GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

In-Depth Interviews with Healthcare Professionals about *C. Diff* Materials

OMB Control No. 0920-1154

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Supporting Statement A

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- **Goals of the project:** To test a set of draft *C. diff* communications materials among healthcare professionals (HCPs) to ensure materials effectively communicate information about *C. diff* risks, answer questions about *C. diff* risk factors, and are useful in assessing patient risk for *C. diff* and discussing it with patients.

- **Intended use of the resulting data:** To refine and improve the effectiveness of communications materials drafts prior to publication and potential dissemination to HCPs as part of CDC's *Be Antibiotics Aware (BAA)* campaign.

- **Methods to be used to collect data:** In-depth interviews.

- **The subpopulation to be studied:** HCPs in dental, primary care, urgent care, hospital, and emergency department roles.

- **How data will be analyzed:** Descriptive and thematic analyses 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) under OMB Control No. 0920-1154: "In-Depth Interviews with Healthcare Professionals about *C. Diff*. Materials."

Information collection activities are limited to formative work that will result in the refinement of draft communications materials (tested in this project) that are intended to help healthcare professionals (HCPs) optimize antibiotic prescribing, improve patient safety, combat antibiotic resistance, and prevent *C. diff* infections. In this project, HCPs will be interviewed to ensure materials: effectively communicate information about *C. diff* risks, answer HCPs' questions about *C. diff* risk factors, are useful in assessing patient risk for *C. diff*, and encourage regular conversations with patients and their families.

C. diff (also known as *Clostridioides difficile* or *C. difficile*) is a germ that causes diarrhea and colitis (an inflammation of the colon). According to CDC, C. diff is estimated to cause almost half a million infections in the United States each year, and about one in six patients who get *C. diff* will get it again with in the subsequent 2-8 weeks.[1]

C. diff can affect anyone. C. diff bacteria are commonly found in the environment, but most cases of *C. diff* occur while taking antibiotics or not long after they have finished. Risk factors include antibiotic exposure, older age (65+), recent stay at a hospital or nursing home, a weakened immune system, or a previous *C. diff* infection. People are seven to ten times more likely to get *C. diff* while on antibiotics and during the month after.[2] (According to CDC, this is "because antibiotics that fight bacterial infections by killing bad germs can also get rid of the good germs that protect the body against harmful infections, like *C. diff* infection."[3])

In 2003, CDC launched its *Get Smart* communications campaign as an effort to improve antibiotic prescribing and use in primary care settings. In November 2017, CDC relaunched *Get Smart* as *Be Antibiotics Aware (BAA)*, a national educational effort that supports healthcare professionals in their efforts to improve antibiotic prescribing and use and fight antibiotic resistance, as well as helps patients understand when antibiotics do and do not work. Current communications initiatives related to *C. diff* and its risk factors fall under this BAA campaign, primarily because of the important connection between antibiotic use and *C. diff* infection.

Today, CDC and the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) is continuing communications campaign activities related to *C. diff* via the development of HCP and patient materials (e.g., fact sheets) that communicate the most up-to-date information to ensure *C. diff* risk factors are considered in prescribing decisions and other situations. This current proposed data collection will test drafts of new materials to ensure they effectively communicate information, answer questions about *C. diff* risk factors, and are useful for HCPs and their patients. Final materials will be published online by NCEZID and may be disseminated via a variety of channels.

NCEZID has conducted a variety of qualitative data collections to inform the *BAA* campaign[4], including testing of more general materials related to antibiotic prescribing. The results have provided insights about HCP preferences related to certain terminology, materials formats, level of detail, citation of sources, and more. However, such assessments are a few years old and,

[1] "What is *C. diff*?" https://www.cdc.gov/cdiff/what-is.html

[2] "Your Risk of *C. diff*." https://www.cdc.gov/cdiff/risk.html

[3] Ibid.

[4] "Be Antibiotics Aware is a national effort to help fight antibiotic resistance and improve antibiotic prescribing and use." https://www.cdc.gov/antibiotic-use/

more importantly, do not specifically focus on *C. diff*. Moreover, the materials tested in this proposed package are entirely new; NCEZID has not conducted such assessments before.

This data will allow NCEZID to better target communication messaging to priority HCP groups, potentially increasing appropriate antibiotic prescribing behavior and risk assessments for *C. diff*.

2. Purpose and Use of Information Collection

The goal of this project is to test a set of draft *C. diff* communications materials among healthcare professionals (HCPs) to ensure materials effectively communicate information about C. diff risks, answer questions about *C. diff* risk factors, and are useful in assessing patient risk for C. diff and discussing it with patients. The results of this project will be used to refine and improve the effectiveness of communications materials drafts prior to publication and potential dissemination to HCPs as part of CDC's *Be Antibiotics Aware (BAA)* campaign.

This data collection will be executed via a series of 11 online in-depth interviews with HCPs, lasting 60 minutes each. KRC Research, a research firm contracted to work with NCEZID, will conduct all data collection related to the proposed formative research project under NCEZID's supervision. KRC's data collection will include recruiting and screening participants into the project, conducting in-depth interviews, and analyzing and reporting on results. This is a one-time data collection that will not be repeated.

The need for this data collection arises from the importance of ensuring NCEZID's HCP materials are clear, understandable, and actionable; effectively convey information; convey the *right* information with an appropriate level of detail; and do not raise new concerns or questions among intended audiences. The draft materials tested in this proposed package will be evaluated in all these respects. In contrast, if the data were not collected, materials would be published without first gathering feedback from the target audience to confirm they work as intended, which may result in a suboptimal use of government resources and ineffective efforts to combat C. diff.

This data collection involves two instruments: a screener (Attachment 1) and an interview guide (Attachment 3).

The screener is designed to ensure the participants recruited for interviews meet the criteria and parameters established by NCEZID when evaluating the priority audiences for the communications materials. The screener will be administered by KRC Research and its recruiting team to ensure a respondent (a) qualifies for participation and (b) fills quotas for variables like healthcare specialty or role and demographic characteristics. In this project, participants include five types of HCPs: dentists, primary care HCPs, urgent care HCPs, hospitalist providers (physicians working with hospitalized patients), and emergency department HCPs.

Once a participant has been recruited and scheduled for an interview, a trained KRC Research interviewer will use the interview guide to facilitate the conversation. The guide has been jointly developed by NCEZID and KRC and will be used to ensure the interview covers key areas of

inquiry and allocates appropriate time to different topics. In this project, the interview guide includes questions designed to elicit, among other topics:

- HCPs' knowledge, attitudes, and beliefs about *C. diff* and its relationship to antibiotics
- Frequency, content, and challenges with conversations about *C. diff* with patients
- Trusted sources of information about *C. diff* and preferences for *C. diff* materials
- Assessments of a set of *C. diff* materials designed for HCPs and their patients; questions focus on reactions, questions, clarity, improvements, likelihood and ways of using, and priority takeaways and key information

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via online interviews through a web-based platform, meaning that participants will not have to download anything to their personal devices (participants need only to have an internet connection). All interviews will be conducted by professional moderators from KRC Research, a contracted company. All interviews will be audio and video recorded to ensure participant responses are captured accurately and transcribed. Questions included on the interview moderator guide have been limited to only those relevant to the target audience to reduce burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

NCEZID has conducted previous formative qualitative data collections to inform the broader *Be Antibiotics Aware* communications campaign. The materials to be tested in this package are informed by those previous learnings, including findings about healthcare professionals' preferences and needs for communications resources and fact sheets. However, the materials to be tested in this package are new in format, design, and/or information content, and they have not been tested before. As such, this is an entirely new data collection.

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 interview 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. KRC Research, a contracted research firm, has been consulted in the development of the research plan, sampling parameters, and interview guide. Under the supervision of NCEZID, 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 eleven 60-minute-long online interviews with healthcare professionals in the U.S.

9. Explanation of Any Payment or Gift to Respondents

Interview participants will receive a monetary incentive of $75 for their participation. Such an incentive is a standard practice in the market research industry and helps to ensure efficient recruitment and ultimate participation among the qualified and scheduled participants. The amount is also standard for participation in a 60-minute interview. The incentive is also intended to offset the cost of personal or professional time taken to participate.

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

NCEZID has determined that the Privacy Act does not apply to this information collection. KRC Research, a contracted firm, will manage recruitment and interviewing for this initiative, and PII will not be transmitted to NCEZID.

The screening instrument for this evaluation is provided in Attachment 1. This screening instrument will be used to evaluate the qualification of potential interview participants. The screening instrument includes information about privacy and confidentiality; only those individuals who agree to these terms will qualify for participation in interviews. After an individual agrees to the terms and has qualified for interview scheduling, they will be given a separate consent form 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 interviewing team. The participant will be reminded that participation is entirely voluntary.

After the consent form (Attachment 2) is signed, participants will confirm their interview slots. During the introduction to each interview, the trained interviewer will review key parts of the privacy and confidentiality agreement:

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 NCEZID team that manages the evaluation will have access to these files. Files will be deleted within 30 days of NCEZID approval of the final report of findings.

No participants' personally identifiable information will be shared or made available to NCEZID. No recordings will be shared (audio or video), and shared transcripts will have names and any other identifiable information redacted. All findings will be reported in aggregate only.

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 4).

Justification for Sensitive Questions
All the questions asked in the interviews will be non-sensitive in nature and focus on knowledge, attitudes, and beliefs about *C. diff*, experiences with patient conversations about *C. diff*, and assessments of healthcare professional- and patient-focused *C. diff* fact sheets. All participants will be informed that they need not answer any question that makes them feel uncomfortable or that they do not wish to answer.

12. Estimates of Annualized Burden Hours and Costs

The total estimated burden is 22 hours (rounded). Table 1 below describes the burden associated with the information collection.

The burden table assumes that 10 respondents will be screened for each one successfully recruited and scheduled for an interview. (This one in ten rate is relatively high because sampling is conducted from within a panel of individuals already opted in surveys, focus groups, and interviews. Each individual also has a preexisting demographic profile that makes targeting recruitment much more efficient.) The burden table assumes screening will take 5 minutes per person for those 11 individuals who are successfully recruited. Interviews last 60 minutes.

Table 1. Annualized Burden (total burden hours rounded)

Form Name	**Type of Respondent**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden Per Response (hours)**	**Total Burden Hours**
Screener for C. diff Materials Testing Interviews (Attachment 1)	Dentist	20	1	5/60	2
	Primary care physician	10	1	5/60	1
	Primary care NP or PA	10	1	1	1
	Urgent care physician	10	1	5/60	1
	Urgent care NP or PA	10	1	5/60	1
	Emergency physician	10	1	5/60	1
	Emergency NP or PA	10	1	5/60	1
	Hospitalist physician	30	1	5/60	3
Discussion	Dentist	2	1	1	2

Guide for C. diff Materials Testing Interviews (Attachment 3)	Primary care physician	1	1	1	1
	Primary care NP or PA	1	1	1	1
	Urgent care physician	1	1	1	1
	Urgent care NP or PA	1	1	1	1
	Emergency physician	1	1	1	1
	Emergency NP or PA	1	1	1	1
	Hospitalist physician	3	1	1	3
Total					22

The total estimated cost burden of this information collection is $1,990.86.

The cost burden has been calculated with the use of median hourly wages for different HCPs from the U.S. Bureau of Labor Statistics (BLS) May 2022 National Occupational Employment and Wage Estimates. According to BLS, the hourly wages are:

- $59.53 median for Nurse Practitioners and Physician Associates/Assistants (average of $58.47 median for Nurse Practitioners and $60.58 median for Physician Associates/Assistants)
- $74.54 median for Dentists (BLS: “Dentists, General”)
- $103.11 median for Primary Care, Urgent Care, and Hospitalist Physicians (BLS: “General Internal Medicine Physicians”)
- $152.21 mean[5] for “Emergency Medicine Physicians”

Table 2. Cost burden associated with information collection (total burden hours rounded)

Form Name	**Type of Respondent**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Screener for C. diff Materials Testing Interviews (Attachment 1)	Dentist	2	$74.54	$149.08
	Primary care physician	1	$103.11	$103.11
	Primary care NP or PA	1	$59.53	$59.53
	Urgent care physician	1	$103.11	$103.11
	Urgent care NP or PA	1	$59.53	$59.53
	Emergency physician	1	$152.21	$152.21
	Emergency NP or PA	1	$59.53	$59.53
	Hospitalist physician	3	$103.11	$309.33
Discussion Guide for C. diff Materials Testing Interviews (Attachment 3)	Dentist	2	$74.54	$149.08
	Primary care physician	1	$103.11	$103.11
	Primary care NP or PA	1	$59.53	$59.53
	Urgent care physician	1	$103.11	$103.11
	Urgent care NP or PA	1	$59.53	$59.53
	Emergency physician	1	$152.21	$152.21
	Emergency NP or PA	1	$59.53	$59.53
	Hospitalist physician	3	$103.11	$309.33
Total				$1,990.86

[5] BLS does not provide a median hourly wage for this role but does provides a mean, used here instead.

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 annualized cost to the Federal Government to collect this information is $30,614,94. Table 3 below describes the cost in more detail.

Recruiting and interviewing will be conducted by KRC Research, a contracted firm. KRC's work includes project management, recruitment, screening, scheduling, management of consent forms, conducting interviews, transcription and data cleaning, reporting, and presentation. Contractor costs cover the work of an existing team working with NCEZID on this and other communications initiatives and include 23 hours of labor for KRC Vice President-level staff, 37 hours of labor for KRC Director-level staff, 86 hours for KRC Analyst-level staff, and 16 hours for a Field Director (recruitment management). 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.

Oversight and review of all materials and reports will be conducted by one GS-13 federal government employee who is co-leading 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 interview guide 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 the transcripts and reports; and sharing topline findings with NCEZID staff so they can use the findings to strengthen communication messages. The estimate includes 20 hours for the Health Communication Specialist.

Estimated federal employee cost is tabulated based on the employee's current hourly wage (locality-adjusted GS pay table for Atlanta-area workers):

- Health Communication Specialist 1: 20 hours @ $57.60/hour = $1,152.00

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	**Estimated Annualized Cost**
Contractor personnel costs: costs to oversee recruit, conduct interviews	$7,043.82
Contractor personnel costs: costs to report on results	$12,571.12
Contractor expenses: recruitment, transcription, incentives	$11,000.00
Federal government personnel costs: oversight, report review	$1,152.00
Total	$30,614,94

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This initiative is expected to take six weeks from start to finish. Four weeks will be spent recruiting and interviewing, and two weeks will be spent in analysis and reporting. A timeline is in Table 4.

Table 4. Project Time Schedule

Activity	**Time Schedule**
Recruit interview participants	2 weeks, beginning immediately after gen-IC approved
Conduct interviews	2 weeks, following recruitment
Transcription, analysis, and report	2 weeks, following completion of interviews
Disseminate results/reports	As soon as summary report is approved

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 written report with an assessment of findings, recommendations for the optimization of tested *C. diff* materials, and considerations for potential future NCEZID communications intended for the same healthcare professional audiences.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

1. Screener
2. Consent Form
3. Interview Guide
4. Human Subjects Determination