Request for genIC Approval
CDC/ATSDR Formative Research and Tool Development

0920-1154

CIO: NCBDDD

PROJECT TITLE: Messaging to Improve Patient-Provider Communication and Engagement on Risks of Alcohol Use During Pregnancy

PURPOSE AND USE OF COLLECTION:

Fetal alcohol spectrum disorders (FASDs) are conditions that can result from prenatal alcohol exposure. Estimates of FASDs—a continuum of completely preventable disorders—are between 2 and 5 percent of school-aged children in the United States. The effects of FASDs include lower IQ, neurological damage, and a variety of behavioral disorders, which can significantly limit children throughout their lives and cause unnecessary burden on medical, educational, and social service systems. Excessive alcohol consumption also leads to a variety of negative health and social consequences that effect individuals, families, and communities.

Fortunately, effective prevention strategies are available to reduce alcohol consumption among women of reproductive age. However, it is difficult to craft public health messages and communication strategies to change alcohol-related attitudes and behaviors because of the range of knowledge and beliefs about alcohol use and pregnancy. Even though public health experts recommend alcohol SBI for adults in primary care settings, data indicate that only about one in six U.S. adults (17%) report ever discussing alcohol use with a health professional. A roughly equal share of pregnant women (17%), a population at greater potential risk of adverse health effects from alcohol, report ever having conversations about their consumption with health care providers. To develop an effective, consistent messaging strategy, a deeper understanding of how both women and healthcare providers think about and discuss alcohol use is needed.

The purpose of this study is to conduct formative research to assess perceptions among women of reproductive age regarding alcohol use during pregnancy, determine women's comfort with discussing alcohol use, contraception, and pregnancy with their healthcare providers, and examine provider comfort with and use of alcohol SBI. The contractor will conduct all data collection related to the proposed study. There are three components to this study: 1) Online survey of healthcare providers; 2) Individual in-depth, telephone interviews with healthcare providers; and 3) Individual in-depth, in-person interviews with women of reproductive age. Data collection will consist of a screening process to facilitate recruitment of participants into the study. For the purposes of conducting the online survey and individual in-depth interviews with healthcare providers, EurekaFacts will use the Healthcare Professional Panel from ResearchNow, a renowned commercial panel provider. The healthcare providers will be physicians or nurse practitioners in primary care. For the individual in-depth interviews with healthcare providers, participants will consist of a targeted mix of providers who currently deliver alcohol SBI, those who previously delivered alcohol SBI, and those who have never delivered alcohol SBI. For the individual in-depth interviews with women of reproductive age (21 to 45 years of age), the contractor will recruit through: 1) the EurekaFacts database of

previous research participants in the desired geographical regions, 2) a general advertisement method, and 3) individual/direct recruitment with multiple modes such as individual emails and telephone recruiting.

The research conducted under this GenIC will be used to inform the development of patient and provider materials and messages about how to discuss the risks of alcohol use during pregnancy.

DESCRIPTION OF RESPONDENTS:

Primary care providers who are physicians or nurse practitioners
Women of reproductive age (21 to 45 years of age)

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: *Mary Kate Weber*

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [x] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [x] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [x] Yes [ ] No

The healthcare provider online survey is expected to take 15 minutes to complete. The individual in-depth interviews for healthcare providers will take approximately 30 minutes to complete, while the individual in-depth interviews for women of reproductive age will each take about 60 minutes to complete. ResearchNow will distribute survey and in-depth interview incentives to the healthcare provider participants who complete the survey and who complete the in-depth interview. The Federal government will not directly pay incentives to the healthcare provider participants. Panel members may receive points for participation in surveys. These points can be accumulated for a variety of rewards. The incentive agreement between ResearchNow and panel participants is proprietary information based on the vendor's

experience with successful data collection. The cost of this research effort for access to a sample of healthcare providers remains static, regardless of incentive agreements between ResearchNow and their panel participants.

Women of reproductive age who participate in individual in-depth interviews will receive $40 at the end of the interview. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). The token of appreciation amounts were determined through discussions with contract staff with expertise in conducting interviews with the study population and interviews about alcohol. Removing the incentive could negatively affect recruitment, which could threaten the development of a messaging strategy resulting from this testing.

BURDEN HOURS

Table 1: Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total hours
Recruitment: Online Survey – Initial Contact for Healthcare Providers	Attachment A	600	1	2/60	12
Recruitment: Online Survey – Consent and confirmation for Healthcare Providers	Attachment A	500	1	2/60	10
Participation: Online Survey – Healthcare Providers	Attachment D	500[a]	1	25/60	125
Recruitment: In-Depth Interviews – Initial contact for Healthcare Providers	Attachment D	72	1	15/60	11
Recruitment: In-Depth Interviews – Follow-up contact for Healthcare Providers	Attachment D	36*	1	15/60	5
Recruitment: In-Depth Interviews – Consent and confirmation for Healthcare Providers	Attachment B	36*	1	13/60	5
Participation: In-Depth Interviews – Healthcare Providers	Attachment F	36[a]	1	30/60	18
Recruitment: Initial contact – Women	Attachment H	300	1	5/60	15

Recruitment: Follow-up contact – Women	Attachment G	150*	1	15/60	23
Recruitment: Consent and confirmation – Women	Attachments C	85	1	13/60	11
Participation: In-depth Interviews – Women	Attachment K	72[a]	1	60/60	72
Total					**307**

* Subset of initial contact group, not double counted in the total number of respondents.

[a] Estimated number of actual participants will be somewhat less than confirmation numbers.

FEDERAL COST:

The estimated annual cost to the Federal government is **$246,196.** The federal government personnel estimate is based on cost of the two CDC staff such as the CDC Behavioral Scientist/Technical Monitor (GS-14) and CDC Behavioral Scientist (GS-13). Federal staff responsibilities include overall management and oversight of the project and provision of content matter expertise in the development of the research strategy and data collection instruments. Contractor costs include direct labor for development of instruments, data collection, analysis and reporting for both phases of the formative research. Other direct contractor costs include subcontractors, travel, and facility rental, participant recruitment and incentives; and indirect costs such as fringe, overhead, general and administrative fees

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Sampling Plan: Healthcare Provider

According to ResearchNow's 2015 panel data, the following numbers represent the total available physicians in the United States within the targetable universe: 102,660 family practice physicians; 8,681 general practice physicians; 123,947 internal medicine physicians; and 41,967 obstetrics and gynecology physicians. Likewise, there are 184,395 nurse practitioners available in the targetable universe (ResearchNow – Healthcare Professionals Panel, 2015). ResearchNow maintains panels of approximately 65,000 primary care physicians and 2,200 nurse practitioners, including providers in the study's target practice areas of family medicine, obstetrics/gynecology and internal medicine. These panels offer access to specialized

populations of healthcare providers built with individuals screened on qualifying characteristics, and are estimated to provide access to 95% of the physicians in the United States. The utilization of panels allows a quick turnaround of a survey in a cost-efficient manner.

For the healthcare provider online survey and individual healthcare provider in-depth interviews, the same respondent universe applies to each. There are two frames by which the provider sample will be drawn. One frame consists of the online panel for selecting a sample of online survey respondents. Another frame for the in-depth interviews consists of panel survey respondents who satisfy specific study parameters and meet screening characteristics for provider practice area and alcohol SBI practice.

Sampling Plan: Women of Reproductive Age

The study sample of women of reproductive age (21 to 45 years of age) will be a nonprobability-based purposeful sample as opposed to probability-based. A purposeful sampling strategy is widely used in qualitative research for identifying cases that match core criteria for the subject of interest, while maximizing use of limited resources (Patton, 2002).

The sampling frame for selecting women of reproductive age will include female members of the EurekaFacts database of individuals and households in desired geographic locations, as well as lists of women of reproductive age from reputable list vendors. The EurekaFacts participant database includes approximately 30,000 individuals nationwide and is routinely refreshed and updated through independent participant outreach methods in both English and Spanish. EurekaFacts uses a recruitment strategy that integrates multiple outreach methods and resources such as Internet ads, individual emails, telephone recruiting, and on-site location-based recruiting. To further ensure the quality of the data, EurekaFacts' policy states that respondents may only participate in qualitative research once every three to six months, greatly reducing the likelihood of respondent conditioning.

The participants will be recruited across four locations: Chicago, IL; Boston, MA; Atlanta, GA; and Denver, CO. These cities were selected based upon their internal demographic and socio-economic diversity and their geographic diversity from one another.

Details on the sampling plans for this study can be found in **Supporting Statement B**.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

   [x] Web-based or other forms of Social Media

   [x] Telephone

   [x] In-person

   [x] Mail

   [ ] Other, Explain

2. Will interviewers or facilitators be used? [x] Yes [ ] No

The contractor will conduct all data collection related to the proposed study. There are three components to this study: 1) Online survey of healthcare providers; 2) Individual in-depth, telephone interviews with healthcare providers; and 3) Individual in-depth, in-person interviews with women of reproductive age. The contractor will use the online Healthcare Professional Panel from ResearchNow, a renowned commercial panel provider to recruit healthcare providers for the online survey. The in-depth interviews will be conducted by staff trained in conducting behavioral interviews with various audiences.

Please make sure all instruments, instructions, and scripts are submitted with the request.

Documentation (Supporting Statements A and B) and Attachments:

- OMB Supporting Statement A
- OMB Supporting Statement B
- Attachment A. Consent script for Healthcare Provider Survey
- Attachment B. Consent script for Healthcare Provider In-Depth Interview
- Attachment C. Consent form for Women of Reproductive Age In-Depth Interviews
- Attachment D. Healthcare Provider Survey, Including Screening Questions
- Attachment E. Screenshots of Healthcare Provider Survey, Including Screening Questions
- Attachment F. Healthcare Provider Interview Guides
- Attachment G. Recruitment Materials for Interviews with Women of Reproductive Age
- Attachment H. Screening Questions for Women of Reproductive Age In-Depth Interviews
- Attachment I. Screenshots of Screening Questions for Women of Reproductive Age
- Attachment J. Screenshot of Landing Page for Screening Women of Reproductive Age
- Attachment K. Interview Guides for Women of Reproductive Age In-Depth Interviews
- Attachment L. IRB Approval Letter

Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

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TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is requested.

PURPOSE and USE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Briefly describe the targeted group/groups for this collection.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

Form: Provide the title of the information collection form.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group).

Burden in Minutes: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Estimate the annual cost to the Federal government for this collection.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.