

OMB No. 0920-0572

Exp. Date 08/31/2021

A Tailored Communications Campaign to Reduce Pregnancy-related Complications and Death

Attachment 1: Background Information

Purpose

The Division of Reproductive Health (DRH) is planning a communications campaign to reduce pregnancy-related complications and death. The campaign planning includes conducting focus groups to assess how pregnant and postpartum women and their support systems perceive messaging intended to reduce the risk of severe pregnancy-related complications and deaths. Information gathered through focus groups will help improve public health communication messaging on this topic among pregnant and postpartum women, as well as members of their support system.

Nearly 700 women die annually in the United States due to pregnancy-related complications¹ and 50,000 more experience severe maternal morbidity² – that is, unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman’s health.

Significant racial disparities have been noted since the late 1980s and persist today. In fact, the rate of pregnancy-related mortality ratio among black or African American women is nearly three times that of white women (40.0 deaths per 100,000 live births v. 12.4 deaths per 100,000 live births).¹

Recent research found that overall most pregnancy-related deaths were caused by heart disease and stroke, infections, and hemorrhage. Research has also found that 3 in 5 pregnancy-related deaths could be prevented. The most common factors contributing to death were determined to be patient/family factors (e.g., lack of knowledge on warning signs and the need to seek care), health care provider factors (e.g. misdiagnosis), and systems of care factors (e.g., lack of coordination between health care providers).³

Methods

The project team plans a one-time data collection using focus groups. The focus groups will primarily include *pregnant women in their second trimester up to 32 weeks and women who experienced a pregnancy-related complication within the past two years (hereafter referred to as “postpartum women”)*. There will also be focus groups of *members of women’s support systems* (defined below).

A total of eight, three-hour focus group sessions will be conducted by a trained moderator using an approved discussion guide (the discussion guide will be the same for all focus groups). Eight to ten pregnant and postpartum women of various racial/ethnic backgrounds will participate in one of five focus groups (specific racial/ethnic makeup of groups is outlined on page 3). Eight to ten members of the women’s “support system” will also participate in one of three separately held focus groups. Women will be asked if they can identify one member of their support system who could participate in a separate focus group. This person is defined as someone who is in a position to help or who helped the woman advocate for her health or can advocate on her behalf, such as a partner, family member, or

¹Pregnancy Mortality Surveillance System. Centers for Disease Control and Prevention. <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-mortality-surveillance-system.htm>. Accessed May 1, 2019.

² Severe Maternal Morbidity. Centers for Disease Control and Prevention. <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html>. Accessed May 1, 2019.

³ Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention, 13 States, 2013-2017. <https://www.cdc.gov/vitalsigns/maternal-deaths>. Accessed May 7, 2019.

friend. This person could also be a doula, as doulas (lay professionals who support women during pregnancy and/or delivery) can provide additional insight into message development. For the remainder of this document, we will refer to these respondents as “advocates.” During the focus groups, the team will solicit feedback from women and advocates on the selected tools and messages. The team will observe how participants respond to the messaging, message usefulness, and impact, as well as how and when the messaging could be used.

The sample will consist of up to 80 respondents (8-10 per focus group). The majority of the respondents (40-50) will be women who are currently pregnant or postpartum. The remainder will be advocates of these women. Of the postpartum women, we will make an effort to recruit at least two respondents in each focus group who self-reported during screening having experienced one of the following severe complications of pregnancy: pulmonary embolism, hemorrhage, pre-eclampsia or eclampsia, infection, cardiomyopathy associated with pregnancy, or other cardiovascular disease associated with pregnancy. These are complications defined in available research and by subject matter experts on the topic to be the most severe and life threatening. A question will be included in the recruitment screener about whether or not they experienced one of these complications.

We will also prioritize recruitment of an ethnically diverse sample of women, specifically by oversampling black or African American women. Two of the five focus group discussions made up of pregnant and postpartum women will consist of only black or African American respondents. Nationally, women in this population are disproportionately affected by pregnancy-related mortality; the rate of mortality in this population is more than three times that of white women.

All participants in the study must speak English and consent to participation. Pregnant or postpartum participants must be between 25-45 years of age; advocates must be at least 18 years of age. Recruitment flyers will be distributed via email by partners to Atlanta-based women on their contact lists and posted at obstetric/gynecologic offices to target pregnant or postpartum women. Women interested in participating can contact the consulting firm via telephone or email. Partners may also provide contact information of women to the recruiting firm, and the firm would reach out to these women directly. During the screening process, women will be asked to identify a support person who may be interested in participating in the advocate focus groups. The recruitment firm will reach out to the advocates separately via email or phone to explain the project and gauge interest.

Both women and advocates who are chosen to participate in focus groups will be notified by their preferred contact method of phone or email and provided additional details about the focus groups, including date, time and location.

Individuals must meet the universal inclusion criteria above and the following method-specific inclusion criteria in order to be eligible to participate in these focus groups:

Currently Pregnant & Postpartum Women (within 2 years)	Advocates
GROUP 1	GROUP 6

<p>8-10 women ages 25-45, representing a mix of race/ethnicities (including black or African American).</p> <p>At least two postpartum women experienced one of the identified health conditions.</p>	8-10 Advocates of Groups 1-5
<p>GROUP 2</p> <p>8-10 women ages 25-45, representing a mix of race/ethnicities (including black or African American).</p> <p>At least two postpartum women experienced one of the identified health conditions.</p>	<p>GROUP 7</p> <p>8-10 Advocates of Groups 1-5</p>
<p>GROUP 3</p> <p>8-10 women ages 25-45, representing a mix of race/ethnicities (including black or African American).</p> <p>At least two postpartum women experienced one of the identified health conditions.</p>	<p>GROUP 8</p> <p>8-10 Advocates of Groups 1-5</p>
<p>GROUP 4</p> <p>8-10 women ages 25-45, black or African American.</p> <p>At least two postpartum women experienced one of the identified health conditions.</p>	
<p>GROUP 5</p> <p>8-10 women ages 25-45, black or African American.</p> <p>At least two postpartum women experienced one of the identified health conditions.</p>	

Estimated Burden to Respondents

We estimate 245 hours for total burden to respondents. This is based on a conservative estimate of 100 pregnant or postpartum women being screened for two minutes each, with 50 participating in the focus groups for three hours each; and 50 advocates being screened for two minutes each, with 30 participating in the focus groups for three hours each.

	No. of Respondents	Participation Time	Burden
<i>Screening</i>			

Women	100	2 minutes	3 hours
Advocates	50	2 minutes	2 hours
<i>Focus Groups</i>			
Women	50	3 hours	150 hours
Advocates	30	3 hours	90 hours
Total			245 hours

Overview of Messages Concepts

In this project, the team will test four messages and related concepts:

- **Hear Her** - This message is about listening to pregnant or postpartum women who express concerns when they know something is wrong.
- **Moments Matter** - This message depicts special moments in a family’s life when a mother either is or isn’t present due to pregnancy-related complications or death.
- **Be The One** - This message encourages the audience to learn the warning signs of pregnancy-related complications and to be the one to listen and act quickly when a pregnant or postpartum woman expresses a health concern.
- **Stop. Look. Listen.** - This message is also about listening to a pregnant or postpartum woman’s concerns when she knows something is wrong.

Hear Her, Moments Matter, and Be The One were informed by in-depth interviews with DRH subject matter experts, as well as an analysis of stories of women and their families who experienced “near misses” or mortality during their pregnancy or post-partum period pulled from the media between January 2017 – April 2019.

The remaining concept – Stop. Look. Listen. – was developed by the Tara Hansen Foundation based on the personal story of Tara Hansen, who died of a pregnancy-related complication in 2017.

The concepts aim to highlight the importance of listening to women when they express concerns and learning about warning signs as important steps in getting women the care they need.

How the Data Will Be Used

The data collected from the focus groups will be used to assess the primary audiences’ perception of creative concepts and messaging intended to reduce the risk of severe pregnancy-related complications and death.

Feedback from the focus group participants will determine which creative concepts and messaging resonate and inspire action and if any edits should be made. The data from the focus groups will also provide information about where the participants would be most likely to notice the creative concepts and messaging (e.g., in an online ad). In addition, the data will provide information about what types of additional educational information about recognizing and reducing the risk of severe pregnancy-related complications and death participants might find helpful and in what format they would like to receive the information.

Protection of the Privacy and Confidentiality of Information Provided by Respondents

Recruitment and administration will be done by [V&L Research and Consulting, Inc.](#) Respondents will be recruited/identified through an existing system maintained by a contract research organization and all information will be kept confidential.

Original tape recordings (and any back-up copies), notes, and all signed consent forms will be kept in locked cabinets. Participants' contact information will be kept in a digital, password-protected database accessible only to V&L. During focus group sessions, respondents will be identified to the group by a pseudonym to further assure confidentiality and any specific names they mention in their comments during the session will be removed from the final transcript.

V&L will ensure that all project materials are in a locked cabinet at the end of each workday. The V&L staff will be responsible for managing all data and forms that are obtained, such as screeners. The V&L staff will also track, label, store and secure these data, while ensuring the confidentiality of the participant to the extent permitted by law. Contractors will maintain any collected data temporarily; keeping it only until data are entered, quality reviewed for consistency and accuracy, and delivered to the CDC. After results from the focus groups have been summarized, all data, forms, and recordings will be deleted (if in an online format) and shredded (if in a hard copy format.)

Incentives

Participants (pregnant/postpartum women and advocates) will receive a \$75 cash gift card as a token of appreciation for their time. V&L has provided incentives in this amount for similar focus groups in the past and determined it was a reasonable amount for this project given the potential need for coverage of transportation cost, childcare, and/or loss of income of participants. Providing incentives is necessary in order to ensure adequate participation.