Formative Research for Sepsis and Antibiotic Use Campaigns

Generic Information Collection (0920-1154)

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Supporting Statement Part B

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Program Official/Project Officer

Carla Doan, Public Health Advisor

Division of Healthcare Quality Promotion, NCEZID

1600 Clifton Rd, NE, Mailstop A07

770-488-8354

Gon5@cdc.gov

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Section B – Information Collection Procedures

1. Respondent Universe and Sampling Methods

Exhibits 1 and 2 display the expected number of consumer and healthcare provider (HCP) respondents to participate in the sepsis campaign formative research. Exhibits 3 and 4 display the number of respondents to participate in the antibiotic use campaign formative research. A total of 63 participants will be recruited for the sepsis formative research and 60 participants for the antibiotic use formative research. We will conduct focus groups (FGs) with consumers and individual in-depth interviews (IDIs) with HCPs.

Exhibit 1. Number of Consumer Participants for Sepsis Campaign Data Collection

Activity/ Geographic Areas	Urgent Care PAs	Urgent Care NPs	Emergency Dept Triage Nurses	Primary Care Physicians	General Medical Ward Staff, Nursing Home staff, Home Healthcare providers	Total
Consumer Focus Group and PDIS / All U.S. census regions: south census region (18); other census regions (18)	4	5	9	9	9 (n=3 from each group	36

Exhibit 2. Number of HCP Participants for Sepsis Campaign Data Collection

Activity/ Geographic Area	Mothers (age 30-54) with infants (≤1) and aging parents	African American Men with one or more chronic condition	Healthy adults and caregivers ≥65	Total
HCP IDIs and PDIS / All U.S. census regions: south census region (14); other census regions (13)	3 (n=3) • 2 FGs with AA women • 1 FG with white women	3 (n=3)	3 (n=3) • 2 FGs with white women • 1 FG with AA women)	9 FGs (n=27)

Exhibit 3. Number of HCP Participants for Antibiotic Use Campaign Data Collection

Activity/ Geographic Areas	Family HCPs		Emergency/Urgent Care HCPs		Hospitalists	Total
	Family Practitioners	NPs/PAs	ED Attending Physicians	Urgent Care Owner-Physicians	Non-Critical Care Hospitalists	
HCP IDIs and PDIS /All U.S. census regions: south census	5	4	4	5	6	24

region (12); other census regions (12)						

Exhibit 4: Number of Consumer Participants for Antibiotic Use Campaign Data Collection

Activity/ Geographic Areas	Self-Demanders	Caregiver-Demanders	Self-Expectors	Caregiver-Expectors	Total
	White Female Healthy, 21–45 years	White Female Healthy, Child < 5 years, 30-54 years	Hispanic Female, Healthy, 30–45 years	AA Female, Healthy, First-Time Mothers, 30–45 years	
Consumer focus groups and PDIS / All U.S. census regions: south census region (18); other census regions (18)	3 (n=3)	3 (n=3)	3 (n=3)	3 (n=3)	12 (n=36)

The respondent universe and sampling methods are described below for the sepsis and antibiotic use data collection activities.

- **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. Fifty percent of consumers will be sampled from the U.S. south census region—as this region has the highest rates of sepsis and chronic conditions that place individuals at risk of sepsis—and the remainder of consumers will be sampled from various other census regions. 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. Approximately fifty percent of the healthcare professionals will be sampled from the U.S. south census region—as this region has the highest rates of sepsis and chronic conditions that place individuals at risk of sepsis—and the remainder of consumers will be sampled from various other census regions. 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). Half of consumer participants will be recruited from the U.S. south census region—states in which antibiotic prescribing is the highest. The other half of participants will be recruited from all other US census regions. 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. Half of consumer participants will be recruited from the U.S. south census region—states in which antibiotic prescribing is the highest. The other half of participants will be recruited from all other US census regions. 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.

2. Information Collection Procedures

Consumer Focus Groups

Focus groups will be conducted by trained moderators using an online platform, such as Adobe Connect. Structured moderator guides will be used as the data collection tools (see Attachments 11[sepsis] and 19 [AU]). A professional recruiting firm will screen, recruit, and schedule all participants for focus groups; three individuals will participate in each focus group (see Attachments 2-4 [sepsis] and 14-15 [AU]). The recruiting firm will contact participants via telephone and e-mail and distribute/collect the consumer PDIS from eligible participants prior to the focus groups (see Attachments 9 [sepsis] and 17-18 [AU]). Potential participants will be asked for their availability to participate in the focus group. Once a time that works for a sufficient number of participants has been identified, the recruiter will send a calendar invitation and a link to the online session. A note taker will be present during each focus group. Focus groups will be audio taped to serve as a backup to the notes. CDC staff will have the ability to observe all focus groups by logging into the session. Focus groups will last approximately 90 minutes.

At the start of the focus group, the moderator will obtain verbal consent from the participants by reading the informed consent statement aloud and obtaining permission to audio record the focus group (see Attachments 21 [AU] and 23 [sepsis]).

Healthcare Professional IDIs

IDIs will be conducted by trained interviewers using an online meeting platform, such as Adobe Connect. Structured interview guides will be used as the data collection tools (see Attachments 12 [sepsis] and 20 [AU]). A professional recruiting firm will screen, recruit, and schedule all participants for IDIs (see Attachments 5-8 [sepsis] and 13 [AU]). The recruiting firm will contact participants via telephone and e-mail and distribute/collect the HCP PDIS from eligible participants prior to the focus groups (see Attachments 10 [sepsis] and 16 [AU]). Potential participants will be asked for their availability for the IDI. Once a time that works for a sufficient number of participants has been identified, the recruiter will send a calendar invitation and a link to the online session. A note taker will be present during each IDI. IDIs will be audio taped to serve as a backup to the notes. CDC staff will have the ability to observe all IDIs by logging into the session. IDIs will last approximately 60 minutes.

At the start of the IDI, the interviewer will obtain verbal consent from participants by reading the informed consent statement aloud and permission to audio record the IDI from the participant (see Attachments 21 [AU] and 23 [sepsis]).

3. Methods to Maximize Response Rates

A professional recruitment firm will conduct all screening and recruitment of eligible participants. The recruiter will recruit a total of four participants for each consumer focus group to ensure three participants are available; the fourth participant will be dismissed prior to beginning the discussion. All participants will be asked to complete and return the PDIS at least 24 hours prior to their scheduled IDI or focus group. Using online/telephone technology will ensure anonymity to other members of the focus group and allow flexibility in scheduling focus groups and IDIs to accommodate participants' schedules. The focus group and IDI moderator guides were designed with particular focus on open-ended questions to allow participants to provide significant detail and participants will have the option to skip questions they are not comfortable answering. Participants also will be informed that they have the right to end their participation at any time.

4. Test of Procedures or Methods to be Undertaken

The estimate for burden hours is based on previous use of similar data collection instruments developed by the contractor. The average time to complete an instrument that tested the same health campaigns domains, including time for reviewing the verbal consent, instructions, and completing the instrument, were approximately 90 minutes for the focus group instrument and 60 minutes for the IDI instrument. The estimates for burden hours for the consumer and HCP screeners and PDIS are based on pilot tests by the contractor.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data	
Gina Sgro ICF Email: Gina.Sgro@icf.com Phone: (301) 572-0552	Sarah Lattimer Irvin Lattimer Communications Email: Sarah@lattimercommunications.com Phone: (404) 526-9321

Ashani Johnson-Turbes, PhD ICF Email: Ashani.Johnson-Turbes@icf.com Phone: (404) 321-3211	Isadora Brown Lattimer Communications Email: isadora@lattimercommunications.com Phone: (404) 526-9321
Joseph D. Galanek PhD, MPH ICF Email: Joe.Galanek@icf.com Phone: (301) 572-0552	Jennifer Mezzo ICF Email: Jennifer.Mezzo@icf.com Phone: (301) 572-0552