Formative Research for Sepsis and Antibiotic Use Campaigns

Generic Information Collection (0920-1154)

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Supporting Statement Part A

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A. Justification

The goal of formative research for the Sepsis and Antibiotic Use Campaigns is to develop and execute two interrelated communications campaigns to raise awareness and change behavior related to 1) sepsis and 2) antibiotic prescribing and use among select target audiences for each.

A common question among stakeholders of both 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.

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.

Sepsis

- The goal of the formative research is to understand the knowledge, perceptions, and behaviors of consumers and healthcare professionals (HCPs) regarding sepsis and its prevention, including early detection of sepsis and prevention of infections that lead to sepsis.
- Results of the study will be used to inform the development of a national sepsis awareness campaign. Materials to be developed from results include: campaign concepts, messages, and materials to motivate consumers and HCPs to manage infections and be alert to sepsis through early detection of infections and sepsis.
- This qualitative formative research will use stratified, non-probability purposive sampling to recruit consumers for focus groups (FGs) and HCPs for in-depth interviews (IDIs). All consumer and HCP subpopulations will reside in either the South or Midwest across eight (8) states: Alabama, Kansas, North Carolina, South Carolina, Georgia, Maryland, Illinois, and Kentucky.
- The three consumer subpopulations to be studied are: mothers (age 30-54) who are primary caregivers for infants and elderly parents; African American men age ≥65 with one or more chronic condition; and healthy adults and caregivers age ≥65.
- The four HCP types that will be studied are: nurse practitioners and physician's assistants who work at urgent care clinics; primary care physicians; emergency department triage nurses; and general medical ward staff, nursing home staff, and home healthcare professionals.
- Data analysis: Qualitative data will be analyzed using a notes-based analysis that will identify relevant, common, and cross-cutting themes within FG and IDI responses in order to summarize consumer and HCP participants' knowledge, perceptions, and behaviors regarding sepsis and its prevention. Analysis will also consist of summarizing frequencies of pre-discussion information sheets (PDIS).

Antibiotic Use

- The goal of the formative research is to better understand the knowledge, perceptions, and behaviors of consumers and healthcare professionals (HCPs) around antibiotic use and antibiotic prescribing, antibiotic resistance, and adverse drug events. In addition, the study will gather feedback on initial message sets for the campaign.
- Intended use of resulting data: Results of the study will be used to inform the development of campaign concepts, messages, and materials to motivate consumer audiences to use, and HCPs to prescribe, antibiotics only when needed.
- Methods: The study will use stratified, non-probability, purposive sampling to recruit consumers and HCPs for qualitative focus groups and in-depth interviews [IDIs], respectively. IDIs and focus groups will be conducted via telephone and online.
- Subpopulations to be studied: Subpopulations to be studied include consumers who demand and expect antibiotics for themselves or their families and HCPs who exhibit high rates of inappropriate prescribing.
- Data analysis: Data will be analyzed using qualitative methods, including identifying key common themes and summarizing frequencies, and quantitative methods, such as descriptive statistics.

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, Formative Research for the Sepsis Campaign and Antibiotic Use Campaign (contract number 200-2016-F-90343). 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 (PDIS).

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C.241) (Attachment 1).

Sepsis

Sepsis is a complication caused by the body's life-threatening response to an infection (CDC, n.d.; NIH, 2016). It occurs when immune chemicals are released into the blood to combat the infection and trigger an inflammatory response. This leads to blood clots and leaky vessels, and ultimately impaired blood flow that can lead to tissue damage and organ failure. If sepsis progresses to septic shock, blood pressure drops dramatically, and there are risks of multiple organ failure that lead to death. Each year in the United States, more than a million people are infected with sepsis and 80 percent of sepsis cases begin outside of the hospital (NIH, 2016; CDC, 2016). Although an estimated 28–50 percent of patients with sepsis ultimately die, consumers have limited or no knowledge and awareness of sepsis (Shelton, Stanik-Hutt, Kane & Jones, 2016; Sepsis Alliance, n.d.). Fewer than half of individuals in the U.S. surveyed had heard of this deadly disease (Sepsis Alliance, n.d.). Additionally, healthcare professionals who are most likely to encounter patients at risk of sepsis or septic patients may not be aware of the signs of sepsis and treatments for sepsis, due to challenges in identifying and diagnosing sepsis (Baez, Hanudel, Perez, Giraldez & Wilcox, 2013). This is primarily due to the similarity of symptoms

of sepsis with other infections. Healthcare professionals may also not have in-depth knowledge of gold standard sepsis treatment protocols (Shelton, Stanik-Hutt, Kane & Jones, 2016; Sepsis Alliance, n.d.). Infections are a common cause of sepsis, and consequently infection prevention is critical in decreasing the risks of sepsis.

Particular subpopulations are at increased risk of sepsis and death from sepsis. Individuals over the age of 65 are at risk of sepsis and have higher death rates from sepsis due to the rise of implantable device usage, drug resistant bacteria, and immunosuppression (Vanzant & Schmelzer, 2011). Infants are at risk for sepsis due to common infections (e.g. Enterococcus spp.) that may lead to sepsis (Novosad, 2016). Men and individuals with chronic conditions are also at increased risk of sepsis (Barnato, Alexander, Linde-Zwirble & Angus, 2008). In particular, chronic conditions that weaken the immune system place individuals at higher risk of sepsis. Evidence also suggests that the presence of chronic comorbid conditions among African American (AA) men is a driver for disparities in sepsis between AA populations and other racial/ethnic groups (Barnato, Alexander, Linde-Zwirble & Angus, 2008).

Due to lack of knowledge regarding sepsis, patients may present at outpatient settings rather than go directly to emergency departments if symptoms of sepsis are present (Shelton, Stanik-Hutt, Kane & Jones, 2016). Consequently, emergency department staff and outpatient healthcare professionals are the front line staff most likely to encounter patients with symptoms of sepsis or septic patients (Shelton, Stanik-Hutt, Kane & Jones, 2016; Baez, Hanudel, Perez, Giraldez & Wilcox, 2013). Elderly residents in long-term care facilities are more likely to develop sepsis (Mihaljevic & Howard, 2016). Therefore, HCPs that work with long-term care patients or on hospital wards need to be more aware of sepsis.

Given the high rates of sepsis mortality, and the low knowledge and awareness among consumers and HCPs regarding sepsis and its prevention, CDC is proposing to launch a national sepsis campaign. This campaign's goal is to raise awareness of sepsis and its prevention among consumers who are most at risk of sepsis and HCPs most likely to encounter sepsis among the patients they treat. Based on the results of a secondary research literature review, three consumer campaign target audiences were identified: mothers (age 30-54) with infants ≤1 year old and who are caregivers to elderly parents; African American men with one or more chronic condition; and healthy adults age ≥ 65 who are also caregivers. Four HCP campaign target audiences for this national sepsis campaign were also identified: physician assistants and nurse practitioners who work at urgent care clinics; outpatient primary care physicians; emergency department triage nurses; and general hospital medical ward staff, nursing home staff, and home healthcare professionals.

The sepsis campaign's goals are to:

- Raise awareness and knowledge of sepsis among consumers and HCPs to prompt sepsis prevention and early recognition.
- Decrease cases of sepsis and deaths resulting from sepsis.
- Support the CDC research agenda of preventing sepsis, sepsis early recognition, and enhancing sepsis prevention strategies to decrease incidence, prevalence, and mortality attributable to sepsis.

Antibiotic Use

Each year in the United States, at least 2 million people become infected with antibiotic-resistant bacteria and at least 23,000 of these individuals die as a result of their infections (CDC, 2013). Antibiotic resistance—the ability of microbes to resist the effects of an antibiotic—is a specific type of drug resistance caused in part by improper antibiotic prescribing by HCPs and the overuse of antibiotics by consumers. Antibiotics are among the most commonly prescribed medications, yet at least 30 percent are unnecessary, and even more are likely to be inappropriate when antibiotics are prescribed for the wrong drug, dose, or duration. Many bacteria have now become resistant to more than one type or class of antibiotic. Widespread overprescribing and inappropriate use of antibiotics is fueling resistance that compromises the effectiveness of these drugs in the future.

Overuse of antibiotics also unnecessarily increases the problems of side effects caused by *Clostridium difficile (C. diff)*, a bacteria that causes severe and sometimes deadly diarrhea causing at least 15,000 deaths every year in the United States (CDC, n.d.).

In 2003, CDC launched its Get Smart campaign as an effort to improve antibiotic prescribing and use in primary care settings. The campaign used a two-pronged approach of educating both healthcare providers (HCPs) and parents about appropriate antibiotic use. In 2010, the program expanded to include educational materials for inpatient medical settings, such as hospitals and nursing homes.

Still, antibiotic overuse continues to be a problem. While evidence suggests that prescribing rates for children decreased 33 percent over the last two decades, a recent study found that antibiotic prescribing rates for children under 2 years of age (1287 prescriptions/1000 persons) were the highest of all groups and that individuals aged 65 years and older were prescribed antibiotics at the highest rate of all adults (1048/1000) (Hicks et. al, 2015). Women (990/1000) were prescribed antibiotics at a higher rate than men (672/1000). Another study found that 41 percent of Hispanics and more than 25 percent of all patients reported expecting to receive an antibiotic for cold symptoms (Francois-Watkins et. al, 2015). In addition Hispanic consumers often obtain antibiotics without a prescription (Céspedes & Larson, 2006) and antibiotics are available over the counter in some Hispanic communities in the U.S. (Larson, Lin, & Gomez-Duarte, 2003; Coenen, Michiels, Renard, Denekens, & Van Royen, 2006).

Overall antibiotic prescribing is highest in the South census region of the country (931/1000). Within outpatient settings prescribing rates are highest among family practitioners who account for 25 percent of all antibiotic courses prescribed, followed by nurse practitioners (NPs)/physician assistants (PAs) (14 percent combined) and emergency department (ED) physicians (5 percent) (Hicks et. al., 2015). Another recent study found that from 2006–2011, antibiotics were more frequently prescribed during ambulatory visits to NPs/PAs as compared to physician-only visits (Sanchez, Hersh, Shapiro, Cawley, & Hicks, 2016). While many healthcare professionals agree that antibiotics are overprescribed, they often do not see their own prescribing habits as contributing to the problem. Findings from a study of ED physicians found that 76 percent of respondents agreed that antibiotics were overused in the ED, but half did not believe they personally overprescribed antibiotics (May et. al, 2015). Observational studies have found that urgent care physicians report prescribing antibiotics due to concerns about patient satisfaction and retention. Studies have indicated that 30–50 percent of all antibiotics prescribed

in hospitals are unnecessary or inappropriate (Hecker, Aron, Patel, Lehmann, & Donskey, 2003; Dellit, Owens, & McGowan, 2007).

Given these trends, the Get Smart program has an urgent and critical need to better educate antibiotic prescribers and users. CDC seeks to rebrand and expand the Get Smart campaign to ensure that HCPs and consumers understand problems associated with poor antibiotic prescribing and use and to know how to improve their own practices. The goals of the rebranded campaign are to:

- Raise the public consciousness about antibiotic stewardship.
- Make antibiotic prescribing and use messages on par with other "greater good" societal movements such as recycling/sustainability and clean eating.
- Improve prescribing habits of healthcare providers.
- Increase parents' understanding of optimal antibiotic use and administration.
- Improve understanding of appropriate antibiotic use and consequences of misuse.

2. Purpose and Use of the Information

The information collected will be used as the basis for developing effective health communication strategies (e.g., communication channels, materials, messages, and concepts) for the national sepsis and antibiotic use campaigns.

Exhibit 1 provides an overview of the primary research questions for each campaign.

Exhibit 1. Research Questions

Sepsis	
HCPs	**Consumers**
1. What are HCPs general awareness about sepsis? 2. What do HCPs know about sepsis? a. What are perceptions (beliefs or general thoughts) about sepsis? (e.g., the severity of sepsis) 3. Do HCPs believe their patients are at risk of sepsis? a. What patient conditions, demographics, clinical signs and symptoms identify risks for sepsis? 4. Do HCPs believe that preventing infections, being alert to signs and symptoms of sepsis, and treating sepsis quickly will reduce sepsis and deaths from sepsis? 5. How do HCPs seek information about sepsis? a. What are HCPs preferred ways (message, channel, and source) to obtain information about sepsis?	1. What are consumers' general awareness of sepsis? 2. What do consumers know about sepsis? a. What are perceptions (beliefs or general thoughts) about sepsis (e.g. the severity of sepsis?) 3. Do consumers believe they or their family are at risk of sepsis? a. Do consumers believe that undetected, untreated, infections can lead to sepsis? 4. Do consumers believe that knowledge and awareness of sepsis can reduce risk of sepsis infection and death from sepsis? a. What are facilitators and barriers to implementing knowledge? 5. How do consumers seek information about sepsis? a. What are consumers preferred ways (message, channel, and

6. What are HCPs reactions to initial sepsis message sets?	source) to obtain information about sepsis? 6. What are consumers' reactions to initial sepsis message sets?
Antibiotic Use	
HCPs	**Consumers**
1. What is HCPs' general awareness about inappropriate antibiotic prescribing? 2. What are HCPs' perceptions about the severity of antibiotic resistance? 3. What are HCPs perceptions about inappropriate antibiotic prescribing and adverse drug events? 4. How do HCPs seek information about appropriate antibiotic prescribing? 5. What are HCPs' reactions to initial antibiotic prescribing message sets?	1. What is consumers' general awareness about appropriate antibiotic use? 2. What is consumer knowledge about antibiotic resistance? 3. What are consumers' perceptions of adverse drug events? 4. How do consumers seek information about appropriate antibiotic use? 5. What are consumers' reactions to initial antibiotic use message sets?

Consumers and HCPs will be screened for eligibility prior to recruitment for the focus groups and IDIs. All respondents will complete pre-discussion information surveys (PDIS) to gather background information prior to participating in focus groups and IDIs. Exhibit 2 provides an overview of the data collection activities.

Exhibit 2. Data Collection Activities

Sepsis	
Consumer Instruments	
Sepsis Consumer Recruitment Screener	The consumer recruitment screener will be used to determine eligibility and recruit appropriate consumers for focus groups. There are three versions of the screener for each consumer group: 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. All versions request demographics, inclusion criteria and willingness to participate in focus groups. The screener will be administered by telephone by a professional recruiting firm and takes 5 minutes to complete. See Attachments 2-4.
Sepsis Consumer PDIS	The consumer PDIS is a self-administered survey that collects demographic information; information regarding health seeking behaviors; most commonly seen HCP; and preferred sources of information on sepsis, infections, and managing chronic conditions. The consumer PDIS will be completed by consumer participants prior to participating in focus groups and takes 5 minutes to complete. See Attachment 9.
Sepsis Consumer Focus Group Moderato	The consumer focus groups will gather information about consumer attitudes, awareness and knowledge about sepsis and infections; perceptions of risk of sepsis and infections that lead to sepsis; perceptions of self-efficacy and efficacy of communicating with HCPs regarding sepsis, preventing infections, and managing chronic

r Guide	conditions; and perceptions and response to initial consumer target audience message sets and calls to action for a national sepsis awareness campaign. The consumer focus groups will be conducted using teleconference technology online and by telephone (using Adobe Connect) and will take 90 minutes to complete. Respondents include 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. See Attachment 11.
HCP Instruments	
Sepsis HCP Screener	The HCP recruitment screener will be used to determine eligibility and recruit HCPs for participation in interviews: 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. The screener requests information on HCP role, zip code, and willingness to participate in an interview, as well as contact information. The screener will be administered over the telephone by a professional recruiting firm and takes 5 minutes to complete. See Attachments 5-8.
Sepsis HCP Pre-Discussion Information Survey (PDIS)	The HCP PDIS is a self-administered survey that collects demographic information and HCP participant preferences for receiving information on sepsis, and preferred channels to receive patient education information on sepsis and infection. The HCP PDIS will be completed by HCPs prior to participating in interviews and takes 5 minutes to complete. See Attachment 10.
Sepsis HCP IDI Guide	The HCP interview will gather information on HCP attitudes, awareness and knowledge about sepsis; perception of patient risk or risk of not accurately diagnosing sepsis; , perceptions of self-efficacy and efficacy of identifying sepsis and educating patients regarding sepsis and infections that lead to sepsis; influencers (e.g. colleagues) on sepsis information and sepsis prevention; and perceptions and response to initial HCP target audience message sets and calls to action for a national sepsis awareness campaign. The HCP interviews will be conducted using online teleconferencing technology and by telephone (using Adobe Connect) and will take approximately 60 minutes to complete. Respondents will include 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. See Attachment 12.
Antibiotic Use (AU)	
HCP Instruments	
AU HCP Screener	The HCP recruitment screener will be used to determine eligibility and recruit appropriate HCPs (family practitioners, NPs, PAs, emergency department attending physicians, urgent care owner-physicians, and hospitalists) for participation in interviews. The screener requests information on HCP role, work zip code, and willingness to participate

	in an interview, as well as contact information. The screener will be administered over the telephone by a professional recruiting firm and takes 5 minutes to complete. See Attachment 13.
AU HCP Pre-Discussion Information Survey (PDIS)	The HCP PDIS is a self-administered survey that requests background information on HCP practices and resources. Data include demographics, practices related to discussing antibiotic-related topics with patients, and antibiotic-related resources used and desired. The HCP PDIS will be distributed by a professional recruiting firm and completed by HCPs (family practitioners, NPs, PAs, emergency department attending physicians, urgent care owner-physicians, and hospitalists) prior to participating in IDIs. The HCP PDIS takes 5 minutes to complete. See Attachment 16.
AU HCP IDI Guide	The HCP interview will gather information on HCP knowledge, beliefs, and perceptions about antibiotic prescribing, antibiotic resistance, and adverse drug events; personal prescribing approach; consumer profiles; influencers, facilitators, and barriers to antibiotic prescribing; and feedback on initial campaign informational messages and calls to action. Respondents will include family practitioners, NPs/PAs, emergency department attending physicians, urgent care owner-physicians, and hospitalists. The HCP interviews will be conducted online (using Adobe Connect) and by telephone and will take 45-60 minutes to complete. See Attachment 20.
Consumer Instruments	
AU Consumer Recruitment AU Screener (Caregiver and Self Versions)	The consumer recruitment screener will be used to determine eligibility and recruit appropriate consumers for focus groups. There are two versions of the screener: (1) self-expector and self-demander and (2) caregiver-expector and caregiver-demander. Both versions request demographics, behaviors related to antibiotic seeking, and willingness to participate in focus groups. The caregiver version will be used to screen and parents for focus groups. The screener will be administered by telephone by a professional recruiting firm and takes 5 minutes to complete. See Attachment 14-15.
AU Consumer PDIS (Caregiver and Self Versions)	The consumer PDIS is a self-administered survey that provides background information on consumer antibiotic use. There are two versions of the consumer PDIS: (1) self-expector and self-demander and (2) caregiver-expector and caregiver-demander. Data include demographics, knowledge and beliefs about antibiotics, healthcare seeking behaviors, and experience with adverse drug events and antibiotic resistant infections. The consumer PDIS will be distributed by a professional recruiting firm to consumers and collected prior to participating in focus groups. The consumer PDIS takes 5 minutes to complete. See Attachment 17-18.
AU Consumer Focus Group Moderator Guide	The consumer focus groups will gather information about consumer knowledge, beliefs, and perceptions about antibiotics and antibiotic resistance; personal antibiotic use; perceived susceptibility to antibiotic side effects and antibiotic-resistant infections; behaviors related to antibiotic seeking; self-efficacy to delay antibiotic use; and feedback on initial campaign information messages and calls to action. The consumer focus groups will be conducted online (using

	Adobe Connect) and by telephone and will take 90 minutes to complete. See Attachment 19.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via online focus groups and IDIs via Adobe Connect software and telephone. A note taker will be present to take notes for each focus group and IDIs; all focus groups and IDI webinars will be recorded to ensure participant responses are captured accurately. Items on the focus group moderators, IDI guides, and PDIS 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

Sepsis

To date, there has been some research conducted that has attempted to identify the general public's awareness of sepsis. The cross-sectional survey research identified a lack of awareness across general population audiences and was not used to inform the creation of a national sepsis campaign. This survey research was not conducted to assess the attitudes, knowledge, and perspectives of specific members of the general public who may be at more risk of contracting sepsis (e.g. African American men) or among HCPs. The Society of Critical Care Medicine's Surviving Sepsis Campaign was initiated to inform HCPs of sepsis treatment protocols. Previous research on the Surviving Sepsis Campaign has focused on whether HCPs are aware of the recommended sepsis treatment guidelines and whether these guidelines are followed (Shelton, Stanik-Hutt, Kane & Jones, 2016). Research on the Surviving Sepsis Campaign did not focus on testing campaign materials aimed at consumers and HCPs most at risk or most likely to encounter sepsis in their clinical settings. Additionally, the Surviving Sepsis Campaign research was solely focused on treatment outcomes (e.g. initiation of treatment) rather than prevention (Levy et. al., 2014).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

Antibiotic Use

Get Smart is the only national antibiotic use campaign in the United States. CDC previously conducted research for the Get Smart campaign to improve antibiotic prescribing and use in primary care settings. In 2010 the program expanded to include educational materials for inpatient medical settings, such as hospitals and nursing homes. This information collection will contribute information necessary to rebrand, update, and expand the current Get Smart campaign to address recent trends in antibiotic prescribing and use and is not available elsewhere.

5. Impact on Small Businesses or Other Small Entities

Some interviews will involve HCPs from physician's offices, nursing homes, and urgent care centers, which may qualify as small entities. However, these activities will not have a significant impact on the agencies or organizations, as HCPs will participate in interviews outside of working hours. Similarly, ICF anticipates consumer participation in focus groups will be conducted at times that would not impact their employment in a small business or small entity (if applicable). We will provide flexibility in scheduling IDIs and focus groups to minimize the potential impact on small businesses and other small entities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection request.

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

This information collection request does not require publication of a 60-day notice in the *Federal Register*.

CDC has been working with a contractor on the design, instrumentation, and initial message sets for this study. Several CDC experts provided input on target audiences, instrument content, and initial message sets developed by the contractor.

Individuals Consulted Outside the Agency	
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9. Explanation of Any Payment or Gift to Respondents

Focus group and IDI participants will receive a monetary gift of appreciation for their participation. It is assumed that many of these participants will 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).

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

The CDC Human Subjects Advisor has determined that the Privacy Act does not apply to this information collection. IDIs and focus groups will be moderated by the contractors' trained facilitators, with recruitment and data collection support from a professional recruitment firm. All IDIs and focus groups will be conducted online and by telephone. CDC will not have direct contact with participants or access to any personally identifying information (PII) about the participants and PII will not be linked to responses. CDC staff will have the ability to observe the IDIs and focus groups via a password-protected web stream.

PII (e.g., name, address, e-mail address, and telephone number) will be used by the professional recruitment firm to make contact with and send reminders to respondents. This information will be kept separate from any information collected in the IDIs and focus groups (i.e., participant responses will not be connected to any identifiable information). Screeners will be kept in a locked file cabinet at the recruitment firm or in password-protected computer files. The recruiter will only provide a summary of participant information on the recruitment grids, which will be stripped of PII. No PII will be transmitted to CDC. The professional recruiting firms will be instructed to destroy their project-related records upon completion of the study.

All findings will be reported in the aggregate only. The contractor will take precautions to secure participants' identifiable information (see Attachment 22 [AU] and 24 [sepsis]). Participants will use only first names or pseudonyms during the discussions. Notes will not include participants' names. Audio files of the groups will be stored by the contractor on a secure share drive and password-protected computers. Reports will not include PII and will be stored on a secure share drive and password-protected computers.

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

Institutional Review Board (IRB)

To ensure the privacy of data compiled for the protection of human subjects, the data collection protocol and instruments were reviewed and approved through the contractor's institutional review board (IRB) prior to the collection of covered or protected data (Attachments 25a and 25b). The contractor's IRB holds a Federal wide Assurance (FWA00000845; Expiration, April 13, 2019) from the HHS Office for Human Research Protections (OHRP). This review ensures compliance with the spirit and letter of HHS regulations governing such projects.

Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. Questions asked about prevention of infections or managing chronic conditions (sepsis) and personal antibiotic prescribing or use habits (antibiotic use) could be considered sensitive, although these items would not generally be considered highly sensitive. 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 (Attachment 21 [AU] and 23 [sepsis]). To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards.

12. Estimates of Annualized Burden Hours and Costs

Table 1 below describes the burden and costs associated with the information collection. Estimates of average burden per response for screeners and PDIS were derived from previously used screener instrument and PDIS estimations for previous health campaign formative research.

The burden estimates for the HCP IDI guide and the consumer focus group guide include the burden to review the informed consent.

Table 1. Annualized Burden

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	36	1	5/60	3

	for A-A Men				
	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

Table 2 below describes the cost burden associated with this information collection. It was calculated based on the hourly wage rates for appropriate occupational categories from the Bureau of Labor Statistics May 2015 National Occupational Employment and Wage Estimates (BLS, 2015) and from the U.S. Department of Labor Federal Minimum Wage Standards.

The hourly wage rates for the Sepsis PDIS, Sepsis IDI Moderator Guide, AU PDIS, and AU IDI Moderator guide were calculated by averaging the hourly wages of the different categories of healthcare providers that will be participating.

Table 2

Type of	**Form Name**	**Total Burden**	**Hourly Wage**	**Total**

Respondent		Hours	Rate	Respondent Costs
Consumers	Sepsis Screener for mothers	3	$7.50	$22.50
	Sepsis Screener for Healthy Adults	3	$7.50	$22.50
	Sepsis Screener for A-A Men	3	$7.50	$22.50
	Sepsis PDIS	3	$7.50	$22.50
	Sepsis FG Moderator Guide	41	$7.50	$307.50
	AU Screener SD-SE	6	$7.50	$45.00
	AU Screener CD-CE	6	$7.50	$45.00
	AU PDIS SD-SE PDIS	2	$7.50	$15.00
	AU PDIS CD-CE PDIS	2	$7.50	$15.00
	AU FG Moderator Guide	54	$7.50	$405.00
Healthcare Providers	Sepsis Screener for ED Triage Nurse	3	$95.05	$285.15
	Sepsis Screener for NP or PA	3	$48.21	$144.63
	Sepsis Screener for PCP	3	$92.36	$277.08
	Sepsis Screener for Gen Med Ward, NH, and Home HC staff	3	$19.56	$58.68
	Sepsis PDIS	3	$48.93	$146.79
	Sepsis IDI Moderator Guide	36	$48.93	$1,761.48
	AU Screener	8	$94.38	$755.04
	AU PDIS	2	$78.99	$157.98
	AU IDI Moderator Guide	24	$78.99	$1,895.76
Total				$6,405.09

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 total annualized cost to the government is $508,682. The breakdown of how that estimate was reached is below.

Governmental costs for this project include personnel costs for federal staff involved in the plan and data collection design, development of data collection instruments and OMB materials, data collection and analysis, and reporting. This level of effort includes approximately 10 percent of a GS-14 behavioral scientist's time for each campaign assuming a $97,400 annual salary (total $19,480). There are no equipment or overhead costs; however, a contractor is being used to

support the development of the instruments, data collection, and data analysis. The contract amount for the formative research is $244,601 for each campaign for a total of $489,202. Thus, the total cost to the government is $508,682.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be tabulated and a report will be developed. Qualitative findings may be published in a peer-reviewed journal article.

Project Time Schedule

Activity	Timeframe
Recruitment	Within 1 week of OMB approval
Data Collection	1-2 months after OMB approval
Analysis	2-3 months after OMB approval
Submit Report	4 months after OMB approval

Tabulation

A notes- and tape-based method will be used to conduct a qualitative thematic content analysis for both IDIs and FGs. Results of this analysis will be used in reports, conference proceedings, publications, or other dissemination activities. Utilizing both of these techniques will increase rigor of analysis and decrease risk of errors in capturing participants' responses and translating data into findings. An ICF team member trained in qualitative data collection will take notes during each FG and IDI and will capture key discussion points and responses to specific topic areas reflected in each moderator guide. After each FG and IDI, the note takers will debrief their high level summary findings with moderator and fill in any gaps or clarify statements from participants. All IDIs and FG will be audio recorded. This will enable note takers to review audio from FGs and IDIs to clarify any statements, fill in gaps within notes, and verify quotations to ensure accurate capturing of participants' statements and perspectives. For FGs, note takers will further distinguish between any areas of disagreement between participants, and also identify areas of consensus.

After each IDI and FG debriefing with the moderator, the ICF note taker will prepare an electronic summary of each IDI and FG. This summary's content will align with the moderator guides' research framework constructs and corresponding research questions to ensure that notes taken during the FG and IDI are linked to and answer each targeted data collection topic area (see Exhibit 1). After this debriefing and review of audio recording (if necessary), IDI and FG note takers will transfer their notes into an excel spreadsheet that will be dedicated specifically to each consumer and HCP target audience. This spreadsheet will have separate worksheets for each research question/research framework construct. This process will enable note takers to transfer content from multiple note based summaries into one document. This will facilitate rapid review of multiple respondents' perspectives, and will also include key quotations (as appropriate) to capture responses and summaries for each research question and FG and IDI topic area (Exhibit 1).

Each target audience spreadsheet will then be reviewed iteratively by ICF analysts using a thematic content analytic approach. ICF will utilize an inductive approach to coding, which is appropriate for exploratory qualitative research design. Codes will emerge from review of summaries of participant statements and perspectives. Discrepancies in coding and analysis will be resolved through this team-based approach and revisiting audio files to clarify participant statements and perspectives. These approaches will further increase rigor of analysis. After initial coding, ICF will create a qualitative codebook to guide analysis and ensure consistent coding across target audience summaries. Codes will be linked to target audience summary statements and quotations reflective of each research questions and topic areas. This will identify patterns and trends in participant responses and facilitate summaries of target audience responses. High-level summaries will be created to identify trends and patterns in all target audience responses and perspectives to inform the creation of testable health campaign messages.

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

The expiration date of OMB approval will be displayed on all information collection instruments.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320

19. References

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