# Assessment for the *Get Ahead of Sepsis* Consumer and Healthcare Professional Campaign

Request for OMB approval of a New Information Collection: OMB 0920-1384

Friday, June 16, 2023

**Supporting Statement A** 

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• **Goal of the study:** To assess if the *Get Ahead of Sepsis (GAOS)* pilot media campaign, along with partner outreach over a 2–3-month period in select markets, successfully reached intended consumer and healthcare professional (HCP) audiences and influenced their awareness, knowledge, and behavior related to early recognition and timely treatment of sepsis, and prevention of infections that can lead to sepsis.

• **Intended use of the resulting data:** The information will be used to inform future refinement and implementation of the *GAOS* pilot campaign (materials and tactics). The CDC will also use this information to inform resource needs for future *GAOS* campaign activities.

• **Methods to be used to collect data:** Individuals who have opted to be contacted for surveys (survey panels) will be screened for eligibility based on the inclusion/exclusion criteria for participation. Qualified participants who sign a consent form will be given access to an online survey and the data collected will be de-identified before proceeding with data sharing and analysis.

• **The subpopulation to be studied:** Consumer audiences include: (1) Cancer patients and their caregivers; (2) Patients who survived severe COVID-19 or sepsis and their caregivers; (3) Parents of children 12 and younger; (4) Adults who care for a family member age 65+; (5) Men aged 65+ with one or more chronic conditions; and (6) Healthy adults 65+. HCP audiences include: (1) Emergency Medical Services (EMS) personnel; (2) Nurse practitioners (NPs) and physician assistants (PAs) who work at urgent care clinics; (3) Emergency department triage nurses; (4) General medical ward staff; (5) Primary care physicians; (6) Long-Term Care (LTC) nurses; and (7) LTC medical technicians and sitters.

• **How data will be analyzed:** The data will be analyzed using the Statistical Package for the Social Sciences (SPSS) to determine changes in awareness, knowledge, and behavior between the two independent groups (pre versus post campaign) and between exposed versus unexposed to the *GAOS* media campaign and partner outreach.

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#### 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) requests a three-year approval for a new information collection titled "Assessment of the *Get Ahead of Sepsis (GAOS)*" Consumer and Healthcare Professional Campaign." This one-time data collection will assess the reach and appeal of the *Get Ahead of Sepsis (GAOS)* campaign messaging and partner outreach in select markets and examine differences in sepsis knowledge, awareness, beliefs, and behavioral intentions among consumer and healthcare professional (HCP) audiences who have and have not been exposed to the *GAOS* messaging and partner outreach. The data collection activities proposed in this new information collection will allow CDC to capture critical information needed to inform refinement and implementation of the *GAOS* campaign's materials and tactics.

#### Background

Sepsis is a life threating emergency, and it is the body's overactive and toxic response to an infection. Each year 1.7 million adults in the U.S. develop sepsis, with 270,000 fatalities (CDC,2022). Sepsis is the leading cause of death in hospitals and one out of three hospital fatalities are due to sepsis infection (CDC, 2022; Liu et al., 2014; Rhee et al., 2017; *Sepsis a Leading Cause of Death in U.S. Hospitals but Many Deaths May Not Be Preventable*, n.d.; "What Is Sepsis," n.d.). Sepsis management in U.S. hospitals is the highest when compared to inpatient cost for all other medical conditions (Paoli et al., 2018). Annual costs are estimated to be over \$62 billion (Buchman et al., 2020; Martin et al., 2016).

Bacterial infections cause most cases of sepsis. Sepsis can also be a result of other infections, including viral infections, such as COVID-19 or influenza. Many patients who require hospitalization for COVID-19 meet the definition of sepsis, such as those who require assistance with breathing (CDC, 2021b).

In media and public health campaigns, antimicrobial resistance and sepsis are rarely presented together which does not make their linkage apparent (Fitzpatrick et al., 2019). It has been concluded that sepsis and antimicrobial stewardship should not be discussed in isolation. Surprisingly, 24 percent of adults in the U.S. have never heard of sepsis, so this presents a unique opportunity for future messaging campaigns (*Sepsis Information Guide - Sepsis Fact Sheet*, 2020).

Public education is critical to save lives since, for many patients, sepsis develops from an infection that begins outside the hospital. The goals of the *GAOS* national educational campaign are to prevent and reduce infections that lead to sepsis, and to optimize healthcare quality and patient safety by raising awareness, knowledge, and motivating behavior change related to sepsis prevention, early recognition, and appropriate treatment among consumer and HCP audiences (CDC, 2021a). In addition, the *GAOS* campaign aligns with antibiotic stewardship efforts by emphasizing the importance of rapid appropriate antibiotic treatment when sepsis is suspected (Dante & Epstein, 2018).

This information collection emphasizes the importance of early recognition and timely treatment of sepsis, as well as the importance of preventing infections that could lead to sepsis. CDC is authorized to

conduct these activities by the Public Health Service Act (42 U.S.C. 242), Section 301(a) (Attachment A).

### 2. Purpose and Use of Information Collection

The purpose of this new information collection (study) is to determine if the *GAOS* campaign pilot assessment intervention efforts, including a large-scale paid media buy and partner promotion over a 2–3-month period in New York, Illinois, and Louisiana, successfully reached intended consumer and HCP audiences and influenced their awareness, knowledge, and behavior related to early recognition and timely treatment of sepsis, and prevention of infections that can lead to sepsis.

Consumer audiences are defined as individuals who have a higher risk for developing infections that can lead to sepsis, including: (1) Cancer patients and their caregivers; (2) Patients who survived severe COVID-19 or sepsis and their caregivers; (3) Parents of children 12 and younger; (4) Adults who care for a family member age 65+; (5) Men aged 65+ with one or more chronic conditions; and (6) Healthy adults 65+. HCP audiences are defined as healthcare professionals who play a role in diagnosing and treating sepsis, including: (1) Emergency Medical Services personnel; (2) Nurse practitioners and physician assistants who work at urgent care clinics; (3) Emergency department triage nurses; (4) General medical ward staff; (5) Primary care physicians; (6) Long-Term Care (LTC) nurses; and (7) LTC medical technicians and sitters.

Data from this study will provide insights into the effectiveness of the *GAOS* campaign efforts. Without this information, CDC DHQP will not know if the *GAOS* pilot campaign is effectively reaching and educating the intended audiences nor how to refine or refresh the campaigns messaging to improve clarity, receptivity, relevance, and effectiveness.

CDC will use the information obtained from this study in three primary ways: (1) to inform future refinement and implementation of the *GAOS* campaign (materials and tactics); (2) to inform CDC and its partners and stakeholders who seek to combat sepsis about the potential effects of campaign messages among the intended audiences; and (3) to inform resource needs for future *GAOS* campaign act activities.

### Overview of the data collection procedures

CDC has contracted with CATMEDIA, a program management, training, and creative services company, to design and implement the study. The study design was informed by key foundational activities, including a review of the literature and existing *GAOS* materials and resources, the development of two logic models (consumer and HCP), an assessment framework, and guidance from CATMEDIA research experts and CDC DHQP sepsis subject matter experts, researchers, and program leaders.

A monitoring and evaluation plan, which includes evaluation questions and sub-questions that map to the two logic models, along with indicators that will be used to measure results, was developed to inform data collection, analysis, and reporting. Four survey instruments, namely the consumer surveys (pre-and-post campaign) and the HCP surveys (pre-and-post campaign), were developed to collect data from participants.

The overarching evaluation questions that will guide the study are:

- What are the extent and magnitude of *GAOS* campaign pilot assessment reach among the intended audiences?
- What are the effects of *GAOS* campaign pilot assessment on awareness of sepsis among the intended audiences?
- What impact did *GAOS* campaign pilot assessment have on the intended audiences' knowledge, attitudes, beliefs, and behavior about sepsis?

CATMEDIA will subcontract with an online survey panel vendor (hereafter called vendor) to collect data from a sample of consumer (Table 1) and HCP audiences (Table 2) in three priority markets: New York, Illinois, and Louisiana. The priority markets are based on media buy, budgeting, the presence of urban and rural populations across the recommended markets, and the feasibility of attaining the number of participants needed in this assessment.

The vendor will recruit individuals who match the intended audiences using their proprietary research panels. Individuals who consent and are deemed eligible to participate will be invited to participate in an online survey. The survey will be available in English only. Data will be collected from respondents in each audience group at two different points in time— pre-campaign and post-campaign —using different participants in each time point (i.e., these are two independent groups).

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Table 1. (	JAOS Consumei	Audiences	and Select Markets	

Consumer audiences who have a higher risk for developing infections that can lead to sepsis	New York (Northeast)	Illinois (Midwest)	Louisiana (Southeast)
Cancer patients and their caregivers			
	Х	Х	Х
Patients who survived severe COVID-19 or sepsis and their caregivers	Х	Х	Х
Parents of children 12 and younger	Х	Х	Х
Adults who care for a family member age 65+	Х	Х	Х
Men aged 65+ with one or more chronic conditions	Х	Х	Х
Healthy adults 65+	Х	Х	Х

HCP audiences who play a role in diagnosing and treating sepsis	New York (Northeast)	Illinois (Midwest)	Louisiana (Southeast)
Emergency Medical Services personnel	Х	Х	Х
Nurse practitioners and Physician assistants who work at urgent care clinics	Х	х	Х
Emergency department triage nurses	Х	Х	Х
General medical ward staff	Х	Х	Х
Primary care physicians	Х	Х	Х
Long-Term care TC) nurses	Х	Х	Х
LTC medical technicians and sitters	Х	Х	Х

Table 2. GAOS HCP A	udiences and Select Markets
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Following the pre-campaign data collection, CDC will launch the *GAOS* pilot media campaign and partner outreach within the priority markets for a period of 2-3 months. Campaign materials may include but are not limited to fact sheets, brochures, prescription pads, and public service announcements. The avenues for distribution of the campaign materials and messages to the intended audiences may include, but are not limited to earned media, paid media, social media, and direct partner dissemination. The post-campaign recruitment and data collection will follow the media campaign and partner outreach.

#### Information to be collected

The online surveys will consist of dichotomous (yes/no), multiple response, interval (rating scales), and open-ended questions. Efforts were made to limit the number of questions to only those questions that tie to the key components of the two logic models and corresponding outcome indicators. The survey questions vary to some extent depending on the campaign phase and intended audience. Tables 3 and 4 describe the various sections in the survey and the differences and similarities between the surveys during the pre-and post-campaign phases. A series of questions on knowledge and behavior in both the pre-and post-campaign surveys will collect data that may show association between COVID-19 and the outcomes of the campaign. The findings will be useful in determining whether to incorporate messages about COVID-19 prevention practices, resources for educational purposes, and ways to reduce COVID-

19 fatigue into future *GAOS* materials. Copies of the formatted surveys can be found in Attachments C - F.

Survey Section	Pre-Campaign (Exposed to GAOS messaging)	Pre-Campaign (Unexposed to GAOS messaging)	Post-Campaign (Exposed to GAOS messaging)	Post-Campaign (Unexposed to GAOS messaging)
Screener	X	Х	Х	Х
Exposure to Campaign	X	Х	Х	Х
Frequency and Channel of Exposure	X		Х	
Knowledge	X	Х	Х	Х
Attitudes and Beliefs	X	Х	Х	Х
Behavior	X	Х	Х	Х
Sources of Information	X	Х	Х	Х
Use of Campaign Materials			Х	
Media Use and Habits				Х
Demographic Characteristics	X	Х	Х	Х

Table 3: Sections in the GAOS Consumer Pre-and Post-Surveys

Table 4: Sections in the GAOS HCP Pre-and Post-Campaign Survey

Survey Section	Pre-Campaign (Exposed to GAOS messaging)	Pre-Campaign (Unexposed to GAOS messaging)	Post-Campaign (Exposed to GAOS messaging)	Post-Campaign (Unexposed to GAOS messaging)
Screener	X	Х	Х	Х
Exposure to Campaign	X	Х	Х	Х
Frequency and Channel of Exposure	X		Х	
Knowledge	X	Х	Х	Х
Attitudes and Beliefs	X	Х	Х	Х
Behavior	X	Х	Х	Х
Use of Campaign Materials			Х	
Media Use and Habits				Х
Demographic Characteristics	X	Х	Х	Х

### 3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based survey. The vendor will use responsive design to facilitate completion of the survey on different types of devices (e.g., desktop/laptop computer, tablet, mobile phone). Use of web-based surveys reduces respondent burden by automating "skip" instructions rather than asking participants to interpret and implement the instructions themselves. This approach is less cognitively demanding and reduces the amount of time it will take participants to complete the survey. In addition, the survey will automatically place results in a format that can be read by statistical analysis software such as SPSS.

# 4. Efforts to Identify Duplication and Use of Similar Information

Since its inception in 2017, the *GAOS* campaign has successfully built strong relationships with other federal agencies, academic institutions/non-government organizations to strategically identify messaging and materials for the *GAOS* campaign, with the same goals to prevent and reduce infections that can lead to sepsis and optimize healthcare quality and patient safety. These groups include the Biomedical Advanced Research and Development Authority (BARDA), as part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) and patient representative and safety partners such as Sepsis Alliance, END SEPSIS, Sepsis Alliance, Niles Project, and others.

The *GAOS* campaign greatly values these key relationships and relies on regular communication with these groups to provide feedback on materials and promotional support to ensure the continued success of the campaign in reaching HCP and consumer audiences with vital, life-saving information. Coordination with these groups includes but is not limited to regular partner calls and emails to share the latest research and opportunities for collaboration, HCP training development, promotional support for key initiatives, subject matter expert presentations, and event attendance. These collaborations help prevent redundancy and promote use of consistent messaging and measures of campaign effectiveness.

- 1. No other governmental or institutional agencies are attempting to collect this data as this work is specific to evaluating the *GAOS* campaign.
- 2. Because this evaluation work is specific to assessing the reach and impact of CDC's *GAOS* campaign, there are no other data sources applicable as no other agency has conducted this work.

CDC DHQP will plan to regularly share findings from our work with those partners whom we work closely with.

# 5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

# 6. Consequences of Collecting the Information Less Frequently

This request is for a one-time information collection.

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

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5.

# 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on January 31, 2022, Vol. 87, No. 20, pp. 4890 (Attachment B). CDC received two comments related to this notice and responded accordingly (Attachment B1.).

B. The data collection instruments were designed by CDC DHQP and CATMEDIA. No consultations outside of CDC other than with the contractor occurred.

# 9. Explanation of Any Payment or Gift to Respondents

Participants who complete either the pre-or post-campaign survey will receive a token of appreciation for their participation within seven days of taking the survey. Based on OMB's guidance (OMB, 2016) on factors that may justify provision of a token of appreciation, we have determined that the following reasons apply.

*Past Experience*. Multiple studies using a variety of data collection methodologies have shown that offering incentives increases participation rates. When applied reasonably, incentives are not an unjust inducement, but rather an approach that acknowledges participants for their participation (Halpern et al., 2004; Vellinga et al., 2020). Respondents will receive \$25 (consumers) or \$75 (HCPs) in the form of Venmo or PayPal (electronic delivery) or a pre-paid gift card as a token of appreciation for their time and efforts, an amount commensurate with other market surveys (Kuhn, 2020; Pollfish, 2021; Surveytown, 2016). Furthermore, based on CATMEDIA's experience and expertise with recruiting participants for this type of assessment, they believe that the incentives noted above will be adequate to recruit the maximum response from each intended audience.

*Improved coverage of specialized respondents, rare groups, or minority populations*: Key audiences in this data collection include HCPs who play a role in diagnosing and treating sepsis. HCPs have been challenging to recruit for studies as they are a specialized, unique group of people whose time is limited and, thus, quite valuable (Pit et al., 2014). A token of appreciation will ensure participation from HCPs which will improve data quality by improving validity and reliability.

*Data quality:* If we are unable to recruit sufficient numbers of respondents to participate in the data collection, we will be unable to collect information to inform the development of new or revisions to existing *GAOS* messages, concepts, and materials which will limit our ability to determine if they are acceptable, understandable, motivating, etc. to the priority audiences, and avoid unintended negative consequences of messages/materials.

*Reduced data collection costs*: We anticipate that without the token of appreciation, recruitment and data collection costs will be much higher because we will need to screen more people to achieve the desired cooperation rate and recruit additional participants to make up for a higher rate of nonresponses.

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

This information collection request has been reviewed by NCEZID's Information Systems Security Officer who has determined that the Privacy Act does not apply. No personal identifying information (PII), such as names, addresses, or phone numbers, will be collected during the data collection or maintained in any data files held by CDC or CATMEDIA. The online survey panel vendor maintains PII, such as name, address, phone, and email addresses in their database of registered panelist to contact individuals for participation and for following up with incentive payments. The vendor's database is maintained according to privacy regulations. The PII is stored with the vendor and will never be shared with CDC or CATMEDIA.

Demographic information (e.g., age, gender, race/ethnicity, etc.) will be collected as part of the screening to determine participant eligibility, however no direct personal identifiers (e.g., date of birth, full name, phone number, social security number, etc.) will be collected or maintained. All PII will be kept separate from participants responses to the surveys. The *GAOS* surveys do not collect additional PII.

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

# Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that this information collection is not research involving human subjects. IRB approval is not required. The IRB exemption determination for this study is included in [CDC DHQP to provide Attachment G.

Data to be collected is not sensitive in nature

# 12. Estimates of Annualized Burden Hours and Costs

# A. Estimated Annualized Burden (Hours)

The annual burden hours requested (1366) are based on the number of completed responses we expect to collect over the requested period for this information collection. The survey, which will only be administered once to each participant, is estimated at no longer than 20 minutes per respondent. While participants will be screened, there will be a minimal time burden due to prior consent to participate in this study. The screener questions are included with the Informed Consent in Attachment I., but participants will be sent the online screener survey link first, followed by the online cross-sectional survey link for those found eligible to participate.

Type of	Form Name	No. of	No. of	Average	Total
Respondents		Respondents	Responses	Burden per	Burden
			per	Response (in	Hours
			Respondent	hours)	
Consumers	GAOS Consumer	945	1	20/60	315
	Pre-Campaign web				
	survey 1890				
Consumers	GAOS Consumer	945	1	20/60	315
	Post-Campaign				
	web survey				
HCPs	GAOS HCP	1103	1	20/60	368
	Pre-Campaign web				
	survey				
HCPs	GAOS HCP	1103	1	20/60	368
	Post-Campaign				

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	web survey				
Total					1366

#### **B. Estimated Annualized Burden Costs**

The annualized costs for respondents are based on data from the U.S. Department of Labor (DOL), Bureau of Labor Statistics (2022). To calculate annualized costs to consumers, we used the mean hourly wage rate of \$28.01 which represents the DOL estimated mean for state, local, and private industry earnings and assumes an average hourly wage rate for respondents who work an estimated 40-hour work week. In calculating annualized costs to healthcare professionals, we used \$43.80 per hour which represents DOLs estimated mean hourly wage for healthcare practitioners and technical occupations (e.g., physicians, registered and licensed nurses, advanced practice professionals, EMS, medical technicians, etc.). The estimated annual cost to all participants will be \$49.882.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Consumers	GAOS Consumer	315	\$28.01	\$8,823
	Pre-Campaign web			
	survey			
Consumers	GAOS Consumer	315	\$28.01	\$8,823
	Post-Campaign web			
	survey			
HCPs	GAOS HCP	368	\$43.80	\$16,118
	Pre-Campaign web			
	survey			
HCPs	GAOS HCP	368	\$43.80	\$16,118
	Post-Campaign web			
	survey			
Total				\$49,882

#### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

#### 14. Annualized Cost to the Government

Total estimated annualized cost to the government is [CDC DHQP to provide \$XXX] based on expenses incurred in the following categories: salary of CDC staff who are responsible for the overall project design and project oversight, and contractor costs associated with data collection and analysis activities.

#### **15. Explanation for Program Changes or Adjustments**

This is a new information collection.

#### 16. Plans for Tabulation and Publication and Project Time Schedule

Estimated Project Schedule				
Activity	Estimated Time Schedule			
Formal pilot test with intended audiences	2—3 months after OMB approval			
Pre-campaign survey recruitment	3—4 months after OMB approval			
Pre-campaign information/data collection	3—4 months after OMB approval			
Media campaign and partner outreach	4—7 months after OMB approval			
Post-campaign survey recruitment	7—8 months after OMB approval			
Post-campaign information/data collection	7—8 months after OMB approval			
Data cleaning and analyses	8—9 months after OMB approval			
Final report	9—11 months after OMB approval			
Dissemination of findings	12 months onward after OMB approval			

The following is the estimated project schedule anticipated for this study.

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

The display of the OMB Expiration date is not inappropriate.

#### 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

#### **List of Attachments**

- A. Authorizing Legislation
- B. GAOS 60-Day FRN Published
  - B1. Comments Received to 60-Day FRN
- C. GAOS Consumer Pre-Campaign Screener and Survey
- D. GAOS Consumer Post-Campaign Screener and Survey
- E. GAOS HCP Pre-Campaign Screener and Survey
- F. GAOS HCP Post-Campaign Screener and Survey
- G. GAOS IRB Determination
- H. GAOS Recruitment Invitation
- I. GAOS Informed Consent Form
- J. GAOS Reminder email

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