

Health Message Testing System Expedited Review Form

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

Sepsis Campaign Development: Round 2 Concept/Materials Testing for 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 (e.g., consumers) know little about sepsis and healthcare professionals (HCPs), (such as outpatient providers) who most frequently encounter patients at risk of sepsis may be unaware of the need to rapidly diagnose and treat sepsis in order to prevent sepsis complications and death.² Research also indicates that among consumers, some racial/ethnic and age groups (e.g., African American men *and* infants, and persons over 65 years of age) and individuals with chronic conditions are disproportionately affected by sepsis, suggesting a need to focus communication efforts to raise sepsis awareness in these populations.³⁻⁶

In response to the public health threat posed by sepsis, the CDC is developing a national sepsis awareness campaign for launch during Sepsis Awareness month in September 2017 for consumers and HCPs. The goal of the campaign is to raise awareness and motivate behavior change related to sepsis prevention, early recognition, and appropriate treatment among HCP and consumer target audiences to prevent and reduce sepsis cases.

CDC requests approval to test creative concepts/messages and materials for the sepsis awareness campaign developed on the basis of results from a first round of exploratory/formative research (OMB Control No. 0920-1154). This information collection is necessary to test sepsis campaign concepts/messages and materials to ensure they appeal to and meet the needs of consumer and HCP target audiences. The purpose of this project is to rapidly test initial sepsis awareness building campaign concepts/messages and materials (using survey methods) to ensure that they resonate with target audiences prior to launching the national campaign. The results of this testing will be used to refine and finalize campaign materials on the basis of target audience feedback for campaign launch in September 2017.

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

Consumers: 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. We are targeting 3 consumer target audiences identified as those most at risk for acquiring sepsis, or who are caregivers for groups most at risk for acquiring sepsis. These consumer groups are defined as mothers age 30-54 with infants ≤ 1 year-old and parents ≥ 65 ; African American men age ≥ 65 with one or more chronic condition; and healthy adults and caregivers age ≥ 65 . Mothers age 30-54 and healthy adults and caregivers are further segmented by race/ethnicity to investigate if there are any differences in these groups response to campaign concepts/messages and materials.

Consumers will be recruited by a professional recruiting agency from participants who are registered with an on-line panel provider. Specifically, the online panel provider will use their internal information about panelists to pre-qualify individuals. Eligibility will be confirmed during a self-screening and consent process. Consumers will be identified and recruited from specific states in each region of the

U.S. (south, mid-west, west, and north) that have highest rates of sepsis mortality within their region (See Exhibit 2).⁷ We will recruit a majority of participants from southern states given the high mortality of sepsis and prevalence of associated risk factors (African American race, presence of chronic conditions) present in this region.

A summary of consumer survey respondents and materials to test with consumers is shown below (Exhibits 1-4).

Exhibit 1. Consumer Selection/Sampling

Activity	Mothers (age 30-54) with infants (≤ 1) and aging parents age ≥ 65	African American (AA) Men age ≥ 65 with one or more chronic condition	Healthy adults and caregivers ≥ 65	Total
Online Survey	<ul style="list-style-type: none"> ▪ n=6 ▪ 4 AA women ▪ 2 white women 	6	<ul style="list-style-type: none"> ▪ n=6 ▪ 2 AA women ▪ 4 white women 	18

Exhibit 2. Targeted States for Consumer Sample

Region	Targeted States	Consumer Recruitment Goals
South	Georgia	2
	Louisiana	2
	Mississippi	2
	Tennessee	2
	Washington DC	2
Northeast	New York	~2
	New Jersey	~2
Midwest	Missouri	~2
	Illinois	~2
West	Nevada	1
Total		18

Exhibit 3. Consumer Inclusion Criteria

Consumer Audience	Consumer Inclusion Criteria
Mothers age 30-54	<ul style="list-style-type: none"> ▪ African American or White ▪ Female ▪ Have infants ≤ 1 year old ▪ Primary caregiver of at least one aging parent ≥ 65 age ▪ Age 30-54 ▪ Reads and writes English ▪ Currently lives in targeted state
African American Men with one or more chronic condition	<ul style="list-style-type: none"> ▪ Presence of one or more chronic condition, such as diabetes and/or hypertension ▪ Black or African American ▪ Age ≥ 65 ▪ Reads and writes English

Consumer Audience	Consumer Inclusion Criteria
	<ul style="list-style-type: none"> ▪ Currently lives in targeted state
Healthy Adults and caregivers	<ul style="list-style-type: none"> ▪ Age 65 or older ▪ Female ▪ White or African American ▪ No chronic conditions ▪ Caregiver for a family member ▪ Reads and writes English ▪ Currently lives in targeted state

To ensure effective messages are created for the campaign, we will use an online survey to test initial campaign concepts/messages and materials. All consumers will be asked to review the following campaign materials – Visual Identities, Print Ads, TV Ad concepts, and a sepsis definition for consumers. Exhibit 4 shows that we will test all of these materials with consumers.

Exhibit 4. Consumer Campaign Materials Testing

Campaign Materials	Mothers (age 30-54) with infants (≤1) and aging parents age ≥65	African American Men age ≥65 with one or more chronic condition	Healthy adults and caregivers ≥65
Visual Identity: <ul style="list-style-type: none"> • A • B • C • D • E 	✓	✓	✓
Print Ads <ul style="list-style-type: none"> • A • B • C 	✓	✓	✓
TV Ad Concepts <ul style="list-style-type: none"> • A • B • C 	✓	✓	✓
Sepsis Definition for Consumers	✓	✓	✓

Attachments:

HMTS Expedited Review Form

Project Description

Attachment A – Sepsis R2 Screener and Survey – HCPs [not part of this gen-IC submission]

Attachment B – Sepsis R2 Screener and Survey – Consumers

Attachment C – Sepsis R2 Informed Consent

Attachments D – Health messages

1. Visual with Slogan A
2. Visual with Slogan B
3. Visual with Slogan C
4. Visual with Slogan D

5. Visual with Slogan E
6. Sepsis Print Concept A
7. Sepsis Print Concept B
8. Sepsis Print Concept C
9. Sepsis Campaign Stimulus – TV Ads
10. HCP Sepsis flier for R2 testing [not part of this gen-IC submission]
11. Consumer Sepsis definition

Consumer Respondent characteristics:

Number of subjects:

Number of males:

Number of females:

Age range:

Racial/ethnic composition:

Type of group/s:

Geographic location/s:

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 participants' efforts, boosts response rates, and may improve the quality of information collected. Incentives are necessary for online data collection for initial campaign stimulus materials to ensure that those who are willing to participate are as representative as possible of the target audience, which in this case includes participants of hard-to-reach racial/ethnic groups, healthcare professionals who may have limited time to participate due to professional responsibilities, and participants who may have caregiving responsibilities. As a token of appreciation for participating in the survey, participants 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 development of the sepsis awareness building campaign. Information collected will inform revisions to draft campaign concepts/messages and materials (developed based on Round 1 formative research) and help ensure that the national

campaign meets the needs of intended target audiences.

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 sepsis campaign provides information to raise knowledge and awareness about the threat of sepsis. Because campaign launch is scheduled for fall of 2017, it is critical to rapidly test initial campaign concepts and materials to ensure that they resonate with target audiences prior to the campaign launch.

8. Number of burden hours requested: 24 BURDEN HOURS*

Category of Respondent	Form Name	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hours
Consumers	Consumer Screener	180	5/60	15
	Consumer Online Survey	18	30/60	9
Total				24

*Per our discussion with professional marketing firm that will conduct recruitment, we anticipate 10% response rate for online surveys.

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

<p>*** Items Below to be completed by Office of Associate Director for Communication (OADC)***</p> <p>1. Number of burden hours remaining in current year's allocation: _____</p> <p>2. OADC confirmation of time-sensitivity:</p> <p>Yes: _____</p> <p>No: _____</p> <p style="text-align: center;">_____</p> <p style="text-align: center;">Project Officer Signature</p>

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.
3. Barnato, A. E., Alexander, S. L., Linde-Zwirble, W. T., & Angus, D. C. (2008). Racial variation in the incidence, care, and outcomes of severe sepsis: analysis of population, patient, and hospital characteristics. *American Journal of Respiratory and Critical Care Medicine*, 177(3), 279-284.
4. Novosad, S. A. (2016). Vital Signs: Epidemiology of Sepsis: Prevalence of Health Care Factors and Opportunities for Prevention. *MMWR. Morbidity and Mortality Weekly Report*, 65.
5. Co-morbid Esper, A. M., Moss, M., Lewis, C. A., Nisbet, R., Mannino, D. M., & Martin, G. S. (2006). The role of infection and comorbidity: Factors that influence disparities in sepsis. *Critical Care Medicine*, 34(10), 2576.
6. Mihaljevic, S. E., & Howard, V. M. (2016). Incorporating Interprofessional Evidenced-Based Sepsis Simulation Education for Certified Nursing Assistants (CNAs) and Licensed Care Providers Within Long-term Care Settings for Process and Quality Improvement. *Critical Care Nursing Quarterly*, 39(1), 24-33.
7. Wang, H. E., Devereaux, R. S., Yealy, D. M., Safford, M. M., & Howard, G. (2010). National variation in United States sepsis mortality: a descriptive study. *International Journal of Health Geographics*, 9(1), 9.