

Intervention Resources Concept Testing

A. Product Activity To Be Assessed

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) and the Division of Pharmacologic Therapies (DPT), is requesting Office of Management and Budget (OMB) approval for one new focus group tool consisting of the following:

- Intervention Resources Focus Group Protocol (Attachment A);
- Intervention Resources Focus Group Screening and Recruitment Questionnaire (Attachment B);
- Intervention Resources Focus Group Authorization and Release (Attachment C);
- Intervention Resources Focus Group Facilitator Guide – Parents of Active/Recovering Users (Attachment D);
- Intervention Resources Focus Group Facilitator Guide – Bereaved Parents (Attachment E); and
- Intervention Resources Focus Group Facilitator Guide – Young Adults (Attachment F)

In 2015, over 27 million people in the United States reported current use of illicit drugs or misuse of prescription drugs, and over 66 million people (nearly a quarter of the adult and adolescent population) reported binge drinking in the past month. Alcohol and drug misuse and related disorders are major public health challenges that are taking an enormous toll on individuals, families, and society.¹

Substance misuse can have immediate, direct consequences for health ranging from effects on heart rate and regulation of body temperature to psychotic episodes, overdose, and death. Many more people now die from alcohol and drug overdoses each year than are killed in automobile accidents.² The opioid crisis is fueling this trend with nearly 30,000 people dying due to an overdose on heroin or prescription opioids in 2014.³ An additional roughly 20,000 people died as a result of an unintentional overdose of alcohol, cocaine, or non-opioid prescription drugs.^{4,5}

¹ U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*. Washington, DC: HHS, November 2016.

² Centers for Disease Control and Prevention. (2015). Alcohol poisoning deaths. Vital signs: Alcohol poisoning kills six people each day. Retrieved from <http://www.cdc.gov/media/dpk/2015/dpk-vs-alcohol-poisoning.html>. Accessed on April 6, 2016.

³ National Institute on Drug Abuse. (2015). Overdose death rates. Retrieved from <http://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>. Accessed on January 25, 2016

Most Americans know someone with a substance use disorder, and many know someone who has lost or nearly lost a family member as a consequence of substance misuse. Yet, at the same time, few other medical conditions are surrounded by as much shame and misunderstanding as substance use disorders. Historically, our society has treated addiction and misuse of alcohol and drugs as symptoms of moral weakness or as a willful rejection of societal norms, and these problems have been addressed primarily through the criminal justice system. Only about 10 percent of people with a substance use disorder receive any type of specialty treatment. Further, more than 40 percent of people with a substance use disorder also have a mental health condition, yet fewer than half (48.0 percent) receive treatment for either disorder.⁶

Drug overdose statistics demonstrate an alarming trend. In 2014, 47,055 drug overdose deaths occurred in the United States, with 61 percent of these deaths the result of opioid use, including prescription opioids. The same year witnessed 17,465 overdoses from illicit drugs, including 5,415 deaths from cocaine overdose (a rate higher than the previous six years) and 25,760 overdoses from prescription drugs.⁷

Drug overdose deaths also occur as a result of the illicit manufacturing and distribution of synthetic opioids, such as fentanyl, and the illegal diversion of prescription opioids. Illicit fentanyl, for example, is often combined with heroin or counterfeit prescription drugs or sold as heroin, and may be contributing to recent increases in drug overdose deaths.⁸

Many factors contribute to this “treatment gap,” including the inability to access or afford care, fear of shame and discrimination, and lack of screening for substance misuse and substance use disorders in general health care settings. Further, about 40 percent of individuals who know they have an alcohol or drug problem are not ready to stop using, and many others simply feel they do not have a problem or a need for treatment, which may partly be a consequence of the

⁴ Rudd, R. A., Aleshire, N., Zibbel, J. E., & Gladden, R. M. (2016). Increases in drug and opioid overdose deaths — United States, 2000–2014. *MMWR*, 64(50), 1378-1382.

⁵ Centers for Disease Control and Prevention. (2016). CDC Wonder: Multiple cause of death 1999 - 2014. Retrieved from <http://wonder.cdc.gov/wonder/help/mcd.html>. Accessed on May 17, 2016

⁶ Center for Behavioral Health Statistics and Quality. (2016). Results from the 2015 National Survey on Drug Use and Health: Detailed tables. Rockville, MD: Substance Abuse and Mental Health Services Administration.

⁷ Centers for Disease Control and Prevention. (2016). CDC Wonder: Multiple cause of death 1999 - 2014. Retrieved from <http://wonder.cdc.gov/wonder/help/mcd.html>. Accessed on May 17, 2016. 49. Drug Enforcement Administration. (2016).

⁸ DEA Report: Counterfeit pills fueling U.S. fentanyl and opioid crisis: Problems resulting from abuse of opioid drugs continue to grow. Retrieved from <https://www.dea.gov/divisions/hq/2016/hq072216.shtml>. Accessed on August 16, 2016.

neurobiological changes that profoundly affect the judgment, motivation, and priorities of a person with a substance use disorder.⁹

B. Brief Statement of Objectives

In response to this situation, SAMHSA wants to convene focus groups to develop and test content for two public educational resources. The first resource will target parents of young adults seeking to prevent further escalation of their child's existing substance use or support their children's treatment and recovery efforts. The second resource will target parents bereaved by their child's substance use-related overdose. These resources will take into consideration not only literacy levels but also cultural competence and appropriateness.

SAMHSA will garner audience reaction on the intervention resource materials that address the information and education gap for parents of 17-25 year olds. Focus groups will include representatives of the target population for this task including:

Primary target audience:

- a) Parents of young adults 17 to 25 years old who are currently engaging in or are in treatment for substance use, and
- b) Parents who have lost children aged 17 to 25 years old to an overdose death.

Secondary target audience:

- c) Young adults from 17 to 25 who are currently using drugs or in treatment for substance use.

The proposed focus groups will aim to explore and assess the following:

- Parents' perceptions of the resources, information and skills they need to engage and support the recovery of children using drugs
- The resources, information and skills parents experiencing overdose bereavement require to navigate the grief process and overcome stigma
- The perceptions of young adults engaged in or recovering from substance use regarding supportive social norms and trusted sources of information as well as their lack of knowledge about, or experience addressing, the negative consequences of substance use
- The relevance, completeness and tone of mock-ups of the proposed resource guides

The information obtained from the focus groups will guide the developers of the resource guides as they refine the messaging and products to make them more relevant for the target audiences.

⁹ Center for Behavioral Health Statistics and Quality. (2016). Results from the 2015 National Survey on Drug Use and Health: Detailed tables. Rockville, MD: Substance Abuse and Mental Health Services Administration.

C. Overview of Methods To Collect Information

Data Collection Method

SAMHSA is seeking to conduct six focus groups in two geographical markets: three at Richmond, Virginia, and three at Oklahoma City, Oklahoma, with participation of adults representing diverse racial and ethnic groups and exhibiting different socioeconomic, cultural, educational, and demographic backgrounds.

This effort will assess variables such as: comprehension, readability, appeal, relevance, effectiveness and identification of the written information. The resource guide will address the following potential topics: identification of information gaps related to opioid substance use, treatment and overdose bereavement; parents and family's needs for information and resources, including overcoming stigma and coping skills; and risk and protective factors.

Each focus group will be 90 minutes long. The time breakdown for each focus group is as follows:

- 0.8 minutes to prescreen potential participants; and
- 90 minutes to read and sign consent forms and to participate in the introduction, guidelines, and group discussion.

SAMHSA will provide a screening and recruitment questionnaire to vendors to use in recruiting the focus group participants. This questionnaire ensures the individuals participating in each group will meet the needs of the study. SAMHSA will also provide guidance on timing and setup for the groups and work with its vendors to meet or adjust the logistical requirements as needed.

Identification of Respondents and Provision of Incentives

SAMHSA is looking for a total of 60 potential participants who will be prescreened prior to the focus groups (10 potential participants per focus group). Out of the 60 prescreened potential participants, 48 will be recruited and divided into six groups of 8 to participate in the 90-minute focus group sessions.

Participant recruitment will be based on the results of a screening questionnaire to be applied by EurekaFacts, as well as close monitoring by Synergy Enterprises, Inc.'s staff to gather groups with the appropriate profiles based on the selection criteria. The following procedures will be followed:

- Focus groups will be conducted based on potential participants' availability, explored via screening questionnaire
- At the beginning of each session, participants will complete an authorization/release form of use of the information provided; and
- To incentivize participants and reduce recruiting time and cost, SAMHSA will offer participants a \$50 gift card.

Frequency of Data Collection

SAMHSA is seeking to conduct the proposed six focus groups one time only. Each focus group will be 90 minutes long, and respondents will be asked to provide feedback to the pretest materials. The moderator will ensure that all participants have an equal amount of time to participate.

Methods for Identifying Duplication

The information needed is specific to the Intervention Resources Guides' task and is not collected anywhere else.

D. Annualized Response Burden Estimate

Participant	Number of Respondents	Responses per Respondent	Total Number of Responses	Hours per Response	Total Hour Burden	Wage per Hour	Total Hour Cost
Individuals (screening call to participate)	60	1	60	.08	4.80	0	0
Individuals (focus group participation)	48	1	48	1.5	72	\$35.00	\$2,520.00
Totals	60		108		76.80		\$2,520.00

The estimated annualized cost to respondents for the proposed data collection activities is

\$2,520.00. For the purposes of estimating annual cost, it is assumed that the participants will participate once. The average burden was estimated on the basis of an independent review of the focus groups by the contractor and federal staff.

Estimates of Annualized Cost to the Government

The estimated annualized cost to the government for the proposed data collection activities is \$25,376.00 and includes the cost to the contract as well as the Government Printing Office (GPO) cost.

Position	Percent Full-Time Equivalent	Annual Hours	Rate	Total Annual Cost
CSAP GPO		40	\$59.40/hour	\$2,376.00
Contractor(s)—National Outreach, Public Education and Engagement Initiatives Contract		n/a	n/a	\$23,000.00
Totals	<i>varies</i>	<i>varies</i>	<i>varies</i>	\$25,376.00

E. Methods Used To Develop the Questions

Questions similar to those in the facilitator guide have been asked of participants from focus groups for concept testing to assess the relevance and effectiveness of the campaign materials. Some questions from formative assessments have not been asked before.

F. Consultants Within and Outside SAMHSA

The common measures here for OMB approval are the result of lengthy consultation and discussion among SAMHSA personnel and contract representatives. The final selection of these measures was made by SAMHSA senior officials.

Project Officer

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List of Attachments:

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