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 Healthcare Providers

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.)

HCPs are a major audience segment for this collection because research suggests that HCPs 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. Moreover, it is thought that increasing HCPs' knowledge and awareness about infections that can lead to sepsis, sepsis, and the importance of rapid diagnosis is critical to preventing sepsis complications and death.

We are targeting 7 HCP target audiences who are most likely to encounter patients at risk of sepsis (patients at risk for infection that can lead to sepsis) or who are currently septic. These include non-specialist primary care physicians (internist, pediatrician, or family practitioner); nurse practitioners and physician assistants who work at urgent care health centers; emergency department triage nurses, general medical ward staff, nursing home staff, and home healthcare staff.

We will use an online survey as the method to test sepsis awareness campaign concepts/messages and

materials. HCP study participants to complete the survey will be recruited and selected by a professional recruiting agency from participants who are registered with an on-line panel provider. Eligibility criteria will be established for all survey respondents. Potential respondents will be screened initially by the professional marketing firm, and then through an online self-administered rescreening form to ensure eligibility to take survey. Specifically, the panel provider will use its internal information about panelists to pre-qualify individuals. Eligibility will be confirmed during a self-screening and consent process. HCPs will be recruited and selected 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 HCP respondents and materials to test with HCPs is shown below (Exhibits 1-4). We expect that HCPs will include a mix of people from different ethnic and racial backgrounds.

Exhibit 1. HCP Selection/Sampling

Activity	Primary Care Physicians	Urgent Care Physician Assistants	Urgent Care Nurse Practitioners	Emergency Dept. Triage Nurses	General Medical Ward Staff	Home Healthcare providers	Nursing Home Staff	Total
Online Survey	6	6	6	6	6	6	6	**42**

Exhibit 2. Targeted States for HCP Sample

Region	Targeted States	HCP Recruitment Goals
South	Georgia	5
	Louisiana	5
	Mississippi	5
	Tennessee	4
	Washington DC	4
Northeast	New York	5
	New Jersey	4
Midwest	Missouri	4
	Illinois	4
West	Nevada	2
Total		**42**

Exhibit 3. HCP Inclusion Criteria

HCP Audience	HCP Inclusion Criteria
Primary Care Physician	▪ Licensed, practicing physician who is family practitioner, pediatrician, or internist (**not** a specialist, such as an allergist, for example) ▪ Works as a primary care physician ▪ Reads and writes English ▪ Works in targeted state ▪ Currently treating patients

HCP Audience	HCP Inclusion Criteria
• Nurse practitioner • Physician assistant	▪ Licensed, practicing NP or PA ▪ Works in urgent care clinic ▪ Reads and writes English ▪ Works in targeted state ▪ Currently treating patients
Emergency Department Triage Nurse	▪ Works in a hospital emergency department as a triage nurse ▪ Reads and writes English ▪ Works in targeted state ▪ Currently treating patients
• General Hospital Ward Staff • Nursing Home Staff • Home Healthcare Staff	▪ Examples include: RN's, LPNs and LVNs, CNAs, and/or aides (should not be Primary Care Physician, Nurse practitioner, or Physician Assistant) ▪ Reads and writes English ▪ Works in targeted state ▪ Currently treating patients

As previously stated, to ensure effective messages are created for the campaign, we will use an online survey to test initial campaign concepts/messages and materials. All HCP survey respondents will be asked to review the following campaign materials – Visual Identities, Print Ads, TV Ad concepts, and sepsis content for action tools. Exhibit 4 shows that we will test all of these materials with HCPs.

Exhibit 4. HCP Campaign Materials Testing

Campaign Materials	Urgent Care Physician Assistants	Urgent Care Nurse Practitioners	Emergency Dept. Triage Nurses	Primary Care Physicians	General Medical Ward Staff	Home Healthcare providers	Nursing Home Staff
Visual Identity: • A • B • C • D • E	✔	✔	✔	✔	✔	✔	✔
Print Ads • A • B • C	✔	✔	✔	✔	✔	✔	✔
TV Ad Concepts • A • B • C	✔	✔	✔	✔	✔	✔	✔
Sepsis Content for Action	✔	✔	✔	✔	✔	✔	✔

Campaign Materials	Urgent Care Physician Assistants	Urgent Care Nurse Practitioners	Emergency Dept. Triage Nurses	Primary Care Physicians	General Medical Ward Staff	Home Healthcare providers	Nursing Home Staff
Tools							

Attachments:

HMTS Expedited Review Form
Project Description
Incentive Justification
Attachment A – Sepsis R2 Screener and Survey – HCPs
Attachment B – Sepsis R2 Screener and Survey – Consumers [not part of this gen-IC submission]
Attachments C – 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
      11. Consumer Sepsis definition [not part of this gen-IC submission]

HCP Respondent characteristics:
      Number of subjects: 420
            Number of males: 210
            Number of females: 210
      Age range: 18 and older
      Racial/ethnic composition: Mix of racial/ethnic backgrounds
      Type of group/s: Healthcare Professionals
      Geographic location/s:

> Georgia, Louisiana, Mississippi, Tennessee, Washington DC, New York, New Jersey, Missouri, Illinois, Nevada

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

For the R2 research, we are requesting approval for incentives equivalent to $55 for all HCPs. Points will be provided by the online panel provider and will be redeemable online or at a retailer. These incentives are different from those used in R1 because, unlike R1 which involved conduct of online in-depth interviews, in R2 we will conduct a 30 minute online survey. Please see the attached incentive justification.

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: 56 BURDEN HOURS*

Category of Respondent	Form Name	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hours
Healthcare Providers (HCP)	HCP Screener	420	5/60	35
	HCP Online Survey	42	30/60	21
Total				**56**

*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___

*** 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.
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.