**Health Message Testing System Expedited Review Form**

**1. Title of Study: (Please append screener and questionnaire)**

Sepsis Educational Awareness Message/Materials Assessment with Consumers

**Overall Purpose/Background**

Each year in the U.S., more than a million people acquire sepsis and it is estimated that 28-50% of those individuals die each year from sepsis.1 Sepsis is a complication caused by the body’s overwhelming and life-threatening response to infection, which can lead to tissue damage, organ failure, and death. Despite the danger and prevalence of sepsis, research indicates that the general public and healthcare professionals (HCPs) may be unaware of the need to rapidly diagnose and treat sepsis in order to prevent sepsis complications and death.2

In response to the public health threat posed by sepsis, the CDC developed the *Get Ahead of Sepsis* educational effort (GAOS), a national sepsis knowledge and awareness building effort (see materials here <https://www.cdc.gov/sepsis/get-ahead-of-sepsis/index.html>). The GAOS effort is a national effort targeting consumers/patients and HCPs throughout the United States. The GAOS effort was launched in September 2017 with the goals to increase knowledge and awareness, and motivate behavior change related to sepsis prevention, early recognition, and appropriate treatment among target audiences to prevent and ultimately reduce sepsis cases.

The purpose of this data collection is to test the GAOS effort messages/materials for effectiveness and persuasiveness to affect expected outcomes of the effort, which are increased knowledge, awareness, perceptions of susceptibility and severity, self and response efficacy and behavioral intentions. The data collection will use an online survey to gather information to assess target audiences exposure to and reaction to the GAOS effort messages and materials. The data collection is not intended for program evaluation, and the utility of the data collection is to test the final, launched GAOS messages/materials with audiences to inform improvements for continued future implementation.

These data will enable CDC to improve the GAOS effort messages by ensuring quality and preventing waste in future dissemination of health information by the CDC to the public.

**2. Study Population: (Discuss study population and explain how they will be selected/recruited.)**

**Primary Audience:** Adults aged 18 and older who are registered with an online panel provider and living in the United States.Adult consumers are a major audience segment for this collection because despite the danger and prevalence of sepsis, research indicates that they know little about infections that can lead to sepsis and sepsis. This is a national campaign targeting the general public, however messages/materials target those persons most at risk for acquiring sepsis, or who are caregivers for groups most at risk for acquiring sepsis.

This data collection uses a quasi-experimental Proxy Pretest Design, also referred to as a retrospective pretest (or post-then-pre) design (RPTP design) to assess GAOS effort message/materials. The RPTP design administers the pre effort assessment concurrently with the posttest by asking individuals to recall their knowledge or behavioral intentions prior to the GAOS. It is a post only design in which after the fact, a pretest measure is constructed from data.  These designs are convenient, reliable and valid way to assess impact (you capture both the pretest and posttest information at the same time) with data collected via retrospective thoughts or recollection to stand in for the pretest. Using this design requires that the proxy measures on the SEMS to test messages/materials are conceptually related to and correlated with the expected outcomes for the GAOS effort (as described in the GAOS logic model).

Respondents will be classified as either “exposed” or “unexposed” based on their ability to identify the educational effort name (*Get Ahead of Sepsis*) and where they may have seen GAOS messages and/or materials. The surveys for the exposed audiences will include nine additional questions that ask specifically about the educational effort materials that they saw or heard. Both exposed and unexposed respondents will then answer the same set of questions pertaining to their knowledge, attitudes and beliefs related to sepsis now and prior to the launch of the effort. Collecting unexposed responses will provide a baseline against which to compare the change (or lack thereof) in exposed respondents’ scores after seeing/hearing the educational effort materials. That will provide key information that can then be used to further tailor the materials and messages to maximize the effectiveness of future rounds of the educational effort.

**Attachments:**

1. Project Description
2. HMTS Expedited Review Form
3. Screen Shots of the Sepsis Educational Effort Message/Materials Survey (SEMS) for Consumers
4. Incentive justification
5. IRB

Consumer Respondent characteristics:

Number of subjects: 1594

Number of males: n~50% males

Number of females: n~50% females

Age range: Age 18 and older

Racial/ethnic composition: Mix of racial and ethnic backgrounds

Type of group/s: Adults 18 years of age or older

Geographic location/s:

|  |
| --- |
| United States – Specifically randomly selected states in the 4 US census regions 1, 2, 3 and 4. |

**3. Incentives: (If an incentive will be used, state what incentive will be offered and justify proposed incentives to be used in study.)**

Incorporating modest incentives to aid in recruitment acknowledges respondents’ efforts, boosts response rates, and may improve the quality of information collected. As a token of appreciation for participating in the survey, respondents will receive a point equivalent of $10 to redeem online or at a retailer (commonly provided to survey panel respondents who complete on-line surveys). The "points" will not be sent from CDC, but instead be provided by an on-line panel provider to respondents who complete the survey.

**4. Study method: (Please check one below)**

Central location intercept interview: \_\_\_

Telephone interview: \_\_ CATI used: yes or no) \_\_

Individual in-depth interview (cognitive interview):\_\_\_

Focus group:

Online interview: \_\_

Other: (describe): **Online (or Web-based survey)**

**5. Purpose of the overall communication effort into which this health message/s will fit: (Please provide 2-3 sentences below.)**

CDC requests OMB approval to collect information related to assessing exposure to the GAOS effort and testing reactions to the GAOS effort messages and materials. Information collected will inform enhancements to the GAOS for continued, future implementation.

**6. Category of time sensitivity: (Please check one below)**

Health emergency: \_\_\_\_\_

Time-limited congressional/administrative mandate: \_\_ \_\_

Press coverage correction: \_\_\_\_\_

Time-limited audience access: **\_\_X\_\_\_**

Ineffective existing materials due to historical event/social trends: \_\_\_\_\_

Trend tracking: \_\_\_\_\_

**7. Describe nature of time sensitivity: (Please provide 2-3 sentences below.)**

Each year in the U.S., more than a million people are infected with sepsis and it is estimated that 28-50% of those infected die each year from sepsis. The GAOS effort provides information to raise knowledge and awareness about the threat of sepsis. Because effort launched in September 2017, it is critical to rapidly assess the GAOS messages/materials effect on expected GAOS outcomes to determine if modifications are needed for continued implementation.

**8. Number of burden hours requested:** **893 BURDEN HOURS\***

| **Category of Respondent** | **Form Name** | **No. of Respondents** | **Average Burden per Response**  **(in hours)** | **Total Burden Hours** |
| --- | --- | --- | --- | --- |
| Consumers | SEMS Online Survey unexposed | 797 | 20/60 | 266 |
| SEMS Online Survey exposed | 797 | 25/60 | 332 |
| **Total** |  | 1594 |  | **598** |

9. **Are you using questions from the approved question bank? If yes, please list the item number(s) for questions used from the question bank.**

Yes: \_\_\_**\_**\_

No: \_X\_\_\_

\*\*\* Items Below to be completed by Office of Associate Director for Communication (OADC)\*\*\*

1. Number of burden hours remaining in current year’s allocation: \_\_\_\_\_\_\_

2. OADC confirmation of time-sensitivity:

Yes: \_\_\_\_\_

No: \_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project Officer Signature

**References**

1. Levinson, A. T., Casserly, B. P., & Levy, M. M. (2011). Reducing mortality in severe sepsis and septic shock. In *Seminars in respiratory and critical care medicine* (Vol. 32, No. 02, pp. 195-205).
2. Shelton, B. K., Stanik-Hutt, J., Kane, J., & Jones, R. J. (2016). Implementing the Surviving Sepsis Campaign in an Ambulatory Clinic for Patients with Hematologic Malignancies. Clinical journal of oncology nursing, *20*(3), 281-288.