Request for genIC Approval
CDC/ATSDR Formative Research and Tool Development

0920-1154

CIO: National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion

PROJECT TITLE: Formative Research for Sepsis and Antibiotic Use Campaigns

PURPOSE AND USE OF COLLECTION:

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new generic information collection, Formative Research for the Sepsis Campaign and Antibiotic Use Campaign (contract number 200-2016-F-90343).

The goal of the formative research is to assess the knowledge, perceptions, and behaviors of consumers and healthcare professionals regarding sepsis and antibiotic use, as well as to obtain feedback on initial campaign messaging, to develop separate but complementary messaging for the sepsis and antibiotic use campaigns. A common question among stakeholders of these topics is how to achieve balance. On one hand, CDC strongly urges judicious antibiotic prescribing and use, yet the agency also supports starting antibiotics quickly in the event that sepsis is suspected. While these messages can sound contradictory, they both actually represent strategies to reach the very best patient outcomes possible. We must preserve antibiotics and use them only when needed so that antibiotic resistance does not take stronger hold and leave future sepsis patients without treatment options. If we squander these precious resources, there will be no hope for people, such as sepsis patients, who need them. Because of this delicate message balance, CDC believes that it is in the agency's and public's best interest to develop this campaign research simultaneously.

This information collection involves formative research to understand consumers' and healthcare professionals' (HCPs) knowledge, perceptions, and behaviors regarding sepsis and its prevention, as well as antibiotic use/prescribing, antibiotic resistance, and adverse drug events. Respondents also will provide feedback on initial informational messages and calls-to-action. This information collection uses mixed methods consisting of short-term focus groups, in-depth interviews (IDIs), recruitment screeners, and pre-discussion information surveys.

DESCRIPTION OF RESPONDENTS:

Sepsis

- Healthcare Providers: Nurse practitioners and physician assistants who work at urgent care centers; primary care physicians; emergency department triage nurses; and general medical ward, nursing home, and home healthcare professionals.
- Consumers: Mothers (age 30-54) with infants ≤1 and who care for elderly parents; African American men age ≥65 with one or more chronic condition; and healthy adults who are also caregivers age ≥65

Antibiotic Use

- Healthcare Providers: Family practitioners, NPs/PAs, emergency department attending physicians, urgent care owner-physicians, and hospitalists.
- Consumers: Those who demand and expect antibiotics for themselves or their families (1. self-expector and self-demander and 2. caregiver-expector and caregiver-demander)

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: Carla Doan

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [X] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [X] No Not applicable

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

Focus group and IDI participants will receive a monetary gift of appreciation for their participation. It is assumed that many of these participants be taking time either during work hours or personal time to complete the focus groups and IDIs. Consumer participants may have children. Therefore the monetary gift may serve to offset childcare costs related to participating in the study in the amount of $35 for participation in 90-minute focus group.

Emergency department triage nurses, general hospital ward/nursing home/home health care staff, and NPs/PAs will receive $75 for their participation.

Physicians (i.e., family practitioners, ED physicians, urgent care owner-physicians, primary care, and hospitalists) will receive a monetary gift of $125.

Experience from previous studies indicates that physicians are frequently inundated by numerous entities requesting interviews, surveys, or time for pharmaceutical sales presentations. As a result physicians often decline to participate. The contractor's experience has shown that a smaller token of appreciation does not appear sufficiently attractive to physicians. Suggested standard

token of appreciation rates range from $200 to $350 for physicians depending on specialty and geographic location. This amount is consistent with quotes CDC received in 2014 from recruitment firms for recruiting primary care providers and infectious disease specialists. The contractor understands the providers will not need to physically travel to a location therefore the token of appreciation is substantially lower than what is generally offered. The work being proposed needs to be completed in such a short timeframe and with a specific sub-segment of providers, as such offering a token of appreciation to providers can help ensure that the work is completed within the time allotted.

Numerous empirical studies have shown that a monetary gift can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000; Robinson, Dennison, Wayman, Pronovost & Needham, 2007). In the contractor's experience conducting multiple formative research projects, a monetary gift of $50-75 for general consumers is adequate for 60-90 minute focus groups and $125-200 is adequate for physicians. They found a reduction in respondent commitment with any lower amount. In response to offering this level, respondents are much more likely to honor their commitment of participating in the IDIs and focus groups. Lower amounts could actually result in higher recruiting costs and burden to the public due to the need for additional recruitment (Krueger & Casey, 2009).

BURDEN HOURS

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Consumers	Sepsis Screener for mothers	36	1	5/60	3
	Sepsis Screener for Healthy Adults	36	1	5/60	3
	Sepsis Screener for A-A Men	36	1	5/60	3
	Sepsis PDIS	27	1	5/60	3
	Sepsis FG Moderator Guide	27	1	1.5	41
	AU Screener SD-SE	72	1	5/60	6
	AU Screener CD-CE	72	1	5/60	6
	AU PDIS SD-SE PDIS	24	1	5/60	2
	AU PDIS CD-CE PDIS	24	1	5/60	2
	AU FG Moderator Guide	36	1	1.5	54
Healthcare Providers	Sepsis Screener for ED Triage Nurse	36	1	5/60	3

	Sepsis Screener for NP or PA	36	1	5/60	3
	Sepsis Screener for PCP	36	1	5/60	3
	Sepsis Screener for Gen Med Ward, NH, and Home HC staff	36	1	5/60	3
	Sepsis PDIS	36	1	5/60	3
	Sepsis IDI Moderator Guide	36	1	1	36
	AU Screener	96	1	5/60	8
	AU PDIS	24	1	5/60	2
	AU IDI Moderator Guide	24	1	1	24
Total					208

FEDERAL COST:

The estimated annual cost to the Federal government is $508,682.00.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

- **Sepsis Consumer Focus Groups**: Up to 27 consumers will participate in formative research data collection for the sepsis campaign. A stratified, non-probability, purposive sample will be used to recruit consumer participants. A professional recruitment firm will conduct all recruitment using the inclusion criteria identified in Exhibit 1 above. For the sepsis campaign, consumers will be sampled from the U.S. South and Mid-West census region across eight states: Alabama, Kansas, North Carolina, South Carolina, Georgia, Maryland, Illinois, and Kentucky. Participants will be recruited from these regions and states as these have the highest rates of sepsis and chronic conditions that place individuals at risk of sepsis. A professional recruitment firm will conduct all recruitment, including delivering the consumer screener to potential participants to determine their eligibility and distributing/collecting the consumer pre-discussion information sheet (PDIS) from all eligible participants prior to the focus groups.

- **Sepsis HCP Individual In-Depth Interviews (IDIs):** Up to 36 healthcare professionals will participate in the formative research data collection for the sepsis campaign. A stratified, non-probability, purposive sample will be used to recruit healthcare professional participants. The contractor will work with a third party recruitment firm to create participant lists of healthcare professionals that are part of the campaign target audiences. A professional recruitment firm will conduct all recruitment using the inclusion criteria identified in Exhibit 2 above, using a sampling panel. Healthcare professionals will be recruited from the U.S. South and Mid-West census region across eight states: Alabama, Kansas, North Carolina, South Carolina, Georgia, Maryland, Illinois, and Kentucky. These regions and states have the highest rates of sepsis and chronic conditions that place individuals at risk of sepsis. A professional recruitment firm will conduct all recruitment, including delivering the HCP screener to potential participants to determine their eligibility and distributing/collecting the HCP PDIS from all eligible participants prior to the focus groups.

- **Antibiotic Use Consumer Focus Groups**: Up to 36 consumers will participate in the online, synchronous consumer focus groups. Three focus groups with three participants each will be conducted with each consumer group. A professional recruiting firm will use a stratified, non-probability, purposive sample to recruit consumer participants. In addition to the criteria in Exhibit 4, the recruiter will screen participants as follows: consumers (self-demander and self-expector) and/or their children (caregiver-demander and caregiver-expector) must have been prescribed an antibiotic in the previous year and must have either outright requested an antibiotic in the past for themselves (self-demander) or their child (caregiver demander) OR expected an antibiotic for themselves (self-expector) or their child (caregiver expector). Consumer participants will be recruited from the U.S. South census region, Missouri, and Washington—states in which antibiotic prescribing is the highest. A professional recruitment firm will conduct all recruitment, including delivering the consumer screener to potential participants to determine their eligibility and distributing/collecting the consumer PDIS from all eligible participants (i.e., 36) prior to the focus groups.

- **Antibiotic Use Healthcare Professional IDIs:** Up to 24 healthcare professionals (HCPs) will participate in the online IDIs. IDIs will be conducted with six types of HCPs—family practitioners, nurse practitioners (NPs), physician assistants (PAs), emergency department (ED) attending physicians, urgent care owner-physicians, and hospitalists. A professional recruiting firm will use a stratified, non-probability, purposive sample to recruit HCP participants. HCP participants will be recruited from the U.S. South census region, Missouri, and Washington—states in which antibiotic prescribing is the highest. A professional recruitment firm will conduct all recruitment, including delivering the HCP screener to potential participants to determine their eligibility and distributing/collecting the HCP PDIS from all eligible participants (i.e., 36) prior to the focus groups.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

    [X] Web-based or other forms of Social Media

    [X] Telephone

    [ ] In-person

    [ ] Mail

    [ ] Other, Explain

2. Will interviewers or facilitators be used? [X] Yes [ ] No

Please make sure all instruments, instructions, and scripts are submitted with the request.

Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

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TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is requested.

PURPOSE and USE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Briefly describe the targeted group/groups for this collection.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

Form: Provide the title of the information collection form.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group).

Burden in Minutes: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Estimate the annual cost to the Federal government for this collection.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.