (Consumer Caregivers)
9. Interview Guide (Medical Association Experts)
10. Interview Guide (Consumers with Past Infection)
11. Survey (Policy Audience)
12. Human Subjects Determination